

PROJECT 25

DISCUSSION PAPER 145

**STATUTORY LAW REVISION:
LEGISLATION ADMINISTERED BY
DEPARTMENT OF HEALTH**

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South African Law Reform Commission

The South African Law Reform Commission (SALRC) was established by the South African Law Reform Commission Act, 1973 (Act No. 19 of 1973).

Vision

The vision of the SALRC is to be a centre of excellence producing ground-breaking research pivotal to the improvement and renewal of the legal system.

Mission

The mission of the SALRC is the continuous reform of the law of South Africa, in an open and inclusive manner, in accordance with the principles and values of the Constitution to meet the needs of a changing society operating under the rule of law.

Values

In the execution of its duties the Commission strives to uphold the Constitution, the rule of law and the values of equality, integrity, inclusiveness, professionalism, impartiality, responsiveness, efficiency and respect for the dignity of others.

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Preface

The SALRC has been mandated with the task of reviewing the South African statute book with a view to identifying and recommending for repeal or amendment legislation or provisions in legislation that are redundant, obsolete or inconsistent with the equality clause in the Constitution. Pursuant to this mandate, the SALRC has established that there are 2800 Acts on the statute book. Furthermore, the SALRC has identified 25 principal Acts, 4 general Amendment Acts and 79 Amendment Acts, in total 108 Acts, as being statutes or including provisions administered by the Department of Health (DOH).

This discussion paper has been prepared to elicit comment on the preliminary findings and proposals put forward in this paper. It will serve as a basis for the SALRC's deliberations in the development of a report with proposed draft legislation. This discussion paper contains **preliminary proposals** and the views, conclusions and recommendations that follow should not be regarded as the SALRC's final views.

Specific attention is drawn thereto that there are several provisions in the various pieces of legislation for which no date of commencement has been proclaimed. An example of such an instance is the National Health Laboratory Service Amendment Act 24 of 2001, which has not been fully put into operation more than a decade after its adoption.

Another example is sections 43 and 46 of the Occupational Diseases in Mines and Works Act 78 of 1973. Sections 43 and 46 were intended to be respectively repealed by sections 13 and 15 of the Occupational Diseases in Mines and Works Amendment Act 208 of 1993. The repealing provisions were never operationalized and sections 43 and 46 of Act 78 of 1973 have since been amended by the Occupational Diseases in Mines and Works Amendment Act 60 of 2002, which creates the impression that the repeal of the sections is no longer on the table. The repealing provisions however still appear on the statute book. These issues should be addressed as it creates legal uncertainty.

It is possible that some of the statutes recommended for repeal are still useful, and thus should not be repealed. Moreover, it is also possible that there are statutes or provisions not identified for repeal in this discussion paper which are of no practical utility anymore and which could be repealed. These should be identified and brought to the attention of the SALRC.

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List of acronyms

| | |
|---------------------|---|
| AE Act | Administration of Estates Act 66 of 1965 |
| AHPA | Allied Health Professions Act 63 of 1982 |
| AIDS | Acquired Immune Deficiency Syndrome |
| CALS | Centre for Applied Legal Studies |
| CLA | Christian Lawyers Association of South Africa |
| CTOP Act | Choice on Termination of Pregnancy Act |
| DFLI | Doctors for Life International |
| DTA | Dental Technicians Act 19 of 1979 |
| DOH | Department of Health |
| ETOMCCA | Extension of Terms of Office of Members of Certain Councils Act 45 of 1997 |
| FCDA | Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 |
| FSLG Amendment Act | Financial Services Laws General Amendment Act 45 of 2013 |
| GG | Government <i>Gazette</i> |
| GTZ | <i>Gesellschaft für Technische Zusammenarbeit</i> , also known as the German Technical Cooperation Agency |
| HASA | Hospital Association of South Africa |
| HIV | Human immunodeficiency virus |
| HL Amendment Act | Health Laws Amendment Act 36 of 1977 |
| HO Amendment Act | Hospitals Ordinance Amendment Act 111 of 1992 |
| HPA | Health Professions Act 56 of 1974 |
| HP | Health Professions |
| HSA | Hazardous Substances Act 15 of 1973 |
| HWM Amendment Act | Health and Welfare Matters Amendment Act 118 of 1993 |
| IHR | International Health Regulations |
| MHA | Mental Health Act 18 of 1973 |
| MHCA | Mental Health Care Act 17 of 2002 |
| MHC Amendment Act | Mental Health Care Amendment Act |
| MIPLI Amendment Act | Mentally Ill Persons' Legal Interests Amendment Act 108 of 1990 |
| MRC | Medical Research Council |
| MRSA | Medicines and Related Substances Act 101 of 1965 |
| MSA | Medical Schemes Act 131 of 1998 |
| NHA | National Health Act 61 of 2003 |
| NH Amendment Act | National Health Amendment Act 12 of 2013 |
| NHI | National Health Insurance |
| NHLSA | National Health Laboratory Service Act 37 of 2000 |

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| NHLS | National Health Laboratory Service |
| NHREC | National Health Research Ethics Council |
| NRF | National Revenue Fund |
| ODMW | Occupational Diseases in Mines and Works |
| ODMWA | Occupational Diseases in Mines and Works Act 78 of 1973 |
| PFMA | Public Finance Management Act 1 of 1999 |
| REF | Risk Equalisation Fund |
| SADA | South African Dental Association |
| SALRC | South African Law Reform Commission |
| SALRC Act | South African Law Reform Commission Act 19 of 1973 |
| SAMRC | South African Medical Research Council |
| SAMRC Act | South African Medical Research Council Act 58 of 1991 |
| SARS | Severe acute respiratory syndrome |
| STI | Sexually transmitted infections |
| TB | Tuberculosis |
| WHA | World Health Assembly |
| WHO | World Health Organisation |

SUMMARY OF RECOMMENDATIONS

1 The SALRC has established that there are 2800 Acts on the statute book. Furthermore, the SALRC has identified 25 principal Acts, 4 general Amendment Acts and 79 Amendment Acts, thus 108 Acts in total, that are administered by the Department of Health (DOH) (see Annexure A). Since “health services” is a functional area of concurrent national and provincial legislative competence as set out in Schedule 4 of the Constitution, the 59 pieces of health provincial legislation (provincial Acts and ordinances) currently in force are also listed.

A Legislation recommended for repeal

2 After an analysis of the statutes administered by DOH, the SALRC proposes that the Acts stipulated in the Schedule of the proposed draft Health and Related Matters Repeal and Amendment Bill be repealed to the extent set out in that Schedule.

3 The Acts and Amendment Acts stipulated below are recommended for repeal or partial repeal for the reasons explained in this paper:

1. Public Health Act 36 of 1919
2. Public Health Amendment Act 57 of 1935
3. Public Health Amendment Act 51 of 1946
4. Public Health Amendment Act 44 of 1952
5. Mental Health Amendment Act 48 of 1976
6. Health Laws Amendment Act 36 of 1977 – sections 1 to, 3, 9, 10 and 13 to 18.
7. Mental Health Amendment Act 10 of 1978
8. Mental Health Amendment Act 38 of 1981
9. Mental Health Amendment Act 3 of 1984
10. Mental Health Amendment Act 16 of 1985
11. Mental Health Amendment Act 55 of 1987
12. Mental Health Amendment Act 52 of 1988
13. Mental Health Amendment Act 19 of 1992
14. Mentally Ill Persons’ Legal Interests Amendment Act 108 of 1990
15. Health and Welfare Matters Amendment Act 118 of 1993 – sections 14 and 15
16. Extension of Terms of Office of Members of Certain Councils Act 45 of 1997
17. Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 91 of 1997

18. Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 6 of 2000
19. Traditional Health Practitioners Act 35 of 2004
20. Choice on Termination of Pregnancy Amendment Act 38 of 2004

B Legislation recommended for amendment

4 The SALRC proposes that the following Acts be amended to the extent set out and explained in this paper:

1. Administration of Estates Act 66 of 1965
2. Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972
3. Hazardous Substances Act 15 of 1973
4. Dental Technicians Act 19 of 1979
5. Allied Health Professions Act 63 of 1982
6. South African Medical Research Council Act 58 of 1991
7. Choice on Termination of Pregnancy Act 92 of 1996
8. Sterilisation Act 44 of 1998
9. Medical Schemes Act 131 of 1998
10. National Health Laboratory Service Act 37 of 2000
11. National Health Act 61 of 2003
12. Nursing Act 33 of 2005
13. Traditional Health Practitioners Act 22 of 2007

C Legislation recommended for consolidation

5 The SALRC proposes that the Pharmacy Act 53 of 1974, the Health Professions Act 56 of 1974 and the Medicines and Related Substances Act 101 of 1965 be consolidated and promulgated afresh as these Acts have been amended so often and to such an extent that the Acts have become confusing. The relevant current Acts and Amendment Acts will then be repealed.

6 The consolidation of the Pharmacy Act 53 of 1974 will lead to the repeal of the following legislation:

1. Pharmacy Act 53 of 1974
2. Health Laws Amendment Act 36 of 1977 – sections 9 to 11

3. Pharmacy Amendment Act 20 of 1979
4. Pharmacy Amendment Act 39 of 1982
5. Pharmacy Amendment Act 20 of 1983
6. Pharmacy Amendment Act 69 of 1985
7. Pharmacy Amendment Act 6 of 1995
8. Pharmacy Amendment Act 88 of 1997
9. Pharmacy Amendment Act 1 of 2000
10. Veterinary and Para-Veterinary Professions Amendment Act 10 of 2002 – section 18

7 The consolidation of the Health Professions Act 56 of 1974 will lead to the repeal of the following legislation:

1. Health Professions Act 56 of 1974
2. General Law Amendment Act 57 of 1975 – sections 46, 47 and 48
3. Medical, Dental and Supplementary Health Service Professions Amendment Act 33 of 1976
4. Health Laws Amendment Act 36 of 1977 – sections 12 to 18
5. Medical, Dental and Supplementary Health Service Professions Amendment Act 52 of 1978
6. Medical, Dental and Supplementary Health Service Professions Amendment Act 43 of 1980
7. Medical, Dental and Supplementary Health Service Professions Amendment Act 66 of 1981
8. Medical, Dental and Supplementary Health Service Professions Amendment Act 38 of 1982
9. Medical, Dental and Supplementary Health Service Professions Amendment Act 58 of 1984
10. Medical, Dental and Supplementary Health Service Professions Amendment Act 79 of 1990
11. Medical, Dental and Supplementary Health Service Professions Amendment Act 58 of 1992
12. Medical, Dental and Supplementary Health Service Professions Amendment Act 18 of 1995
13. Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997
14. Medical, Dental and Supplementary Health Service Professions Amendment Act 1 of 1998

15. Health Professions Amendment Act 29 of 2007

8 The consolidation of the Medicines and Related Substances Act 101 of 1965 will lead to the repeal of the following legislation:

1. Medicines and Related Substances Act 101 of 1965
2. Drugs Control Amendment Act 29 of 1968
3. Drugs Control Amendment Act 88 of 1970
4. Drugs Laws Amendment Act 95 of 1971
5. Drugs Control Amendment Act 65 of 1974
6. Medicines and Related Substances Control Amendment Act 19 of 1976
7. Health Laws Amendment Act 36 of 1977 – sections 1, 2 and 3
8. Medicines and Related Substances Control Amendment Act 17 of 1979
9. Medicines and Related Substances Control Amendment Act 20 of 1981
10. Medicines and Related Substances Control Amendment Act 94 of 1991 – sections 1 to 8, 10 to 18, 20, 22 and 26
11. Health and Welfare Matters Amendment Act 118 of 1993 – section 11
12. Abolition of Restrictions on the Jurisdiction of Courts Act 88 of 1996 – section 32
13. Medicines and Related Substances Control Amendment Act 90 of 1997
14. Medicines and Related Substances Amendment Act 59 of 2002
15. Medicines and Related Substances Amendment Act 72 of 2008
16. Medicines and Related Substances Amendment Act 14 of 2015

D Legislation to be assigned to another Department

9 The DOH has indicated that there is a Ministerial Task Team working on the consolidation of health compensation as provided for in the Occupational Diseases in Mines and Works Act 78 of 1973 (ODMWA) and labour compensation as provided for in the Compensation for Occupational Injuries and Diseases Act 130 of 1993 (COIDA). It is envisaged that a single compensation system will result in the ODMWA being merged with COIDA and the repeal of ODMWA.

CHAPTER 1: BACKGROUND AND SCOPE OF PROJECT 25

A Introduction

1 Objects of South African Law Reform Commission

1.1 The objects of the South African Law Reform Commission (SALRC) are set out as follows in the South African Law Reform Commission Act 19 of 1973 (SALRC Act):

... to do research with reference to all branches of the law of the Republic and to study and to investigate all such branches of the law in order to make recommendations for the development, improvement, modernization or reform thereof, including –

- (a) the repeal of obsolete or unnecessary provisions;
- (b) the removal of anomalies;
- (c) the bringing about of uniformity in the law in force in the various parts of the Republic;
- (d) the consolidation or codification of any branch of the law; and
- (e) steps aimed at making the common law more readily available.

1.2 In short, the SALRC is an advisory body established by statute, whose aim is the renewal and improvement of the law of South Africa on a continual basis.

2 History of investigation

1.3 Shortly after its establishment in 1973, the SALRC undertook a revision of all pre-Union legislation as part of *Project 7 – Revision of pre-Union statutes*. The revision resulted in the repeal of approximately 1 200 laws, ordinances and proclamations of the former Colonies and Republics. In 1981 the SALRC finalised a report on the repeal of post-Union statutes as part of *Project 25 – The establishment of a permanently simplified, coherent and generally accessible statute book*. This report resulted in Parliament adopting the Repeal of Laws Act 94 of 1981, which repealed approximately 790 post-Union statutes.

1.4 On the advent of constitutional democracy in South Africa in 1994, the legislation enacted prior to that year remained in force. However, many pre-1994 provisions do not comply with the country's new Constitution. This discrepancy is exacerbated by the fact that some older provisions were enacted to promote and sustain the policy of apartheid.

1.5 In 2003 Cabinet approved that the Minister of Justice and Constitutional Development should co-ordinate and mandate the SALRC to review provisions in legislation that would result in discrimination as defined by section 9 of the Constitution. This section prohibits unfair discrimination against anyone on any grounds, including race, gender, sex, pregnancy, marital status, ethnic and social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.

1.6 In February 2004 the SALRC included in its law reform programme an investigation into statutory law with the aim of reviewing all statutes from 1910 to date. Whereas previous investigations had focused on identifying obsolete and redundant provisions for repeal, the current investigation emphasises compliance with the Constitution. The constitutional inquiry has focused mainly on identifying statutory provisions that blatantly violate the provisions of section 9 (the equality clause) of the Constitution, but redundant and obsolete provisions identified in the course of this investigation are also recommended for repeal.

1.7 In 2004 the SALRC conducted a provisional audit of national legislation that has remained on the statute book since 1910. It was established that roughly 2 800 individual statutes existed at that time. These comprised principal Acts, amendment Acts, private Acts, additional or supplementary Acts, and partially repealed Acts. A substantial number of Acts on the statute book no longer serve any useful purpose and many others have retained unconstitutional provisions. This situation has already resulted in expensive and sometimes protracted litigation.

B What is statutory law revision?

1.8 Statutory law revision ordinarily focuses on the identification and repeal of statutes that are no longer useful in practice. As the Law Reform Commission for England and Wales explains, the purpose of statute revision is to modernise and simplify statutes that need updating, and to reduce the size of the statute book to the benefit of legal professionals and other people who use it.¹ Revision lessens the chance of people being misled by redundant laws that still appear in the statute book and seem to be relevant or “live” law. If statutory provisions appear in the statute book and are referred to in legal textbooks, readers may reasonably assume they still serve a purpose.

¹ Law Commission for England and Wales Background Notes on Statute Law Repeals par 1 (LCE&W Statute Law Repeals) available at <http://www.lawcom.gov.uk> accessed on 14 November 2016.

1.9 As is the case in other jurisdictions (and will be evident in this review), once legislation is deemed no longer to apply, the question arises whether it should remain on the statute book or be repealed.² Usually such legislation has no legal effect and is considered obsolete, redundant or spent. A statutory provision may be identified for repeal because the grounds for which it was passed have lapsed or are presently remedied by another measure or provision. In the context of this investigation, the statutory law revision primarily targets statutory provisions that are obviously at odds with the Constitution, particularly section 9.

1.10 The Law Commission for England and Wales lists the following guidelines for identifying statutory provisions that are candidates for repeal:³

- (a) references to bodies, organisations, etc. that have been dissolved or wound up or which have otherwise ceased to serve any purpose;
- (b) references to issues that are no longer relevant as a result of changes in social or economic conditions (e.g. legislation about tithes or tin mines);
- (c) references to Acts that have been superseded by more modern (or EU) legislation or by international Convention;
- (d) references to statutory provisions (i.e. sections, schedules, orders, etc.) that have been repealed;
- (e) repealing provisions e.g. "Section 33 is repealed/shall cease to have effect";
- (f) commencement provisions once the whole of an Act is in force;
- (g) transitional or savings provisions that are spent;
- (h) provisions that are self-evidently spent – e.g. a one-off statutory obligation to do something becomes spent once the required act has duly been done;
- (i) powers that have never been exercised over a period of many years or where any previous exercise is now spent.

1.11 The Law Commission of India notes that in England the terms "expired", "spent", "repealed in general terms", "virtually repealed", "superseded", and "obsolete" were defined in memoranda to Statute Law Revision Bills as follows:⁴

1. Expired – that is, enactments which having been originally limited to endure only for a specified period by a distinct provision, have not been either perpetuated or kept in force by continuance, or which have

² LCE & W *Statute Law Repeals* par 6.

³ LCE & W *Statute Law Repeals* par 7.

⁴ Law Commission of India *Ninety-Sixth Report on Repeal of Certain Obsolete Central Acts* March 1984 at 6.

merely had for their object the continuance of previous temporary enactments for periods now gone by effluxion of time;

2. Spent – that is, enactments spent or exhausted in operation by the accomplishment of the purposes for which they were passed, either at the moment of their first taking effect or on the happening of some event or on the doing of some act authorised or required;
3. Repealed in general terms – that is, repealed by the operation of an enactment expressed only in general terms, as distinguished from an enactment specifying the Acts which it is to operate;
4. Virtually repealed – where an earlier enactment is inconsistent with, or is rendered nugatory by, a later one;
5. Superseded – where a later enactment effects the same purposes as an earlier one by repetition of its terms or otherwise;
6. Obsolete – where the state of things contemplated by the enactment has ceased to exist, or the enactment is of such a nature as to be no longer capable of being put in force, regard being had to the alteration of political or social circumstances.

1.12 Statutory provisions usually become redundant as time passes.⁵ Generally, the redundancy of legislation is not signalled by a single occurrence; rather, legislation is simply overtaken by social and economic changes. Inevitably some provisions fade away more quickly than others. Relatively short-lived provisions include commencement and transitional provisions and those that confer powers to be exercised during the period between the passing of a law and its implementation (in some jurisdictions known as “pump-priming” provisions). Provisions that provide for delegated legislation-making powers might also become unnecessary over time, or a committee or board established by a statute might no longer be required.

1.13 Substantial revision of statutory law is possible in South Africa because of the general savings provisions of section 12(2) of the South African Interpretation Act. The South African Interpretation Act 33 of 1957⁶ mirrors section 16(1) of the Interpretation Act of 1978 of England and Wales.⁷ Section 12(2) of the South African Interpretation Act provides as follows:

(2) Where a law repeals any other law, then unless the contrary intention appears, the repeal shall not –

⁵ LCE & W *Statute Law Repeals* para 9 and 10.

⁶ With the exception of a few minor changes, the South African Interpretation Act 5 of 1910 mirrors the provisions of the United Kingdom Interpretation Act of 1889 (Interpretation Act 1889 (UK) 52 & 53 Vict c 63).

⁷ LCE & W *Statute Law Repeals* par 8.

- (a) revive anything not in force or existing at the time at which the repeal takes effect; or
 - (b) affect the previous operation of any law so repealed or anything duly done or suffered under the law so repealed; or
 - (c) affect any right, privilege, obligation or liability acquired, accrued or incurred under any law so repealed; or
 - (d) affect any penalty, forfeiture or punishment incurred in respect of any offence committed against any law so repealed; or
 - (e) affect any investigation, legal proceeding or remedy in respect of any such right, privilege, obligation, liability, forfeiture or punishment as is in this subsection mentioned,
- and any such investigation, legal proceeding or remedy may be instituted, continued or enforced, and any such penalty, forfeiture or punishment may be imposed, as if the repealing law had not been passed.

C Initial investigation

1.14 During 2001 the SALRC and the *Gesellschaft für Technische Zusammenarbeit* (GTZ), also known as the German Technical Cooperation Agency, commissioned the Centre for Applied Legal Studies (CALs) at the University of the Witwatersrand to conduct a preliminary study on law reform. The study examined the feasibility, scope, and operational structure of a revision of the South African statute book for constitutionality, redundancy, and obsolescence. The findings were submitted to the SALRC in April 2001. CALs pursued four main avenues of research for this study:⁸

1. A series of interviews was conducted with key role-players drawn from the three governmental tiers, Chapter 9 institutions, the legal profession, academia, and civil society. These interviews revealed a high level of support for a law reform project.
2. All Constitutional Court judgments up to 2001 were analysed. The results were compiled as schedules summarising the nature and outcome of these cases, and the statutes impugned. The three most problematic categories of legislative provisions were identified, and the Constitutional Court's jurisprudence in each category was analysed. The three most problematic categories were reverse onus provisions, discriminatory provisions, and provisions that infringe on the separation of powers. Guidelines summarising the Constitutional Court's jurisprudence were compiled for each category.

⁸ Centre for Applied Legal Studies, University of the Witwatersrand *Feasibility and Implementation Study on the Revision of the Statute Book* (prepared by the Law and Transformation Programme) 2001. Document is available from the SALRC library on request.

3. Sixteen randomly-selected national statutes were tested against the guidelines. The results were compared with the results of a control audit that tested the same statutes against the entire Bill of Rights, excluding socio-economic rights. Comparison of the outcomes showed that a targeted revision of the statute book in accordance with the guidelines had produced highly effective results.
4. A survey of law reform in five other countries (United Kingdom, Germany, Norway, Switzerland and France) was conducted. Apart from France, all these countries had conducted or were conducting statutory revision exercises. The motivation for the revision and the outcomes of the exercises differed by country.

1.15 The SALRC subsequently finalised the following reports, proposing reform of discriminatory areas of the law or the repeal of specific discriminatory provisions:

1. Recognition of Customary Marriages (August 1998)
2. Review of the Marriage Act 25 of 1961 (May 2001)
3. Application of the Bill of Rights to Criminal Procedure, Criminal Law, the Law of Evidence and Sentencing (May 2001)
4. Traditional Courts (January 2003)
5. Recognition of Muslim marriages (July 2003)
6. Repeal of the Black Administration Act 38 of 1927 (March 2004)
7. Customary Law of Succession (March 2004)
8. Domestic Partnerships (March 2006).

D Scope of project

1.16 The constitutional validity aspect of this project focuses on statutes or provisions in statutes that are clearly inconsistent with the right to equality entrenched in section 9 of the Constitution. In practical terms, this leg of the investigation is limited to statutes or provisions in statutes that:

1. Differentiate between people or categories of people in a manner that is not rationally connected to a legitimate government purpose; or
2. unfairly discriminate against people or categories of people on one or more grounds listed in section 9(3) of the Constitution; or
3. unfairly discriminate on grounds which impair, or have the potential to impair, a person's fundamental human dignity as a human being.

1.17 Consequently, a law or a provision in a law which appears on the face of it to be neutral and non-discriminatory, but which has or could have discriminatory effect or consequences, has been left to the judicial process. This investigation focuses on the constitutionality of provisions in statutes of South African law, with special attention paid to consonance with section 9 of the Constitution. The investigation however also attends to obsolescence or redundancy of provisions. In 2003 Cabinet directed that the highest priority be given to reviewing provisions that would result in discrimination as defined in section 9 of the Constitution, which prohibits unfair discrimination on the basis of race, gender, sex, pregnancy, marital status, ethnic and social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language or birth.

1.18 The SALRC agreed that the project should proceed by scrutinising and revising national legislation that discriminates unfairly.⁹ However, as explained in the preceding sections of this chapter, even the section 9 inquiry is limited, since it deals primarily with statutory provisions that are blatantly in conflict with section 9 of the Constitution. This delimitation arose mainly from considerations of time and capacity. Nonetheless, during the investigation certain other anomalies and obvious inconsistencies with the Constitution were identified. The SALRC also draws attention to these issues.

1.19 The Commission has finalised the following reports as part of the Project 25 investigation:

1. Legislation administered by the Department of Transport, in October 2009.
2. Legislation administered by the Department of Energy, in October 2011.
3. Legislation administered by the Department of Labour, in October 2011.
4. Legislation administered by National Treasury (non-tax), in October 2011.
5. Legislation administered by the Department of Human Settlements, in December 2011.
6. Legislation administered by the Department of Mineral Resources, in December 2011.
7. Legislation administered by the Department of Public Works, in December 2011.
8. Legislation administered by the Department of Rural Development and Land Reform, in December 2011.

⁹ Cathi Albertyn "Summary of Equality jurisprudence and Guidelines for assessing the SA Statute Book for Constitutionality against section 9 of the 1996 Constitution" February 2006, prepared for the SALRC on request. The document is available from the SALRC on request.

9. Legislation administered by the Department of Defence and Military Veterans, in July 2014.
10. Legislation administered by the Department of Basic Education, in December 2014.
11. Legislation administered by the Department of Higher Education and Training, in December 2014.
12. Legislation administered by the Department of International Relations and Cooperation, in December 2014.
13. Legislation administered by the Department of Cooperative Governance and Traditional Affairs, in June 2015.
14. Legislation administered by the Department of Justice and Constitutional Development (Legislation on family law and marriage), in June 2015.
15. Legislation administered by the Department of Tourism, in June 2015.
16. Legislation administered by the Department of Justice and Constitutional Development (Legislation on the legal professions, courts and institutions, civil procedure and evidence, substantive criminal law, substantive civil law, wills, estates and insolvency, constitutional and political legislation), in December 2015.
17. Legislation administered by the Department of Science and Technology, in December 2015.
18. Legislation administered by the Department of Justice and Constitutional Development (Legislation on criminal procedure), in May 2016.
19. Legislation administered by the Department of Communications, in September 2016.
20. Legislation administered by the Department of Environmental Affairs, in September 2016.
21. Legislation administered by the Department of Water and Sanitation, in September 2016.
22. Legislation administered by the Department of Home Affairs, in December 2016.

E Consultation with stakeholders

1.20 In 2004, Cabinet endorsed the proposal that government departments should be asked to participate in and contribute to this investigation. In certain instances, legal researchers cannot decide whether to recommend a provision for repeal unless they have access to factual information that might be considered “inside” knowledge – of the type usually accessible only within a specific department or organisation. Examples

include savings or transitional provisions that are instituted to preserve the status quo until an office-holder ceases to hold office or until a loan has been repaid. In such cases, the consultation paper drafted by the SALRC invites the department or organisation being consulted to supply the necessary information. The SALRC relies on the assistance of departments and stakeholders. This process should ensure that all relevant provisions are identified during this review, and are dealt with responsively and without creating unintended negative consequences.

1.21 The methodology adopted in this investigation is to review the statute book by department. The SALRC identifies a department, reviews the national legislation administered by that department for constitutionality and redundancy, sets out the preliminary findings and proposals in a consultation paper, and consults with that department to verify the SALRC's preliminary findings and proposals. The next step the SALRC undertakes is the development of a discussion paper in respect of legislation of each department, and upon its approval by the Commission, the paper is published for general information and comment. Finally, the SALRC develops a report in respect of each department, which reflects the comments submitted on the discussion paper. The report also contains a draft Bill that proposes amending legislation.

1.22 The SALRC has liaised with DOH in the phases of this investigation and on the consultation paper. In February 2016 the SALRC submitted its consultation paper containing the SALRC's preliminary findings and proposals to DOH. In August 2016 DOH submitted its comments to the SALRC on the SALRC consultation paper. The SALRC then commenced developing its draft discussion paper, which reflects the comments it had received from DOH. The SALRC acknowledges the valuable assistance it received, particularly from officials in the Legal Services section of DOH. The purpose of this discussion paper is to consult with stakeholders and the broader public on the preliminary findings and proposals contained in the discussion paper and for stakeholders and members of the public to comment on the provisionally proposed repeals and amendments.

CHAPTER 2: HISTORY OF DEPARTMENT OF HEALTH

A Purpose of Department of Health

2.1 It took many years, after the Union of South Africa came into existence, before a single, unified Department of Health was created. Its eventual establishment was the result of the health crisis that was caused by the Spanish influenza epidemic that claimed many lives and revealed the need for a national health department. The initial functions of the health department were therefore aimed at protecting public health, controlling the spread of infectious diseases and ensuring a safe environment.

2.2 The current Department of Health, however, operates under a broader mandate. It is the primary organ of state responsible for giving effect to the constitutional provisions that are directly related to health. These provisions not only require the protection of public health, but place positive obligations on the state, and the DOH in particular, to progressively realise the right of access to health care services. Section 27 of the Constitution of the Republic of South Africa, 1996 (the Constitution) provides in relevant part:

- (1) Everyone has the right to have access to –
 - (a) health care services, including reproductive health care;
 - ...
 - (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
 - (3) No one may be refused emergency medical treatment.

2.3 Children's right to health is given special protection in section 28 of the Constitution, which provides that "Every child has the right to . . . basic nutrition, shelter, basic health care services and social services". While the right of everyone to have access to health care services is subject to available resources and progressive, rather than immediate, realisation, the right to emergency medical treatment and the right to basic health care services for children are not subject to these qualifications.

2.4 Further, section 35(2)(e) provides all detained individuals with the right "to conditions of detention that are consistent with human dignity, including at least exercise and the provision, at state expense, of adequate accommodation, nutrition, reading

material and **medical treatment**" (emphasis added). While the protection of this right is also the responsibility of other government departments such as the Department of Correctional Services, there are implications for the DOH. This is especially so given the nature of the burden of disease in South Africa, which includes the twin epidemics of HIV and TB. The protection of public health requires a seamless transition between treatment that is provided in detention facilities and in public health sector facilities.

2.5 The DOH is therefore responsible for one of the most important portfolios in government. The performance of its functions is central to narrowing inequalities in health through the realisation of equitable access to health care services. To this end, the stated mission of the DOH is: "To improve the health status of South Africans through the prevention of illnesses and the promotion of healthy lifestyles and to consistently improve the health care delivery system by focusing on access, equity, efficiency, quality and sustainability."¹⁰

B Structure of Department of Health

1 Budget programmes

2.6 The budget structure of DOH consists of six budget programmes:

1. Programme 1: Administration
2. Programme 2: National Health Insurance, Health Planning and Systems Enablement
3. Programme 3: HIV and AIDS, TB and Maternal and Child Health
4. Programme 4: Primary Health Care Services
5. Programme 5: Hospital, Tertiary Health Services and Human Resource Development
6. Programme 6: Health Regulation and Compliance Management

2.7 Each of these programmes has subprogrammes to assist in achieving the purpose of the programme.

¹⁰ Department of Health 2015/16 Annual Report at 10 available at <http://www.gov.za/documents> accessed 26 January 2017.

(a) Programme 1: Administration

2.8 Purpose: Provide overall management of the Department and centralised support services. This programme consists of the following four subprogrammes:¹¹

1. Ministry
2. Management
3. Financial Management
4. Corporate Services

(b) Programme 2: National Health Insurance, Health Planning and Systems Enablement

2.9 Purpose: Improve access to quality health services through the development and implementation of policies to achieve universal coverage, health financing reform, integrated health systems planning, reporting, monitoring and evaluation and research. This programme consists of the following five subprogrammes:¹²

1. Technical Policy and Planning
2. Health Information Management, Monitoring and Evaluation
3. Sector-wide Procurement
4. Health Financing and National Health Insurance
5. International Health and Development

(c) Programme 3: HIV / AIDS, TB and Maternal and Child Health

2.10 Purpose: Develop national policies, guidelines, norms and standards, and targets to decrease the burden of disease related to the HIV and tuberculosis epidemics; to minimise maternal and child mortality and morbidity; and to optimise good health for children, adolescents and women; support the implementation of national policies, guidelines, and norms and standards; and monitor and evaluate the outcomes and impact of these. This programme consists of the following four subprogrammes:¹³

1. HIV and AIDS
2. TB Control and Management

¹¹ DOH 2015/16 Annual Report at 17.

¹² DOH 2015/16 Annual Report at 20.

¹³ DOH 2015/16 Annual Report at 28.

3. Women, Maternal, Neonatal and Reproductive Health
4. Child, Youth and School Health

(d) Programme 4: Primary Health Care Services

2.11 Purpose: Develop and oversee implementation of legislation, policies, systems, and norms and standards for: a uniform district health system, environmental health services, communicable and non-communicable diseases, health promotion, and nutrition. This programme consisting of the following six budget subprogrammes:¹⁴

1. District Health Services
2. Environmental and Port Health Services
3. Health Promotion
4. Nutrition
5. Non-Communicable Diseases
6. Communicable Diseases

(e) Programme 5: Hospital, Tertiary Health Services and Human Resource Development

2.12 Purpose: Develop policies, delivery models and clinical protocols for hospitals and emergency medical services. Ensure alignment of academic medical centres with health workforce programmes, and train health professionals to ensure that the planning of health infrastructure meets the health needs of the country. This programme will also assist the government to achieve the population health goals of the country through nursing and midwifery, by the provision of expert policy and technical advice, and recommendations on the role of nurses in the attainment of desired health outputs. This programme consists of the following five subprogrammes:¹⁵

1. Hospitals and Tertiary Health Services
2. Trauma, Violence, EMS and Pathology Medical Services
3. Office of Nursing Services
4. Health Facilities Infrastructure Planning
5. Workforce Development and Planning

¹⁴ DOH 2015/16 Annual Report at 37.

¹⁵ DOH 2015/16 Annual Report at 43.

(f) Programme 6: Health Regulation and Compliance Management

2.13 Purpose: Regulate the sale of medicines, health technology and food. Promote accountability and compliance by Statutory Health Councils and Public Entities to legislative requirements. To diagnose mineworkers affected by occupation related cardio-pulmonary disease. This programme has the following three budget subprogrammes:¹⁶

1. Food Control Pharmaceutical Trade and Product Regulation
2. Compensation Commissioner for Occupational Diseases and Occupational Health
3. Public Entities Management

2 Statutory bodies

2.14 The following statutory bodies report to the Minister of Health:¹⁷

1. Council for Medical Schemes
2. South African Medical Research Council
3. National Health Laboratory Service
4. Compensation Commissioner for Occupational Diseases
5. Health Professions Council of South Africa
6. SA Nursing Council
7. SA Pharmacy Council
8. Dental Technicians Council
9. Allied Health Professions Council
10. Interim Traditional Health Practitioners Council
11. Medicines Control Council¹⁸
12. Office of Health Standards Compliance
13. National Health Research Ethics Council (NHREC)¹⁹

¹⁶ DOH 2015/16 Annual Report at 49.

¹⁷ DOH 2015/16 Annual Report at 12.

¹⁸ In terms of the Medicines and Related Substances Amendment Act 72 of 2008 the Medicines Control Council is to be subsumed under an entity called the South African Health Products Regulatory Authority. The date of commencement of the Act and the subsequent Medicines and Related Substances Amendment Act 14 of 2015 is still to be proclaimed.

¹⁹ The NHREC is not mentioned in the list (see footnote 17 above) contained in the DOH 2015/16 Annual Report. However, the NHREC is a statutory body established by section 72 of the National Health Act of 2003 and the members are appointed by the Minister of Health.

C Legislative mandate of Department of Health

2.15 The list of statutes that DOH administers is attached to this discussion paper as **Annexure A**. These statutes are evaluated in this discussion paper.

2.16 The SALRC, after conducting an investigation to determine whether any of these statutes or provisions therein may be repealed as a result of redundancy, obsolescence, or infringing section 9 of the Constitution, has identified some statutes that should be repealed wholly, statutes that should be partially repealed or amended, and a number of statutes that should be consolidated and re-enacted. The discussion that follows below provides the motivation for these provisional proposals. Proposals for the repeal, amendment or consolidation and re-enactment of legislation administered by the Department of Health per category are discussed hereunder.

2.17 The statutes are divided into seven categories:

1. Public, Mental and General Health Statutes
2. National Health Act
3. Termination of Pregnancy and Sterilisation Statutes
4. Health Services Statutes
5. Health Professions Statutes
6. Medicines, Substances and Products Statutes
7. Occupational Health Statutes

2.18 Since “Health services” is listed in Schedule 4 of the Constitution as a functional area of concurrent national and provincial legislative competence, the last chapter deals with provincial legislation and the alignment of provincial and national legislation.

CHAPTER 3: PUBLIC, MENTAL AND GENERAL HEALTH STATUTES

A Public, Mental and General Health Statutes: Summary of Recommendations

Refer to the proposed **Health and Related Matters Amendment and Repeal Bill** in **Annexure B**.

1. Repeal sections 16, 48, 50(1)(d) and 66(d) of the Public Health Act 36 of 1919, the only provisions of the Public Health Act of 1919 that are still in force (see paragraphs 3.6 to 3.10).
2. Repeal Public Health Amendment Acts 57 of 1935, 51 of 1946 and 44 of 1952 (see paragraph 3.13).
3. Since the Health Act 63 of 1977 and the Health Amendment Acts 18 of 1979, 33 of 1981, 37 of 1982, 21 of 1983, 2 of 1984 and 70 of 1985 have been repealed *in toto* with effect from 1 March 2012; there are no recommendations in respect of the Health Act or the subsequent Health Amendment Acts. The attention of DOH however is drawn to the following (see paragraphs 3.20 to 3.23):
 - (a) Once it has been ascertained that the affairs of the Kimberley Health Board has been wound up, publish a notice in the Government Gazette to determine the date when the Kimberley Health Board ceases to exist as required by section 63(4) of the Health Act 63 of 1977 and the Health Amendment Act 18 of 1979.
 - (b) The administration of the Health Act 63 of 1977, excluding certain sections as specified, was assigned to the provinces in terms of Proclamation No. 152 of 1994 as published on 31 October 1994 in Government Gazette No. 16049. It is recommended that the national DOH engage with the provinces on the possible repeal of Act 63 of 1977 as assigned to the provinces in view thereof that the Health Act of 1977 as administered by the national DOH has been repealed.
4. Repeal the redundant Mental Health Amendment Acts: Act 48 of 1976; 10 of 1978; 38 of 1981; 3 of 1984; 16 of 1985; 55 of 1987; 52 of 1988 and 19 of 1992 (see paragraphs 3.26 to 3.27).
5. Repeal the Mentally Ill Persons' Legal Interests Amendment Act 108 of 1990 and engage with the Department of Justice and Constitutional Development on amending

the parts of the Administration of Estates Act 66 of 1965 (sections 73 and 77) that were amended by Act 108 of 1990 (see paragraphs 3.30 to 3.31).

6. There is no recommendation in respect of the Mental Health Care Act 17 of 2002 (see paragraph 3.36).
7. There is no recommendation in respect of the Mental Health Care Amendment Act 12 of 2014 (see paragraphs 3.39 to 3.41).
8. Repeal the International Health Regulations Act 28 of 1974 and adopt new legislation in order to incorporate the 2005 International Health Regulations into South African law and to provide for matters incidental thereto (see paragraphs 3.45 to 3.48).
9. Repeal sections 1, 3, 9, 10, 13, 14, 15, 16, 17 and 18 of the Health Laws Amendment Act 36 of 1977 (see paragraphs 3.51 to 3.54).
10. Repeal sections 14 and 15 of the Health and Welfare Matters Amendment Act 118 of 1993 (see paragraph 3.57).

B History of public health legislation

3.1 Although diverse but comparatively rudimentary colonial public health laws existed in South Africa at the turn of the 20th century, vested political interests and the onset of World War I prevented the enactment of a national law on public health for almost a decade after South Africa became a Union in 1910.

3.2 However, the deadly Spanish Influenza that reached South Africa in 1918 proved to be the catalyst in the development of national health law. After a two week incubation period, the pandemic swept through South Africa and by the end of October 1918 – a mere six week period – an estimated 250 000 to 350 000 lives out of a total population of 6.8 million people had been claimed.²⁰ The failure of the public health system to adequately respond to the epidemic softened opposition to a national law on public health and was a catalyst for the drafting of a governing Act.

3.3 The Public Health Act 36 of 1919 was assented to on 20 June 1919, and became operational on 1 January 1920. It was the first codification of law to protect public health in the Union of South Africa. Its purpose was to protect public health, prevent the spread

²⁰ Howard Phillips *'Black October': The impact of the Spanish Influenza Epidemic of 1918 on South Africa* Unpublished thesis, University of Cape Town, Cape Town (1984) on 291.

of infectious diseases, provide for environmental sanitation and to set up, for the first time, a Ministry and department dedicated to public health.²¹

C Public Health Act 36 of 1919

1 Recommendation

3.4 It is recommended that DOH repeal the whole of the Public Health Act 36 of 1919. The only provisions of the Public Health Act of 1919 that are still in force are sections 16, 48, 50(1)(d) and 66(d).

| No. and year of Act | Short title | Extent of repeal |
|---------------------|-------------------------|------------------|
| Act 36 of 1919 | Public Health Act, 1919 | The whole |

2 Purpose of Act

3.5 The long title of the Public Health Act 36 of 1919 (before the repeal thereof by the Health Act 63 of 1977) simply stated that the aim of the Act is to make provision for the public health.

3 Discussion

3.6 As explained in paragraphs 3.2 and 3.3 above, the spread of Spanish Influenza to South Africa was an important factor in the adoption of the Public Health Act 36 of 1919. The Act contained various measures pertaining to the notification, prevention and suppression of infectious diseases. The whole of the Public Health Act of 1919 was repealed by the Health Act 63 of 1977, except sections 16, 48, 50(1)(d) and 66(d). All the retained sections pertain to funding and related financial matters.

3.7 Section 16 deals with refunds to a local authority in respect of salaries of qualified personnel of local authorities conducting health services. Section 48 provides for refunds to local authorities in respect of isolation hospitals and formidable epidemic diseases.

²¹ Howard Philips "The origin of the Public Health Act of 1919" *South African Medical Journal* 1990 77 (10) 531-532.

Section 50(1)(d) and 66(d) pertain to financial provision for refunds to local authorities for treatment provided for persons suffering from TB and venereal diseases respectively.

3.8 The remaining provisions of the Public Health Act of 1919 are completely outdated and have been superseded by the National Health Act 61 of 2003 (NHA). The provisions contain terminology the meaning of which has changed over the years. For example, it refers to the Consolidated Revenue Fund, now known as the National Revenue Fund. The National Revenue Fund (NRF) is constituted by section 213 of the 1996 Constitution, which provides the broad principles for withdrawals from the NRF.

3.9 These sections of the Public Health Act are in contravention of the Public Finance Management Act 1 of 1999 (PFMA) in that it allows the Minister of Health to refund local authorities from a central revenue fund. The PFMA governs financial management in the national and provincial governments and gives effect to section 213 of the Constitution. In terms of the PFMA, the National Treasury has control over the NRF. Only the National Treasury may withdraw money from the NRF, which must be done in compliance with the Constitution and the PFMA. The PFMA also sets up a Provincial Revenue Fund, which is subject to similar controls as the NRF and signals a departure from the previous funding set-up.

3.10 While the national government may allocate money for the establishment of isolation hospitals, it would not be through a process of refunds as contemplated in these sections of the 1919 Public Health Act. Overall oversight of expenditure would rest with the provincial head of department, who is the accounting officer in terms of the PFMA and is vested with specific responsibilities, and the national head of department, who is similarly designated as accounting officer. The manner and terms in which refunds may be made in terms of these provisions to local authorities are therefore obsolete and should be repealed.

D Public Health Amendment Acts 57 of 1935, 51 of 1946 and 44 of 1952

1 Recommendation

3.11 It is recommended that DOH repeal Public Health Amendment Acts 57 of 1935, 51 of 1946 and 44 of 1952.

| No. and year of Act | Short title | Extent of repeal |
|---------------------|-----------------------------------|------------------|
| Act 57 of 1935 | Public Health Amendment Act, 1935 | The whole |
| Act 51 of 1946 | Public Health Amendment Act, 1946 | The whole |
| Act 44 of 1952 | Public Health Amendment Act, 1952 | The whole |

2 Purpose of Amendment Acts

3.12 The Amendment Acts concerned were generally enacted to amend the Public Health Act of 1919 and related Acts.

3 Discussion

3.13 The only provision of the Public Health Amendment Act 57 of 1935 that is still in force is section 14*bis*. The section provides for the refund to a local authority of certain expenditure in respect of public health nursing services. Only three subsections of the Public Health Amendment Act 51 of 1946 are still in force. Subsections (2), (3) and (4) of section 17 provides for refunding by the Minister of Health to the administrator of expenditure incurred in connection with the provision of outpatient services.

3.14 Section 32, the sole section of the Public Health Amendment Act 44 of 1952 that is still in force, sets out the principles that shall apply in respect of the emoluments of officers and employees of the provincial administration, local authority, charitable association, body controlling any mission hospital or statutory Black body that may be severally concerned. As explained in paragraphs 3.9 and 3.10 above, the manner in which refunds may be made to local authorities in terms of these provisions are now contrary to the Constitution and the PFMA. The provisions therefore are obsolete and should be repealed.

E Health Act 63 of 1977

1 Recommendation

3.15 Part of Act 63 of 1977 was repealed by section 93 (1) of the NHA with effect from 2 May 2005. The remaining provisions were repealed with effect from 1 March 2012. In view thereof that the Health Act 63 of 1977 and Health Amendment Acts 18 of 1979, 33 of 1981, 37 of 1982, 21 of 1983, 2 of 1984 and 70 of 1985 have been repealed *in toto*

with effect from 1 March 2012, there are no recommendations in respect of the Health Act or the subsequent Health Amendments Acts.

3.16 Once it has been ascertained that the affairs of the Kimberley Health Board has been wound up, publish a notice in the Government Gazette to determine the date when the Kimberley Health Board ceases to exist as required by section 63(4) of the Health Act 63 of 1977 and the Health Amendment Act 18 of 1979.

3.17 The administration of the Health Act 63 of 1977, excluding certain sections as specified, was assigned to the provinces in terms of Proclamation No. 152 of 1994 as published on 31 October 1994 in Government Gazette No. 16049. It is recommended that the national DOH should engage with the provincial departments of health on the possible repeal of Act 63 of 1977 as assigned to the provinces in view thereof that the Health Act of 1977 as administered by the national DOH has been repealed.

2 Purpose of Act

3.18 The purpose of the Health Act 63 of 1977 is to provide for measures for the promotion of the health of the inhabitants of the Republic; to that end to provide for the rendering of health services; to define the duties, powers and responsibilities of certain authorities which render health services in the Republic; to provide for the co-ordination of such health services; to repeal the Public Health Act, 1919; and to provide for incidental matters.

3 Discussion

(a) *Repeal of Health Act 63 of 1977*

3.19 Section 94 of the NHA determines that the NHA takes effect on a date fixed by the President by proclamation in the *Government Gazette*. Section 13(3) of the Interpretation Act 33 of 1957 makes provision for the fixing of different dates for the commencement of different provisions of an Act.²² Section 93 of the NHA, by reference to the schedule to the NHA, determines that the NHA repeals the whole of the Health Act of 1977. However, different dates were determined for the commencement of section 93(1).

²² If any Act provides that that Act shall come into operation on a date fixed by the President or the Premier of a province by proclamation in the *Gazette*, it shall be deemed that different dates may be so fixed in respect of different provisions of that Act.

The date of commencement of the repeal of sections 14 to 16, 18 to 19, 21 to 26, 29 to 31, 41 and 53 of the Health Act of 1977 was determined as 2 May 2005,²³ while the date for the repeal of the rest of the Health Act of 1977 was determined as 1 March 2012.²⁴

The following Health Amendment Acts were also repealed with effect from 1 March 2012:

- (a) Health Amendment Act 18 of 1979
- (b) Health Amendment Act 33 of 1981
- (c) Health Amendment Act 37 of 1982
- (d) Health Amendment Act 21 of 1983
- (e) Health Amendment Act 2 of 1984
- (f) Health Amendment Act 70 of 1985

(b) Section 63 of Act 63 of 1977: Repeal of laws and savings

3.20 Section 63 of the Health Act of 1977 dealt with the repeal of laws and savings. Section 63(4) was a transitional clause that maintained the existence of the Kimberley Health Board and determined as follows:

(4) (a) Notwithstanding the repeal of the Public Health Extension Act, 1884 (Act 10 of 1884 - Cape), by subsection (1), the Kimberley Health Board established by the said Act (in this subsection referred to as the board) shall continue to exist and shall continue to perform its functions until a date determined by the Minister by notice in the Gazette, which may be a date prior to the date of that notice.

3.21 The Health Amendment Act 18 of 1979 provided for certain measures with regard to the Kimberley Health Board. Act 18 of 1979 maintained the existence of the Board and transferred the assets, rights, liabilities, obligations, officers and employees of the Board to the City Council of Kimberley. The long title of Act 18 of 1979 stated that the Act aims:

To amend the provisions of the Health Act, 1977, so as to provide for the continued existence of the Kimberley Health Board to a date determined by the Minister of Health; for the vesting in the City Council of Kimberley of all assets, rights, liabilities and obligations of the said Kimberley Health Board; and for the transfer of the officers and employees of the said Kimberley Health Board to the City Council of Kimberley; and to provide for incidental matters.

²³ Proclamation No. 19 of 2003 National Health Act 61 of 2003: Commencement GG 27503 of 18 April 2005.

²⁴ Proclamation No. 11 of 2012 Commencement of certain sections of the National Health Act 61 of 2003 GG 35081 of 27 February 2012.

3.22 Section 63(4) states that the “Kimberley Health Board shall continue to exist ... until a date determined by the Minister by notice in the Gazette”. The Health Amendment Act 18 of 1979 provides for “the continued existence of the Kimberley Health Board to a date determined by the Minister of Health”. In spite of a diligent search, no Government Gazette notice or determination indicating the date when the Kimberley Health Board ceases to exist could be found. For the sake of legal certainty, once it has been ascertained that the affairs of the Kimberley Health Board has been wound up, a notice to determine the date when the Kimberley Health Board ceases to exist should be published.

(c) Assignment of Act 63 of 1977 to provinces

3.23 The President assigned the administration of Act 63 of 1977, excluding certain sections,²⁵ to the provinces by Proclamation No. 152 of 1994 (published on 31 October 1994)²⁶ as authorised by section 235(8) of the Constitution of the Republic of South Africa of 1993.²⁷ In spite of the repeal of Act 63 of 1977 by the NHA, the assigned sections of Act 63 of 1977 remain in force in the provinces, as Parliament cannot repeal provincial legislation. For the sake of uniformity and legal certainty, the national DOH should engage with the provincial departments of health on the possible repeal by the provinces of the sections of Act 63 of 1977 assigned to them. See Chapter 10 for a more detailed discussion of provincial health legislation.

²⁵ **1. Extent of assignment**

The whole, excluding-

- (a) sections 14, 20 (2), (3) and (4), 30 (2) (b), 30 (3), 32 to 40, 42 and 45 to 49 and 55;
- (b) section 30 (4), in so far as it is to section 30 (2) (b);
- (c) sections 50, 53, 56, 57 and 58 in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government.

²⁶ Proclamation No. 152 of 1994 Assignment to the provinces of the Health Act, 1977, under section 235(8) of the Constitution of the Republic of South Africa, 1993 GG 16049 of 31 October 1994.

²⁷ (8) (a) The President may, and shall if so requested by the Premier of a province, and provided the province has the administrative capacity to exercise and perform the powers and functions in question, by proclamation in the *Gazette* assign, within the framework of section 126, the administration of a law referred to in subsection (6) (b) to a competent authority within the jurisdiction of the government of a province, either generally or to the extent specified in the proclamation.

F Mental Health Amendment Acts

1 Recommendation

3.24 It is recommended that the Mental Health Amendment Acts 48 of 1976, 10 of 1978; 38 of 1981, 3 of 1984, 16 of 1985, 55 of 1987, 52 of 1988 and 19 of 1992 be repealed.

| No. and year of Act | Short title | Extent of repeal |
|----------------------------|-----------------------------------|-------------------------|
| Act 48 of 1976 | Mental Health Amendment Act, 1976 | The whole |
| Act 10 of 1978 | Mental Health Amendment Act, 1978 | The whole |
| Act 38 of 1981 | Mental Health Amendment Act, 1981 | The whole |
| Act 3 of 1984 | Mental Health Amendment Act, 1984 | The whole |
| Act 16 of 1985 | Mental Health Amendment Act, 1985 | The whole |
| Act 55 of 1987 | Mental Health Amendment Act, 1987 | The whole |
| Act 52 of 1988 | Mental Health Amendment Act, 1988 | The whole |
| Act 19 of 1992 | Mental Health Amendment Act, 1992 | The whole |

2 Purpose of Amendment Acts

3.25 All the Mental Health Amendment Acts amended the Mental Health Act of 1973.

3 Discussion

3.26 The purpose of the 1973 Mental Health Act was to provide for the reception, detention and treatment of mentally ill persons and to provide for incidental matters. The Mental Health Act was amended by the following Mental Health Amendment Acts:

- (a) Mental Health Amendment Act 48 of 1976
- (b) Mental Health Amendment Act 10 of 1978
- (c) Mental Health Amendment Act 38 of 1981
- (d) Mental Health Amendment Act 3 of 1984
- (e) Mental Health Amendment Act 16 of 1985
- (f) Mental Health Amendment Act 55 of 1987
- (g) Mental Health Amendment Act 52 of 1988
- (h) Mental Health Amendment Act 19 of 1992 (date of commencement was never proclaimed)

3.27 The whole of the Mental Health Act 18 of 1973, with the exception of Chapter 8, was repealed by the Mental Health Care Act 17 of 2002. Chapter 8 of Act 18 of 1973 was repealed by the Mental Health Care Amendment Act 12 of 2014, which came into operation on 1 July 2016. The Mental Health Amendment Acts 48 of 1976, 10 of 1978, 38 of 1981, 3 of 1984, 16 of 1985, 55 of 1987, 52 of 1988 and 19 of 1992 (not yet proclaimed) all pertain to the repealed MHA. It is clear that these Acts are obsolete and can be repealed forthwith.

G Mentally Ill Persons' Legal Interests Amendment Act 108 of 1990

1 Recommendation

3.28 It is recommended that the Mentally Ill Persons' Legal Interests Amendment Act 108 of 1990 (MIPLI Amendment Act) be repealed and that DOH engage with the Department of Justice and Constitutional Development on amending sections 73 and 77 (that were amended by Act 108 of 1990) of the Administration of Estates Act 66 of 1965.

| No. and year of Act | Short title | Extent of repeal |
|----------------------------|---|-------------------------|
| Act 108 of 1990 | Mentally Ill Persons' Legal Interests Amendment Act, 1990 | The whole |

Amendment of section 73 of Act 66 of 1965

1. Section 73 of the Administration of Estates Act, 1966 is hereby amended by the deletion in subsection (1) of paragraph (b).

Amendment of section 77 of Act 66 of 1965

2. Section 77 of the Administration of Estates Act, 1966 is hereby amended by the substitution for subsection (1) of the following subsection:

“Every person appointed or to be appointed tutor or curator as provided in section 72 (1) (d) or (2) or under section 73 or 74, shall, **[subject to the proviso to section 57 (3) of the Mental Health Act, 1973 (Act 18 of 1973),]** before letters of tutorship or curatorship are granted or signed and sealed, or any endorsement is made, as the case may be, and at any time thereafter when called upon by the

Master to do so, find security or additional security to the satisfaction of the Master in an amount determined by the Master, for the proper performance of his functions.”.

2 Purpose of Act

3.29 The purpose of the MIPLI Amendment Act is to amend the Mental Health Act, 1973 and the Administration of Estates Act, 1965 so as to make further provision for the appointment of a curator for a mentally ill person who is not detained as or declared to be mentally ill or not detained as a mentally ill prisoner or a President’s patient; to further regulate the furnishing of security by a curator; to regulate the termination of the appointment of a curator on the recovery of such a mentally ill person; and to increase certain fines; and to provide for matters connected therewith.

3 Discussion

3.30 The MIPLI Amendment Act amended the Mental Health Act 18 of 1973 and the Administration of Estates Act 66 of 1965.

3.31 The MIPLI Amendment Act amended the MHA in the following manner:

- (a) Section 1 amended section 56 of the MHA to further provide for the appointment of a curator of property of certain mentally ill persons.
- (b) Section 2 inserted section 56A in the MHA, which was inserted to provide for the appointment by the Master of a curator to mentally ill persons not falling within the ambit of section 56.
- (c) Section 3 amended section 57, which dealt with the cessation of the duties of the Master and a curator.
- (d) Section 4 inserted section 57A, which was inserted to provide for the termination of appointment of a curator referred to in section 56A.
- (e) Section 5 amended section 67 to provide for penalties for the contravention of a provision of the MH Act.

3.32 The Mental Health Act of 1973 has since been repealed in its entirety. That means that sections 1 to 5 of the MIPLI Amendment Act are obsolete and can be repealed.

3.33 The MIPLI Amendment Act also amended the Administration of Estates Act 66 of 1965. This was necessary in order to align Act 66 of 1965 with the amendments effected to the MHA discussed above. The following amendments were effected:

- (a) Section 6 amended section 73 of the Administration of Estates Act. Section 73 provides for proceedings on failure of nomination of tutors or curators, or on death, incapacity or refusal to act, etc. Paragraph (b) of subsection (1) specifically refers to the appointment of a curator in terms of sections 56 and 56A of the MHA. Since sections 56 and 56A have since been repealed, paragraph (b) of section 73(1) of the AE Act is obsolete and can be repealed.
- (b) Section 7 amends section 77 of the Administration of Estates Act. Section 77 pertains to the finding of security by tutors and curators before appointment. Subsection (1) refers to the proviso to section 57(3) of the MHA. Section 57 of the MHA has since been repealed. In addition, Chapter VIII of the Mental Health Care Act 17 of 2002 (MHCA) in sections 59 to 65 thereof provides for the care and administration of the property of a mentally ill person or person with severe or profound intellectual disability. Section 63 of the MHCA deals with the lodging of security by an administrator. In view thereof that the appointment of administrators of the property of mentally ill persons and the applicable procedures and conditions for such appointments are now determined in the MHCA, the reference to the repealed MHA in the Administration of Estates Act has become redundant and can be deleted.

H Mental Health Care Act 17 of 2002

1 Recommendation

3.34 There is no recommendation in respect of the Mental Health Care Act 17 of 2002.

2 Purpose of Act

3.35 The purpose of the Mental Health Care Act 17 of 2002 (MHCA) is to provide for the care, treatment and rehabilitation of persons who are mentally ill; to set out different procedures to be followed in the admission of such persons; to establish Review Boards in respect of every health establishment; to determine their powers and functions and to

provide for the care and administration of the property of mentally ill persons; and, to repeal certain laws.

3 Discussion

3.36 There is no apparent inconsistency with section 9 of the Constitution in this Act. There does not appear to be any obsolete or redundant provisions.

I Mental Health Care Amendment Act 12 of 2014

1 Recommendation

3.37 There is no recommendation in respect of the Mental Health Care Amendment Act 12 of 2014 (MHC Amendment Act).

2 Purpose of Act

3.38 The purpose of MHC Amendment Act is to amend the Mental Health Care Act, 2002 to insert a new section; to provide for the delegation of powers by the head of the national department to officials in the national department; to repeal the Mental Health Act, 1973; and to provide for matters connected therewith.

3 Discussion

3.39 The MHC Amendment Act of 2014 came into operation on 1 July 2016. The Act amends the MHCA by inserting section 72A into the Act and by repealing the Mental Health Act 18 of 1973. Section 72A provides for the delegation of powers by empowering the head of the national department to delegate any power conferred upon him or her by this Act to a competent person in the employ of the national department. However, the powers referred to in sections 5, 6(3), 13(2), 41 and 49 of the MHCA are excluded.

3.40 Section 5 of the MHCA provides for the designation of health establishments administered under the auspices of the State as psychiatric hospitals or as care and rehabilitation centres. Section 6 deals with the provision of mental health care, treatment and rehabilitation services at health establishments. Section 6(3) determines that the head of the national department may, with the concurrence of the heads of the relevant provincial departments in respect of health establishments designated in terms of section

5(1), determine the nature of the care, treatment and rehabilitation services to be provided at designated health establishments.

3.41 Section 13 prohibits a person or health establishment from disclosing any information which a mental health care user is entitled to keep confidential. Only the head of the national department, a head of provincial department or the head of the health establishment concerned may disclose information if failure to do so would seriously prejudice the health of the mental health care user or of other people. Section 41 provides for the designation of health establishments for State patients, while section 49 allows for the designation of health establishments for State patients.

J International Health Regulations Act 28 of 1974

1 Recommendation

3.42 It is recommended that the International Health Regulations Act 28 of 1974 be repealed and new legislation adopted in order to incorporate the 2005 International Health Regulations (IHR (2005)) into South African law, and to provide for matters incidental thereto.

2 Purpose of Act

3.43 The International Health Regulations Act 28 of 1974 was enacted to allow for the implementation in South Africa of the International Health Regulations, adopted by the World Health Assembly (WHA), and for matters related therewith. The International Health Regulations constitute the most important source of international law on public health and is binding on signatory countries.

3.44 As a member of the WHA of the World Health Organisation (WHO), South Africa is bound by the International Health Regulations of the WHO. The IHR are incorporated into South African law through national legislation such as this Act. The purpose of the IHR is to prevent the international spread of disease and to enhance national, regional and global public health security.

3 Discussion

3.45 Section 1 of the International Health Regulations Act 28 of 1974 defines the International Health Regulations as meaning “the International Health Regulations adopted by the World Health Assembly (WHA) at Boston on 25 July 1969”, hereinafter IHR (1969). A copy of the said regulations is included in the schedule of the Act. It also contains provisions that allow the Minister to take decisions that are necessary for the effective implementation of the IHR in South Africa, including issuing notices and making regulations.

3.46 However, the IHR (1969) has undergone substantial revision pursuant to the emergence of new international public health threats, such as severe acute respiratory syndrome (SARS) and biological and chemical threats. The revisions have resulted in the IHR (2005). The 58th World Health Assembly on 23 May 2005 adopted the revised International Health Regulations, hereinafter referred to as IHR (2005), which supersedes in its entirety IHR (1969). IHR (2005) entered into force on 15 June 2005. Accordingly, all references in the Act to the IHR are being made in regard to an obsolete international instrument.

3.47 South Africa is a member of the World Health Organisation and a state party to the IHR (2005). In terms of international law South Africa is legally obliged to give effect to the IHR (2005), creating an obligation for South Africa to adopt legislation to implement the IHR (2005).²⁸ The International Health Regulations Bill, 2013 was published for public comment on 14 October 2013 in Government Gazette No. 36931 by Notice No. 1020 of 2013. Although the Bill is not before Parliament at this stage, DOH has indicated that the DOH plans to revive the Bill in 2017.

3.48 In addition to the use of male-centric terminology, there are a number of provisions in this Act that are obsolete. In view of the recommendation that the Act should be repealed, it is unnecessary to specify these provisions.

²⁸ Section 231(4) of the Constitution of the Republic of South Africa, 1996 (the Constitution) states that an international agreement becomes law in South Africa when it is enacted into law by national legislation. A toolkit on implementing the IHR domestically is available on the WHO website at <http://www.who.int> accessed on 14 September 2015.

K Health Laws Amendment Act 36 of 1977

1 Recommendation

3.49 It is recommended that sections 1, 2, 3, 9, 10, 13, 14, 15, 16, 17 and 18 of the Health Laws Amendment Act 36 of 1977 be repealed. Sections 4 to 8 were repealed by the Allied Health Professions Act 63 of 1982.

| No. and year of Act | Short title | Extent of repeal |
|----------------------------|---------------------------------|----------------------------------|
| Act 36 of 1977 | Health Laws Amendment Act, 1977 | Sections 1 to 3, 9, 10, 13 to 18 |

2 Purpose of Act

3.50 The purpose of the Health Laws Amendment Act 36 of 1977 (HL Amendment Act 1977) was to amend the Medicines and Related Substances Act, 1965 (MRSA); Mental Health Act, 1973 (MHA); Pharmacy Act, 1974 and the Health Professions Act, 1974 (HPA).

3 Discussion

(a) Amendment to the Medicines and Related Substances Act 101 of 1965

3.51 Section 1 of the HL Amendment Act amended section 3 of the MRSA by substituting subsection (1). Section 3 of the MRSA was subsequently amended several times and was substituted by the Medicines and Related Substances Control Amendment Act 90 of 1997. Section 1 of the HL Amendment Act is therefore obsolete and can be repealed.

3.52 Section 3 of the MRS Act stands to be substituted again by section 3 of the Medicines and Related Substances Amendment Act 72 of 2008. Section 3 as substituted will then be amended again by section 4 of the Medicines and Related Substances Amendment Act 14 of 2015. The commencement dates of both Act 72 of 2008 as well as Act 14 of 2015 are still to be proclaimed.

(b) Amendments to Mental Health Act 18 of 1973

3.53 The Health Laws Amendment Act 36 of 1977 amended the Mental Health Act 18 of 1973 in the following manner:

- (a) Section 2 amended section 47 of the MHA. The MHA has since been wholly repealed by the Mental Health Care Act 17 of 2002 and the Mental Health Care Amendment Act 12 of 2014. Section 2 of the HL Amendment Act is therefore obsolete and can be repealed.
- (b) Section 3 amended section 77 of the MHA. Since section 77 of the MHA was repealed by the Mental Health Care Act of 2002, section 3 of the HL Amendment Act is obsolete and can be repealed.

(c) Amendments to Pharmacy Act 53 of 1974

3.54 The Health Laws Amendment Act 36 of 1977 amended the Pharmacy Act 53 of 1974 in the following manner:

- (a) Section 9 amended section 22 of the Pharmacy Act, but since section 22 was later substituted in whole by the Pharmacy Amendment Act 88 of 1977, section 9 of the HL Amendment Act is now obsolete and can be repealed.
- (b) Section 10 inserted section 22A into the Pharmacy Act. Section 22A was substituted in whole by the Pharmacy Amendment Act 88 of 1977, meaning that section 10 of the HL Amendment Act is now obsolete and can be repealed.
- (c) Section 11 of the HL Amendment Act amended section 49(1) of the Pharmacy Act, which amendment is still relevant. However, if the Pharmacy Act, 1977 is consolidated and promulgated afresh as proposed in paragraph 8.3, section 11 can be repealed.

(d) Amendments to Health Professions Act 56 of 1974

3.55 The Health Laws Amendment Act 36 of 1977 amended the Health Professions Act 56 of 1974 in the following manner:

- (a) Section 12 amended section 1 of the Health Professions Act 56 of 1974 by the insertion of the definition of “student intern”. This amendment is still relevant. However, if the Health Professions Act, 1977 is consolidated and promulgated afresh as proposed in paragraph 7.3, section 12 can be repealed.

- (b) Section 13 amended section 18(1) of the HP Act. Section 18(1) of the HP Act has however since been substituted several times, the last time by the Health Professions Amendment Act 29 of 2007. Section 13 is therefore obsolete.
- (c) Section 14 of the HL Amendment Act amended section 32 of the HP Act. Section 32 has since been repealed by the Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997. Section 14 is therefore obsolete.
- (d) Section 15 of the HL Amendment Act inserted sections 32A and 32B in the HP Act. Sections 32A and 32B have since been repealed by Act 89 of 1997. Section 15 is therefore obsolete.
- (e) Section 16 amended section 36(2) by inserting paragraph (aA) in the HP Act, but the entire section 36 had since been repealed. Section 16 is therefore obsolete.
- (f) Section 17 inserted section 52A in the HP Act, but section 52A was later repealed by Act 89 of 1997. Section 17 is therefore obsolete.
- (g) Section 18 amended paragraphs of section 61(1) of Act 56 of 1974, but all the paragraphs concerned have since been substituted or repealed. Section 18 is therefore obsolete.

L Health and Welfare Matters Amendment Act 118 of 1993

1 Recommendation

3.56 Sections 14 and 15 of the Health and Welfare Matters Amendment Act 118 of 1993 (HWM Amendment Act) can be repealed as both sections pertain to the Social Assistance Act 59 of 1992, which has since been repealed.

| No. and year of Act | Short title | Extent of repeal |
|----------------------------|--|-------------------------|
| Act 118 of 1993 | Health and Welfare Matters Amendment Act, 1993 | Sections 14 and 15 |

2 Purpose of Act

3.57 The HWM Amendment Act aimed to amend the Health Act, 1977 to authorize an Administrator to prescribe the moneys payable for the rendering of certain services; and

to further regulate the duties and powers of local authorities in connection with health care services; to amend the Dental Technicians Act, 1979 to allow a non-member of the South African Dental Technicians Council to be the chairman or vice-chairman of a committee of the council; to amend the National Policy for Health Act, 1990 to do away with the Administrators Health Council; and to change the constitution of certain health bodies; to amend the Medicines and Related Substances Control Amendment Act, 1991 to further provide for the commencement of certain sections thereof; to amend the Probation Services Act, 1991 to further provide for the treatment of probationers; to amend the Social Assistance Act, 1992 to define certain expressions; and to provide that grants may be paid in respect of care-dependent children; and to provide for incidental matters.

3 Discussion

3.58 Sections 1 to 10 of the HWM Amendment Act have been repealed. Section 11 substitutes section 29 of the Medicines and Related Substances Control Amendment Act 94 of 1991, which is still relevant. Section 12 amends section 2 of the Probation Services Act 116 of 1991 and section 13 inserts section 3A into Act 116 of 1991. Both sections 12 and 13 are still relevant. Sections 14 and 15 of the HWM Amendment Act respectively amend sections 1 and 2 of the Social Assistance Act 59 of 1992. The Social Assistance Act of 1992 was repealed by the Social Assistance Act 13 of 2004. Sections 14 and 15 of the HWM Amendment Act are therefore obsolete and can be repealed.

CHAPTER 4: NATIONAL HEALTH ACT

A National Health Act: Summary of Recommendations

Note

The DOH indicated that they are working on an amendment to the National Health Act, 2003. The amendments proposed below could be included as part of that amendment. Refer to the proposed **National Health Amendment Bill** in **Annexure C**.

1. The following are recommended regarding the promulgation of the National Health Act 61 of 2003 (NHA) and the review of provincial legislation:
 - (a) Promote outstanding regulations with a view to putting sections 36 to 40 of the NHA into operation (see paragraphs 4.4 and 4.10 to 4.18).
 - (b) Identify the reasons why sections 77 to 79 and 83 of the NHA had not been put into operation yet, address problems, if any, and operationalize the said sections (see paragraphs 4.22 to 4.24 and 4.56).
 - (c) Engage with the provinces on bringing provincial legislation in line with the NHA once fully operationalized (see paragraphs 4.26 to 4.28).
 - (d) Engage with the provinces regarding the repeal of obsolete or redundant provincial legislation (see Chapter 10).
2. The following are recommended regarding the content of the NHA:
 - (a) Section 1
 - i. Insert a definition or a description of “brain death” (see paragraphs 4.30 to 4.34).
 - ii. In the definitions of “health care provider” and “statutory health professional council”, refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978) (see paragraph 4.29).
 - iii. In the definition of “health technology”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) (see paragraph 4.29).
 - iv. In the definition of “user”:
 - refer to section 129 of the Children’s Act, 2005 (Act 38 of 2005) instead of section 39(4) of the repealed Child Care Act, 1983 (Act 74 of 1983) (see paragraph 4.29);
 - refer to “major child or major sibling” instead of “adult child or brother or sister” (see paragraphs 4.35 to 4.39).

- v. Insert definitions for “non-therapeutic research” and “therapeutic research” (see paragraphs 4.43 to 4.46).
- (b) Section 7(1)(b): Refer to “a major child or a major sibling of the user, in the specific order mentioned” instead of “an adult child or a brother or a sister of the user, in the specific order as listed” (see paragraphs 4.37 to 4.41).
- (c) Section 13: Refer to the National Archives and Record Service of South Africa Act, 1996 (Act 43 of 1996) instead of the National Archives of South Africa Act, 1996 (Act 43 of 1996) (see paragraph 4.29).
- (d) Section 45(3): Refer specifically to the Local Authorities: Municipal Finance Management Act, 2003 (Act 56 of 2003) instead of “any municipal finance management legislation” (see paragraph 4.42).
- (e) Sections 59(2): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) (see paragraph 4.29).
- (f) Sections 62(2) and 66(1)(b): Refer to “major sibling” instead of “major brother or major sister” (see paragraphs 4.37 to 4.41).
- (g) Section 71: Amend the wording to incorporate the terms “therapeutic research” and “non-therapeutic research” (as defined) rather than describing research as “research or experimentation ... for a therapeutic purpose” or “research or experimentation ... for a non-therapeutic purpose” (see paragraphs 4.43 to 4.46).
- (h) Section 71(2) and (3):
 - i. Either refer to the “best interest of the child” in both subsections, or do not refer to the “best interest of the child” at all (see paragraph 4.47).
 - ii. Use the term “minor child” consistently to refer to a person under the age of 18 years instead of referring to a “child” in some instances and a “minor” in other instances (see paragraph 4.48).
- (i) Section 71(3): In view of the role and specialised knowledge of health research ethics committees, the requirement for Ministerial approval of non-therapeutic consent is arguably redundant. Give consideration therefore to deleting section 71(3)(a)(ii) of the Act and amending section 71(3)(b) accordingly (see paragraphs 4.49 to 4.52).
- (j) Section 71(3): Give consideration to making provision for the participation of minor children in non-therapeutic research without parental consent or the consent of the child’s guardian in certain circumstances (see paragraph 4.53).

- (k) Section 79E(2)(c): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973), taking into consideration that the processes provided for in the MHCA differs from the processes provided for in the MHA (see paragraph 4.29).
 - (l) Section 82: Amend this section to compel a health officer or inspector to show proof of his or her identity and certificate of appointment as a health officer or inspector, as the case may be, when entering premises or a health establishment (see paragraphs 4.54 to 4.55).
 - (m) Section 86: Amend this section to compel a health officer or inspector to show proof of his or her identity and certificate of appointment as a health officer or inspector, as the case may be, when entering premises or a health establishment (see paragraphs 4.54 to 4.55).
 - (n) Section 90(2): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) (see paragraphs 4.29).
3. There is no recommendation regarding the National Health Amendment Act 12 of 2013 (see paragraphs 4.57 to 4.60).

B National Health Act 61 of 2003

1 Recommendation

4.1 The following are recommended regarding the promulgation of the National Health Act 61 of 2003 (NHA) and the review of provincial legislation:

- (a) Promote outstanding regulations with a view to putting sections 37 to 40 of the NHA into operation.
- (b) Identify the reasons why sections 77 to 79 and 83 of the NHA had not been put into operation yet, address problems, if any, and operationalize the said sections.
- (c) Engage with the provinces on bringing provincial legislation in line with the NHA once fully operationalized.
- (d) Engage with the provinces regarding the repeal of obsolete or redundant provincial legislation.

4.2 The following are recommended regarding the content of the NHA:

- (a) Section 1
- i. Insert a definition or a description of “brain death”.
 - ii. In the definitions of “health care provider” and “statutory health professional council”, refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
 - iii. In the definition of “health technology”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
 - iv. In the definition of “user”:
 - refer to section 129 of the Children’s Act, 2005 (Act 38 of 2005) instead of section 39(4) of the repealed Child Care Act, 1983 (Act 74 of 1983);
 - refer to “major child or major sibling” instead of “adult child or brother or sister”.
 - v. Insert definitions for “non-therapeutic research” and “therapeutic research”.
- (b) Section 7(1)(b): Refer to “a major child or a major sibling of the user, in the specific order mentioned” instead of “an adult child or a brother or a sister of the user, in the specific order as listed”.
- (c) Section 13: Refer to the National Archives and Record Service of South Africa Act, 1996 (Act 43 of 1996) instead of the National Archives of South Africa Act, 1996 (Act 43 of 1996).
- (d) Section 45(3): Refer specifically to the Local Authorities: Municipal Finance Management Act, 2003 (Act 56 of 2003) instead of “any municipal finance management legislation”.
- (e) Sections 59(2): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (f) Sections 62(2) and 66(1)(b): Refer to “major sibling” instead of “major brother or major sister”.
- (g) Section 71: Amend the wording to incorporate the terms “therapeutic research” and “non-therapeutic research” (as defined) rather than describing research as “research or experimentation ... for a therapeutic purpose” or “research or experimentation ... for a non-therapeutic purpose”.
- (h) Section 71(2) and (3):
- i. Either refer to the “best interest of the child” in both subsections, or do not refer to the “best interest of the child” at all.

- ii. Use the term “minor child” consistently to refer to a person under the age of 18 years instead of referring to a “child” in some instances and a “minor” in other instances.
- (i) Section 71(3): In view of the role and specialised knowledge of health research ethics committees, the requirement for Ministerial approval of non-therapeutic consent is arguably redundant. Give consideration therefore to deleting section 71(3)(a)(ii) of the Act and amending section 71(3)(b) accordingly.
- (j) Section 71(3): Give consideration to making provision for the participation of minor children in non-therapeutic research without parental consent or the consent of the child’s guardian in certain circumstances.
- (k) Section 79E(2)(c): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973), taking into consideration that the processes provided for in the MHCA differs from the processes provided for in the MHA.
- (l) Section 82: Amend this section to compel a health officer or inspector to show proof of his or her identity and certificate of appointment as a health officer or inspector, as the case may be, when entering premises or a health establishment.
- (m) Section 86: Amend this section to compel a health officer or inspector to show proof of his or her identity and certificate of appointment as a health officer or inspector, as the case may be, when entering premises or a health establishment.
- (n) Section 90(2): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).

2 Purpose of Act

4.3 The National Health Act 61 of 2003 was enacted to provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith.

3 Discussion

(a) Provisions of National Health Act not in operation

4.4 There are a number of provisions in the National Health Act for which a date of commencement has not yet been determined, or that lack the necessary regulations in order to allow for the operationalization thereof. Refer to **Annexure D** for a detailed list of all the sections of the NHA and the specific dates when sections were operationalized, amended (where applicable) or inserted, as well as references to the relevant enacting proclamations. The provisions of the NHA that are not in operation yet are the following:

- (a) Sections 36 to 40 and 47 in Chapter 6: Health Establishments.
- (b) Sections 77 to 79 and 83 in Chapter 10: Office of Health Standards Compliance, Board, inspections and environmental health investigations, health officers and inspectors, complaints and appeal procedure (as amended).

(b) Status of health legislation under NHA and related legislation

4.5 The “structured uniform health system” envisaged by the NHA is currently applied in the manner set out hereunder.

(i) Definitions, national health, provincial health and district health system

4.6 Section 1, containing the definitions, and Chapter 1 (sections 2 to 5) headed *Objects of Act, responsibility for health and eligibility for free health services*, has been in operation since 2 May 2005. The National Health Amendment Act 12 of 2013 amended section 1 by inserting a number of new definitions,²⁹ amending some of the existing definitions³⁰ and deleting two definitions.³¹ These amendments came into operation on 2 September 2013. The whole of Chapter 2 (sections 5 to 20) dealing with rights and duties of users and health care personnel, with the exception of section 11, has also been in operation since 2 May 2005. Section 11 that deals with health services for experimental or research purposes has been in operation since 1 March 2012.

²⁹ New definitions inserted: “Board”; “Chief Executive Officer”; “inspector”; “Office” and “Ombud”.

³⁰ Definition of “health officer” substituted.

³¹ Definitions deleted: “Inspectorate for Health Establishments” and “Office of Standards Compliance”.

4.7 Chapter 3 (sections 21 to 24) headed *National Health*, sets out the general functions of the national Department of Health, and establishes and determines the composition and functions of the National Health Council. Chapter 3 has been in operation since 2 May 2005. Section 21 provides for the general functions of the national department. The National Health Amendment Act 12 of 2013 amended section 21(1) by substituting paragraph (f). Sections 22 and 23 of the NHA deal with the establishment, composition and functions of the National Health Council. Section 24 imposes a duty on the Minister to establish a National Consultative Health Forum.

4.8 Chapter 4 (sections 25 to 28) headed *Provincial Health*, deals with provincial health services and general functions of provincial departments, and establishes and determines the composition and functions of Provincial Health Councils. Chapter 4 has been in operation since 2 May 2005. Section 25 provides for provincial health services and general functions of provincial departments. The National Health Amendment Act 12 of 2013 amended section 25(1) by substituting paragraph (l). Sections 26 and 27 of the NHA deal with the establishment, composition and functions of the Provincial Health Council. Section 28 imposes a duty on the relevant member of the Executive Council of a province to establish a provincial consultative body.

4.9 Chapter 5 (sections 29 to 34), headed *District health system for Republic*, has been in operation since 2 May 2005. This chapter deals with the establishment of a district health system (section 29), provides for the possible divisions of health districts into subdistricts (section 30) and imposes a duty on the relevant member of the Executive Council of a province to establish district health councils (section 31). Section 32 imposes a duty on municipalities to provide appropriate municipal health services, while section 33 requires the preparation of district health plans. Section 34 pertains to transitional arrangements concerning municipal health services.

(ii) *Health establishments*

(aa) Chapter 6 of NHA

4.10 Chapter 6 (sections 35 to 47) headed *Health Establishments*, deals with the classification of health establishments – such as hospitals (section 35); the issuing, renewal and duration of certificates of need (sections 36 and 37); appeals to the Minister (section 38); regulations relating to and offences and penalties in respect of certificates of need (sections 39 and 40), provision of health services at public health establishments, clinics and community health centre committees (sections 41 and 42); as well as for

prescribing minimum standards for health services at non-health establishments and at public health establishments other than hospitals (section 43). This chapter also addresses referrals between public health establishments (section 44), the relationship between public and private health establishments (section 45); obligations of private health establishments (section 46) and evaluating services of health establishments (section 47).

4.11 From the subject matter of Chapter 6 it is clear that this is a vital chapter since it regulates the health establishments where health services are provided. As stated in paragraph 2.5 above, one of the aspects referred to in the mission of the DOH is: "To improve the health status of South Africans through the prevention of illnesses and the promotion of healthy lifestyles and to consistently improve the health care delivery system by focusing on access, equity, efficiency, quality and sustainability."³² However, sections 36 to 40 and section 47, regarding evaluating services of health establishments, of Chapter 6 has not been put into operation yet and it is not clear when it will commence.

(bb) *President of RSA v SADA*

4.12 Sections 36 to 40 of the NHA formed the subject of a court application in the matter of the *President of the Republic of South Africa and Others v South African Dental Association and Another*³³ (*President of RSA v SADA*). The matter concerns the premature promulgation of a proclamation bringing certain sections of the National Health Act into operation.³⁴ The background to the application was as follows:

4.13 On 21 March 2014 the President signed a proclamation, Proclamation 21 of 2014, to bring sections 36, 37, 38, 39 and 40 of the National Health Act into operation on 1 April 2014.³⁵ Section 36 pertains to the requirement to hold a certificate of need. Section 36(1) prohibits a person from doing the following without a certificate of need issued by the Director-General of DOH:

³² Department of Health *2015/16 Annual Report* at 10 available at <http://www.gov.za/documents> accessed 26 January 2017.

³³ [2015] ZACC 2

³⁴ [2015] ZACC on 2 at [1].

³⁵ Proclamation No. 21 of 2014 Commencement of Certain Sections of the National Health Act 61 of 2003 GG 37501 of 31 March 2014.

- (a) Establishing, constructing, modifying or acquiring a health establishment or health agency;
- (b) Increasing the number of beds at a health establishment or health agency;
- (c) Acquiring prescribed health technology at a health establishment or agency;
- (d) Providing prescribed health services;
- (e) Continuing the operation of a health establishment or health agency 24 months after the NHA takes effect.

4.14 The rest of section 36 deals with the application for and issuing of a certificate of need. Section 37 determines the duration of a certificate of need, section 38 provides for an appeal procedure to the Minister of Health and section 39 provides for regulations relating to certificates of need. Section 40 makes non-compliance with section 36(1) an offence.

4.15 The applicants contended³⁶ that the provisions pertaining to a certificate of need cannot be implemented without regulations regarding the application for and granting of certificates of need. Regulations in terms of section 39 of the NHA, an essential part of the legislative scheme, had not been promulgated when Proclamation 21 of 2014 was issued; therefore health service providers in South Africa were engaging in criminal conduct as no individual or entity that provides health services was in a position to obtain the required certificate of need as long as the regulations had not taken effect.

4.16 Although the President exercised his public power to bring the provisions into operation *bona fide*, the President's decision was made in error and was therefore irrational in law. The President, the Minister in the Presidency, the Director-General in the Presidency, the Minister of Health and the Director-General of the Department of Health (the applicants) therefore sought a court order declaring Proclamation 21 of 2014 invalid and setting it aside. The South African Dental Association (SADA) and the Hospital Association of South Africa (HASA) were cited as respondents in this matter, but they supported the relief sought by the President. Indeed, it was SADA who brought the alarming situation that necessitated the application to the attention of the Presidency.

4.17 The President's issuing of the Proclamation bringing into operation sections 36 to 40 of the National Health Act, before the issuing of regulations that are essential to the operation of these sections, had led to an untenable and unintended situation. The

³⁶ [2015] ZACC on 3 at [2] to 5 at [6].

President was unable to withdraw Proclamation 21 of 2014 because the date for its commencement had long since passed and there is no mechanism contained in the National Health Act itself to remedy the consequences of the Proclamation. Even though the Proclamation was issued in error, it remained in force and had legal effect. It is an inevitable consequence of the rule of law that the Proclamation could not be ignored until it was set aside. This Court was therefore called upon to consider and set aside the Proclamation.³⁷

4.18 The Constitutional Court found that:³⁸

The purpose of the President's power to bring portions of the National Health Act into operation is to achieve an orderly and expeditious implementation of a national regulatory scheme for health services. Clearly the decision to issue the Proclamation before there was any mechanism in place to address applications for certificates of need, thereby rendering the provision of health services a criminal offence, was not rationally connected to this purpose (or any other governmental objective). ... Accordingly, the President's decision was irrational and therefore invalid. The Proclamation must be set aside.

(iii) *Human resources planning and academic complexes*

4.19 Chapter 7 (sections 48 to 52) headed *Human resources planning and academic health complexes* deals with human resources in the national health system (section 48), services of health care providers (section 49), a forum of Statutory Health Professional Councils (section 50) and the establishment of academic health complexes (section 51). With the exception of sections 50 and 51, this chapter has been in operation since 2 May 2005. Sections 50 and 51 were put into operation with effect from 1 March 2012.

(iv) *Control of use of blood, blood products, tissue and gametes in humans*

4.20 Chapter 8 (sections 53 to 68) is headed *Control of use of blood, blood products, tissue and gametes in humans*. Section 53, that imposes a duty on the Minister to establish a national blood transfusion service for the Republic, came into operation on 30 June 2008. Section 55 – removal of tissue, blood, blood products or gametes from living persons, section 56 – use of tissue, blood, blood products or gametes removed or withdrawn from living persons, and section 68 – regulations relating to tissue, cells,

³⁷ [2015] ZACC on 7 at [11] and on 7 and 8 at [12].

³⁸ [2015] ZACC on 9 at [15] and [17].

organs, blood, blood products and gametes, came into operation on 17 May 2010. Sections 54 (designation of authorised institution) and sections 57 to 67 came into operation on 1 March 2012. Sections 57 to 67 pertain to reproductive cloning, the use and donation of human tissue and organs, administering of blood and blood products, post mortem examinations and related matters. The subject matter of the parts of Chapter 8 that came into operation on 1 March 2012 was previously regulated by the Human Tissue Act 65 of 1983.

(v) *National health research and information*

4.21 Chapter 9 (sections 69 to 76) headed *National health research and information* has been in operation since 2 May 2005. Section 71 that deals with research or experimentation on human subjects came into operation on 1 March 2012. The rest of this chapter deals with the National Health Research Committee (section 69); health research priorities (sec 70); research on or experimentation with human subjects (sec 71); the National Health Research Ethics Council (sec 72); health research ethics committees (sec 73); and the national health information system (sections 74 to 76).

(vi) *Office of Health Standards Compliance, Board, inspections and environmental health investigations, health officers and inspectors, complaints and appeal procedure*

4.22 Chapter 10 (sections 77 to 89) is headed *Office of Health Standards Compliance, Board, inspections and environmental health investigations, health officers and inspectors, complaints and appeal procedure*. Chapter 10 was amended substantially by the National Health Amendment Act 12 of 2013 (see also paragraphs 4.58 to 4.61). Section 77 provides for the establishment of the Office of Health Standards Compliance (the Office), section 78 deals with the objects of the Office and section 79 deals with the functions of the Office. Sections 77, 78 and 79 have not been put into operation to date, but were nevertheless substituted by Act 12 of 2013. Sections 79A to 79K were inserted by Act 12 of 2013 with effect from 2 September 2013 to establish the Office of Health Standards Compliance Board and to provide for the composition and appointment of a chairperson, vice-chairperson and members of the board, meetings and committees of the board and the chief executive officer.

4.23 Section 80 provides for the appointment of health officers and inspectors. Section 81 imposes a duty on the Minister of Health to appoint an Ombud, located within the Office, to consider, investigate and dispose of complaints relating to norms and

standards. Sections 81A and 81B pertain to the functions, independence, impartiality and accountability of the Ombud. Section 82 sanctions inspections to ensure compliance with the NHA and section 82A prescribes the procedure to be followed for non-compliance with prescribed norms and standards. Sections 83, which authorises environmental health investigations, has not been put into operation to date, but was substituted by Act 12 of 2013. Sections 84, 85, 86, 86A, and 87 pertain to the entry and search of premises. Section 88 deals with miscellaneous provisions relating to health officers, inspectors and compliance procedures; section 88A provides for a procedure for dealing with appeals against decisions of the Office or the Ombud; and section 89 creates offences and imposes penalties.

4.24 This chapter has been in operation since 2 May 2005, with the exception of section 77 – Establishment of Office of Health Standards Compliance, section 78 – Objects of Office, section 79 – Functions of Office, and section 83 – Environmental health investigations. There is no national legislation that deals with the subject matter of sections 77, 78, 79 and 83 at present. The sections inserted by Act 12 of 2013 (sections 79A to 79K, 81A, 81B, 82A, 86A and 88A) and the operational sections of Chapter 10 that were substituted by Act 12 of 2013 (sections 80 to 82 and 84 to 89) came into operation on 2 September 2013. It is not clear why sections 77 to 79 and 83 have not been put into operation yet.

(vii) Regulations and general provisions

4.25 Chapter 11 (section 90) authorises the Minister to make regulations. Chapter 12 (sections 91 to 94) contain general provisions such as assignment of duties; delegation of powers; and the repeal of laws and savings. Both chapters have been in operation since 2 May 2005. Section 90 was amended by Act 12 of 2013 by the amendment of subsection (1) and the addition of subsection (1A) with effect from 2 September 2013.

(c) Constitution: Health services as a functional area of concurrent national and provincial legislative competence

4.26 In terms of Schedule 4 of the Constitution, “health services” is a functional area of concurrent national and provincial legislative competence. Read with section 44 of the Constitution, it means that the national legislative authority as vested in Parliament confers on the National Assembly the power to pass legislation with regard to any matter, including a matter within a functional area listed in Schedule 4. Section 68 of the Constitution empowers the National Council of Provinces, in exercising its legislative

power, to initiate or prepare legislation falling within a functional area listed in Schedule 4. Section 104 of the Constitution states that the legislative authority of a province is vested in its provincial legislature, and confers on the provincial legislature the power to pass legislation for its province with regard to any matter within a functional area listed in Schedule 4.

4.27 The result of this Constitutional arrangement is that there now are national and provincial legislation that pertain to health services. Some of the national legislation dates back to before 1994 (the two oldest principal Acts being the Public Health Act of 1919 and the Medicines and Related Substances Act of 1965), while a number of new health laws were adopted post 1994. Some of the provincial legislation still in force are pre-1994 provincial ordinances (for example the Provincial Hospitals Ordinances [Natal] 13 of 1938 and the Hospitals Ordinance [Cape of Good Hope] 18 of 1946) or legislation from the former states of Bophuthatswana (Health Act [Bophuthatswana] 12 of 1983) and Venda (Health Act (Venda) 13 of 1984), that were assigned to the provinces, while some (but not all) provinces adopted new provincial legislation after 1994.

4.28 It is strongly recommended that the national Department of Health should engage with the provincial departments of health to align national and provincial legislation. The provinces should also be engaged on possibly repealing redundant or obsolete provincial legislation, paying specific attention to provincial ordinances and legislation from the former independent states of Transkei, Bophuthatswana, Venda and Ciskei. Provincial legislation currently in force is discussed in more detail in Chapter 10 of this document.

(d) *References to outdated and repealed legislation*

4.29 There are several definitions and sections that refer to outdated or repealed legislation. In section 1 there are references to the Nursing Act 50 of 1978 instead of the Nursing Act 33 of 2005 (definitions of 'health care provider' and 'statutory health professional council'), the Medicines and Related Substances Control Act 101 of 1965 instead of the Medicines and Related Substances Act 101 of 1965 (definition of 'health technology') and the Child Care Act 74 of 1983 instead of the Children's Act 38 of 2005 (definition of 'user'). Sections 59(2) and 90(2) similarly refer to the Medicines and Related Substances Control Act 101 of 1965 instead of the Medicines and Related Substances Act 101 of 1965.

(e) Meaning of “brain death”

4.30 The NHA defines “death” as meaning “brain death”. However, in spite of this definition being quite important, especially in view of provisions where it is critical to determine when a person is considered to be dead (for example for purposes of section 61 – Allocation and use of human organs, section 62 – Donation of human bodies and tissue of deceased persons, and section 64 – Purposes of donation of body, tissue, blood or blood products of deceased persons), the NHA contains no further definition or explanation of “death” or “brain death”.

4.31 Brain death is now universally accepted as the criterion for determining when a person is dead, as opposed to cessation of breathing or heartbeat. In 1968 the Harvard Medical School convened a committee to redefine death. The Ad-Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death was composed of neurologists, physiologists, public health clinicians, biochemists, transplant surgeons, a medical historian and an ethicist.³⁹ The Committee’s report described the characteristics of an “irreversible coma”, now referred to as “brain death”, in summary as follows:⁴⁰

1. *Unreceptivity and unresponsivity* – patient shows total unawareness to external stimuli and unresponsiveness to painful stimuli;
2. *No movements or breathing* – all spontaneous muscular movement, spontaneous respiration and response to stimuli are absent;
3. *No reflexes* – fixed, dilated pupils; lack of eye movement even when hit or turned, or ice water is placed in the ear; lack of response to noxious stimuli; unelicitable tendon reflexes.

In addition to these criteria, a flat electroencephalogram (EEG) was recommended. The committee also noted that drug intoxication and hypothermia, which can both cause reversible loss of brain functions, should be excluded as causes.

³⁹ L Dawes “Death by Committee” 6 Junie 2013 available at <https://doctorthen.wordpress.com> under the tag harvard-ad-hoc-committee-to-examine-the-definition-of-brain-death accessed 23 November 2016.

⁴⁰ Euthanasia Procom *Summary of the Report of The Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death (1968)* available at [http://euthanasia.procon.org/sourcefiles document name Harvard_ad_hoc_brain_death.pdf](http://euthanasia.procon.org/sourcefiles/document%20name%20Harvard_ad_hoc_brain_death.pdf) accessed 23 November 2016.

4.32 An Internet search yielded a number of results with regard to a definition of 'brain death'. *The American Heritage Medical Dictionary* defines brain death as:⁴¹

Irreversible brain damage and loss of brain function, as evidenced by cessation of breathing and other vital reflexes, unresponsiveness to stimuli, absence of muscle activity, and a flat electroencephalogram for a specific length of time. Also called *cerebral death*.

4.33 The Uniform Determination of Death Act, 1980, as approved and recommended for enactment in all the states of the United States of America, indicates the criteria for the determination of death as follows:⁴²

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

4.34 The *Encyclopaedia of Death and Dying* describes "brain death" as follows:⁴³

The term *brain death* is defined as "irreversible unconsciousness with complete loss of brain function," including the brain stem, although the heartbeat may continue. Demonstration of brain death is the accepted criterion for establishing the fact and time of death. Factors in diagnosing brain death include irreversible cessation of brain function as demonstrated by fixed and dilated pupils, lack of eye movement, absence of respiratory reflexes (apnea), and unresponsiveness to painful stimuli. In addition, there should be evidence that the patient has experienced a disease or injury that could cause brain death. A final determination of brain death must involve demonstration of the total lack of electrical activity in the brain by two electroencephalographs (EEGs) taken twelve to twenty-four hours apart. Finally, the physician must rule out the possibilities of hypothermia or drug toxicities, the symptoms of which may mimic brain death. Some central nervous system functions such as spinal reflexes that can result in movement of the limbs or trunk may persist in brain death.

(f) References to child, brother and sister

4.35 The definition of "user" in section 1 states in relevant parts:

⁴¹ *The American Heritage® Dictionary of the English Language* 5th edition (2013), Houghton Mifflin Harcourt Publishing Company available at <http://www.yourdictionary.com> accessed 23 November 2016.

⁴² Lloyd Duhaime *Duhaime's Law Dictionary* available at <http://www.duhaime.org/LegalDictionary/D/Death.aspx> accessed 23 November 2016.

⁴³ *The Encyclopedia of Death and Dying* available at <http://www.deathreference.com> accessed 23 November 2016.

“user” means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is –

- (b) incapable of taking decisions, 'user' includes the person's spouse or partner or, in the absence of such spouse or partner, the person's parent, grandparent, **adult child or brother or sister**, or another person authorised by law to act on the firstmentioned person's behalf; (emphasis added)

4.36 Section 7 of the NHA deals with the consent of a user for the provision of a health service. Section 7(1)(b) refers to a scenario where a user is unable to give consent and determines:

(1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless –

- (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, **an adult child or a brother or a sister of the user, in the specific order as listed**; (emphasis added)

4.37 Section 62 that deals with the donation of human bodies and tissue of deceased persons, determines in subsection (2):

(2) In the absence of a donation under subsection (1) (a) or of a contrary direction given by a person whilst alive, the spouse, partner, **major child**, parent, guardian, **major brother or major sister** of that person, **in the specific order mentioned**, may, after that person's death, donate the body or any specific tissue of that person to an institution or a person contemplated in section 63 (emphasis added).

4.38 Section 66 that deals with the post mortem examination of bodies, determines in subsection (1)(b):

(1) Subject to subsection (2), a post mortem examination of the body of a deceased person may be conducted if –

- (b) the spouse, partner, **major child**, parent, guardian, **major brother or major sister** of the deceased, **in the specific order mentioned**, gave consent thereto; or (emphasis added)

4.39 It is not clear whether the expression “adult” that precedes “child” in the definition of user and in section 7(1)(b) also applies to “brother” and “sister”. Sections 62 and 63 that contain similar provisions refer to a “major child”, “major brother” and “major sister”. For the sake of clarity and uniformity, the word “major” should be used throughout the Act to specifically denote a person who has achieved the age of majority. It would also be consistent with the wording of the Children’s Act, which determines in section 17 thereof

that: “A child, whether male or female, becomes a major upon reaching the age of 18 years.”

4.40 Paragraph (b) of the definition of “user”, sections 7(1)(b), 62(2) and 66(1)(b) all contain a list of persons that have to make certain decisions or take certain actions in place of another person. In some of the sections referred to the phrase “in the specific order as listed” or the phrase “in the specific order mentioned” appears. For the sake of uniformity, the phrase “in the specific order mentioned” should be used consistently.

4.41 Another concern with regard to the lists of persons that appear in the definition of “user”, sections 7(1)(b), 62(2) and 66(1)(b), is the use of the terms “brother” and “sister” linked to the requirement that the persons listed should be consulted in the order mentioned. While there is justification for consulting a spouse or partner before consulting a child and consulting a child before consulting a sibling due to marriage, an intimate partnership or degree of family relationship, there is no justification for determining that a brother should be consulted before a sister is consulted. This is discriminatory on the basis of gender and hence in breach of section 9 of the Constitution. The use of the word “sibling” rather than “brother” or “sister” would denote the same degree of family relationship in a gender neutral manner.

(g) Reference to municipal finance management legislation

4.42 Section 45(3) refers to “any municipal finance management legislation”. This reference could be considered too vague and specific reference should rather be made to the Local Authorities: Municipal Finance Management Act 56 of 2003.

(h) Section 71: Research on or experimentation with human subjects

4.43 Section 71 of the Act deals with research on or experimentation with human subjects. Some provisions contained therein, however, may require amendment and others may be considered redundant.

4.44 The Act does not define the term “research”, but defines “health research” in the following manner:

'health research' includes any research which contributes to knowledge of –

- (a) the biological, clinical, psychological or social processes in human beings;
- (b) improved methods for the provision of health services;
- (c) human pathology;
- (d) the causes of disease;
- (e) the effects of the environment on the human body;

- (f) the development or new application of pharmaceuticals, medicines and related substances; and
- (g) the development of new applications of health technology;

4.45 Section 71(2) refers to “research or experimentation ... to be conducted on a minor for a therapeutic purpose”. Subsection (3) refers to “research or experimentation ... to be conducted on a minor for a non-therapeutic purpose”. There is no definition or further explanation in the Act of what “research or experimentation ... for a therapeutic purpose” or “research or experimentation ... for a non-therapeutic purpose” entails.

4.46 To avoid any uncertainty or misunderstanding on the nature of therapeutic and non-therapeutic research as envisaged by the Act, definitions of “therapeutic research” and “non-therapeutic research” should be included in section 1 of the Act. The wording of the Act should then be amended to incorporate the terms “therapeutic research” and “non-therapeutic research” rather than describing research as “research or experimentation ... for a therapeutic purpose” or “research or experimentation ... for a non-therapeutic purpose”.

4.47 Section 71(2)(a), which regulates therapeutic research involving children, requires the child’s best interest to be taken into account in regard to their participation in therapeutic research. However, consideration of this factor is not explicitly mentioned in the context of section 71(3)(a) of the Act, which governs non-therapeutic research on children. The implication that explicitly omitting consideration of the child’s best interest in section 71(3)(a) amounts to such interest not having to be taken into account in the context of non-therapeutic research is untenable given that section 28(2) of the Constitution states that: “a child’s best interest are of paramount interest in **every** matter involving a child” (emphasis added). Accordingly, the explicit inclusion of this consideration in section 71(2)(a) may be considered redundant.

4.48 Section 71(2) refers to a “minor” in paragraphs (a) and (d), but refers to a “child” in paragraph (c). Neither terms are defined; therefore it is unclear what the difference in the meaning of the terms would be in the context of the Act. The same wording should be used consistently throughout the Act. The NHA should consistently use the term “minor child” to refer to a person under the age of 18 years instead of referring to “child” in some instances and “minor” in other instances. Since the expression “major child” is used in several provisions of the NHA (for example the definition of “user”, sections 7(1)(b), 62(2), 66(1)(b)), the use of the expression “minor child” rather than “minor” or “child” would ensure greater clarity.

4.49 Section 71(3)(a) provides as follows:

(3)(a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted –

- (i) in such manner and on such conditions as may be prescribed;
- (ii) with the consent of the Minister (of Health)
- (iii) with the consent of the parent or guardian of the minor; and
- (iv) if the minor is capable of understanding, the consent of the minor.

4.50 Section 71(3)(a)(ii) also requires the Minister's consent for conducting research or experimentation on a minor for a non-therapeutic purpose. It is however important to note that section 73(1) requires every institution, health agency and health establishment at which health research is conducted, to establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.⁴⁴

4.51 Section 73(2)(a) of the National Health Act imposes a duty on research ethics committees to perform an oversight role in research. Section 71(2)(b) imposes an obligation on a health research ethics committee to grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.⁴⁵

4.52 Research may also have to be approved by regulatory authorities such as the Medicine Control Council in some instances. Obtaining approval from a regulatory authority⁴⁶ is often a lengthy process. The requirement that such studies, in addition, also obtain Ministerial approval could threaten the viability and timeliness of certain types of non-therapeutic research. In view of the role and specialised knowledge of health research ethics committees, the Minister's oversight role is arguably redundant. It is accordingly recommended that consideration be given to deleting section 71(3)(a)(ii) of the Act and amending section 71(3)(b) accordingly.

⁴⁴ S 73(1): Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

⁴⁵ S 73(2): A health research ethics committee must –

- (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
- (b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.

⁴⁶ Where applicable, also foreign regulatory authorities.

4.53 The involvement of parents or guardians in certain types of therapeutic or non-therapeutic research may also not always be in the best interest of children. For example, in terms of the National Health Act a study aimed at ascertaining the prevalence of abuse in children would require the consent of the child's parent or guardian for that child's participation in the study. If the parent or guardian is a perpetrator of abuse he or she would likely deny consent for the child to participate in such research. It is therefore recommended that consideration be given to making provision for the participation of children in non-therapeutic research without parental consent or the consent of the child's guardian in certain circumstances, for example by making provision for the research ethics committee overseeing the study to waive parental or a guardian's consent.

(i) Health officers: Proof of identity and certificate of appointment

4.54 Section 14 of the Constitution protects an individual's right to privacy, which includes the right not to have their person, their home or their property searched or their possessions seized. While the right to privacy is not a non-derogable right and may be limited in terms of section 36 of the Constitution, it nevertheless is a constitutionally protected human right. It is therefore advisable that a government official breaching a person's constitutional right in terms of legislation authorising such a breach should identify him- or herself and explain the reason for his or her actions, without being requested to do so.

4.55 Section 82 of the NHA should therefore compel a health officer, without having to be requested to do so, to show proof of his or her identity and certificate of appointment as a health officer when entering premises for a routine inspection and when entering and searching premises on the authority of a warrant. The same principle should be applicable to entering premises with consent in terms of section 86.

(j) Importance of putting NHA fully into operation

4.56 DOH should urgently take steps to fully implement the National Health Act. From the discussion in paragraphs 4.4 to 4.6 above, it is clear that there are a number of concerns with regard to some of the existing legislation. Pre-1994 legislation is no longer adequate for guiding the provision of health services under the current Constitutional dispensation. Pre-1994 statutes do not sufficiently provide for access to health care services as a constitutionally protected human right. A big problem is the fact that pre-1994 Acts were not drafted to guide the delivery of health services in a government

structured along the lines of a three-tiered system of independent national, provincial and municipal governments.

C National Health Amendment Act 12 of 2013

1 Recommendation

4.57 There is no recommendation regarding the National Health Amendment Act 12 of 2013(NH Amendment Act).

2 Purpose of Act

4.58 The purpose of the National Health Amendment Act 12 of 2013 is to amend the National Health Act, 2003, so as to provide for the establishment of the Office of Health Standards Compliance and, for that purpose, to insert, substitute or delete certain definitions; to delete, revise and insert certain provisions; and to provide for matters connected therewith.

3 Discussion

4.59 Section 1 of the NH Amendment Act amends section 1 of the NHA, by inserting, deleting and substituting particular definitions. Act 12 of 2013 also amends sections 21 (General functions of national department), 25 (Provincial health services and general functions of provincial departments), 47 (Evaluating services of health establishments), and 90 (Regulations) of the NHA. The NH Amendment Act effects technical amendments to the arrangement of sections of the NHA and Part A of Schedule 3 of the Public Finance Management Act 1 of 1999. Section 5 of the NH Amendment Act however substitutes Chapter 10, inserting 16 new provisions and substituting 13 provisions in the process.

4.60 The National Health Amendment Act 12 of 2013 was put into operation in two stages. The whole Act, except sections 2 and 3, was put into operation with effect from 2 September 2013. Sections 2 and 3 were put into operation with effect from 1 September 2014.

CHAPTER 5: TERMINATION OF PREGNANCY AND STERILISATION STATUTES

A Statutes relating to Termination of Pregnancy and Sterilisation: Summary of Recommendations

Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**.

1. The following are recommended regarding the Choice on Termination of Pregnancy Act 92 of 1996:
 - (a) Section 1: In the definition of “medical practitioner” refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974) (see paragraph 5.11).
 - (b) Section 2(1)(c): Amend this section in order to clear up the uncertainty regarding whether a medical practitioner may only consult with “another medical practitioner or a registered midwife” or may consult with a “another medical practitioner or a registered midwife or a registered nurse” due to the amendment of section 2(1)(c) of the CTOP Act by the unconstitutional CTOP Amendment Act 38 of 2008 and the specific exclusion from amendment of section 2(1)(c) by the CTOP Amendment Act 1 of 2008 (see paragraphs 5.4 to 5.9).
2. In view of the judgement of the Constitutional Court in *Doctors for Life International v Speaker of the National Assembly and others* 2006 (6) SA 416 (CC) and the subsequent passing of the Choice on Termination of Pregnancy Amendment Act 1 of 2008, it is recommended that the Choice on Termination of Pregnancy Amendment Act 38 of 2004 be repealed (see paragraph 5.4, 5.14 and 5.15).
3. There is no recommendation regarding the Choice on Termination of Pregnancy Amendment Act 1 of 2008 (see paragraph 5.18).
4. The following are recommended regarding the Sterilisation Act 44 of 1998 (see paragraph 5.21 to 5.22):
 - (a) Section 1: In the definition of “nurse”, refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
 - (b) Section 1: In the definition of “social worker”, refer to the Social Service Professions Act, 1978 (Act 110 of 1978) instead of the Social Work Act, 1978 (Act 110 of 1978).
5. There is no recommendation regarding the Sterilisation Amendment Act 3 of 2005.

B Choice on Termination of Pregnancy Act 92 of 1996

1 Recommendation

5.1 The following recommendations are made in respect of the Choice on Termination of Pregnancy Act 92 of 1996 (CTOP Act):

- (a) Section 1: In the definition of “medical practitioner” refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (b) Section 2(1)(c): Amend this section to clear up the uncertainty regarding whether a medical practitioner may only consult with “another medical practitioner or a registered midwife” or may consult with a “another medical practitioner or a registered midwife or a registered nurse” due to the amendment of section 2(1)(c) of the CTOP Act by the unconstitutional CTOP Amendment Act 38 of 2008 and the specific exclusion from amendment of section 2(1)(c) by the CTOP Amendment Act 1 of 2008.

Amendment of section 1 of Act 92 of 1996, as amended by section 68 of Act 32 of 2007 and section 1 of Act 1 of 2008

30. Section 1 of the Choice on Termination of Pregnancy Act, 1996 is hereby amended by the substitution for the definition of “medical practitioner” of the following definition.

“ ‘medical practitioner’ means a person registered as such under the **[Medical, Dental and Supplementary Health Service Professions Act,] Health Professions Act**, 1974 (Act 56 of 1974);

Amendment of section 2 of Act 92 of 1996

31. Section 2 of the Choice on Termination of Pregnancy Act, 1996 is hereby amended by the substitution in subsection (1) for the words preceding subparagraph (i) of paragraph (c) of the following words:

“after the 20th week of the gestation period if a medical practitioner, after consultation with another medical practitioner or a registered midwife, is of the opinion that the continued pregnancy – ”

2 Purpose of Act

5.2 The purpose of the CTOP Act is to determine the circumstances in which and conditions under which the pregnancy of a woman may be terminated, and to provide for matters connected therewith.

3 Discussion

5.3 The CTOP Act repealed the Abortion and Sterilization Act 2 of 1975, thereby granting women access to early, safe, and legal abortions as a matter of choice.⁴⁷ In 1998, a pro-life advocacy group, the Christian Lawyers Association of South Africa (CLA), argued that the CTOP Act violated the foetus' right to life.⁴⁸ The court held that the foetus was not a legal person, and the action accordingly failed. In 2004, the CLA tried again, this time targeting a provision in the CTOP Act that permits minors to terminate their pregnancies without parental knowledge or consent. In dismissing the claim, the court held that the Constitution protects the right of a woman to determine the fate of her own pregnancy, and that everyone, including a woman under the age of 18, is entitled to respect for (and protection of) her right to self-determination.⁴⁹

5.4 When the Choice on Termination of Pregnancy Amendment Act 38 of 2004 was passed by Parliament entitling nurses and midwives to perform terminations of pregnancies, provided they received the requisite training, the constitutionality of the CTOP Amendment Act 2004 was challenged by Doctors for Life International (DFLI) on the basis of insufficient public consultation. In August 2006 the Constitutional Court ruled in favour of DFLI, declaring the CTOP Amendment Act unconstitutional (along with three other statutes passed by Parliament).⁵⁰ The Court found that there had been insufficient or unreasonable levels of public participation at provincial level on the statutes in question. The Court's order invalidating the statutes was suspended for a period of 18

⁴⁷ Singh JA, Govender M & Reddy N 'South Africa a Decade after Apartheid: Realizing Health Through Human Rights' *Georgetown Journal on Poverty Law & Policy* Vol XII No 3 Fall 2005: 355-388.

⁴⁸ *Christian Lawyers Association of SA v Minister of Health* 1998 (11) BCLR 1434 (T)

⁴⁹ *Christian Lawyers Association of SA v Minister of Health* 2004 (10) BCLR 1086 (T). For a more detailed discussion see Singh JA, Govender M & Reddy N 'South Africa a Decade after Apartheid: Realizing Health Through Human Rights' *Georgetown Journal on Poverty Law & Policy* Volume XII, Number 3 Fall 2005 on 355-388.

⁵⁰ *Doctors for Life International v Speaker of the National Assembly and Others* 2006 (6) SA 416 (CC)

months to enable Parliament to re-enact these statutes in a manner that was consistent with the Constitution. After a period of consultation, Parliament passed the Choice on Termination of Pregnancy Amendment Act as Act No. 1 of 2008.

5.5 The wording of the CTOP Amendment Act of 2008 is almost identical to the wording of the unconstitutional CTOP Amendment Act of 2004, but the two Amendment Acts differ in respect of the wording of section 1(c) and (d) and the wording and effect of section 7. Paragraphs (c) and (d) of section 1 of both the 2004 Amendment Act as well as the 2008 Amendment Act respectively substitute the definitions of “registered midwife” and “registered nurse” in section 1 of the CTOP Act of 1996. The 2008 Act correctly refers to the Nursing Act 33 of 2005 instead of the repealed Nursing Act 50 of 1978, while the 2004 Amendment Act refers to the repealed 1978 Nursing Act. Section 7 of the CTOP Amendment Act of 2008 and section 7 of the unconstitutional CTOP Amendment Act of 2004 both deal with the substitution of a certain expression in the CTOP Act of 1996.

5.6 Section 7 of the CTOP Amendment Act 2004 provides as follows:

The principal Act is hereby amended by the substitution for the expression "registered midwife", wherever it appears, of the expression "registered midwife or registered nurse".

5.7 Section 7 of the CTOP Amendment Act 2008 provides as follows:

The principal Act is hereby amended by the substitution for the expression "registered midwife", wherever it appears, of the expression "registered midwife or registered nurse", **except in the circumstances contemplated in section 2(1)(c)**. (Emphasis added.)

5.8 The electronic Juta, Sabinet and LexisNexis data bases contain both the CTOP Amendment Act 38 of 2004 as well as the CTOP Amendment Act 1 of 2008 as valid and current statutes. The Juta and Sabinet data bases refer to the Constitutional Court decision in the case of *Doctors for Life International v Speaker of the National Assembly and others* in a note to the CTOP Act 92 of 1996 and the CTOP Amendment Act 38 of 2004. In the version of the CTOP Act available on the Juta and Sabinet data bases, the expression “another medical practitioner or registered midwife” is employed in section 2(1)(c). However, the electronic LexisNexis data basis does not refer to the case of *Doctors for Life International v Speaker of the National Assembly and others* anywhere in the CTOP Act of 1996 or the CTOP Amendment Act of 2004. In addition, in the version of the CTOP Act available on the LexisNexis data basis, the expression “another medical practitioner or registered midwife or registered nurse” is employed in section 2(1)(c).

5.9 It is clear that confusion currently reigns with regard to the validity of the CTOP Amendment Act of 2004 and the correct wording of section 2(1)(c) of the CTOP Act of 1996. It is therefore proposed that the CTOP Amendment Act of 2004 be formally repealed by an Act of Parliament and that section 2(1)(c) be amended to reflect the true intention with regard to the circumstances contemplated in section 2(1)(c).

5.10 Notwithstanding its numerous constitutional challenges, the CTOP Act contains non-discriminatory, gender-neutral terminology and in this respect, is in accordance with the right to equality enshrined in the Bill of Rights. While the right to freedom of conscience, religion, thought, belief and opinion is explicitly protected in the Constitution,⁵¹ the equality clause also prohibits unfair discrimination on the grounds of religion, conscience, and belief.⁵² Read together, these rights afford protection to health workers who may conscientiously object to performing terminations of pregnancies.

5.11 The CTOP Act does not appear to contain any obviously unconstitutional provisions and actually supports section 12(2) of the Constitution in that it gives effect to a person's right to make decisions concerning reproduction. The CTOP Act also does not appear to contain any redundant or obsolete provisions, except for a reference to Act 56 of 1974 by its previous name.

C Choice on Termination of Pregnancy Amendment Act 38 of 2004

1 Recommendation

5.12 For the sake of legal certainty and in view of the judgement of the Constitutional Court in *Doctors for Life International v Speaker of the National Assembly and others* 2006 (6) SA 416 (CC) and the subsequent passing of the Choice on Termination of Pregnancy Amendment Act 1 of 2008, it is recommended that the Choice on Termination of Pregnancy Amendment Act 38 of 2004 be repealed.

⁵¹ Section 15(1) of the 1996 Constitution

⁵² Section 9(3) of the 1996 Constitution

| No. and year of Act | Short title | Extent of repeal |
|---------------------|--|------------------|
| Act 38 of 2004 | Choice on Termination of Pregnancy Amendment Act, 2004 | The whole |

2 Purpose of Act

5.13 The purpose of this Act was to amend the Choice on Termination of Pregnancy Act, 1996, so as to amend a definition and to insert others; to empower a Member of the Executive Council to approve facilities where a termination of pregnancy may take place; to exempt a facility offering a 24-hour maternity service from having to obtain approval for termination of pregnancy services under certain circumstances; to provide for the recording of information and the submission of statistics; to enable a Member of the Executive Council to make regulations; and to provide for matters connected therewith.

3 Discussion

5.14 The Constitutional Court declared the Choice on Termination of Pregnancy Amendment Act 38 of 2004 inconsistent with the Constitution in a judgement delivered on 17 August 2006 in *Doctors for Life International v Speaker of the National Assembly and others*⁵³. The reason for the invalidity was the failure of the National Council of Provinces and provincial legislatures to fulfil their duty in terms of sections 72(1)(a) and 118(1)(a) of the Constitution to facilitate public involvement in the enactment of Act.

5.15 The order of invalidity was suspended for 18 months to enable Parliament to enact this statute afresh in accordance with the provisions of the Constitution. The Choice on Termination of Pregnancy Amendment Act 1 of 2008 was subsequently promulgated on 18 February 2008. The Choice on Termination of Pregnancy Amendment Act 38 of 2004, however, was not repealed. The existence of two almost identical statutes on the statute book aiming to achieve the same purpose is highly confusing and should be rectified by repealing the redundant 2004 Amendment Act.

⁵³ 2006 (6) SA 416 (CC)

D Choice on Termination of Pregnancy Amendment Act 1 of 2008

1 Recommendation

5.16 There is no recommendation regarding the Choice on Termination of Pregnancy Amendment Act 1 of 2008.

2 Purpose of Act

5.17 The purpose of this Act is to amend the Choice on Termination of Pregnancy Act, 1996, so as to amend a definition and to insert others; to empower a Member of the Executive Council to approve facilities where a termination of pregnancy may take place; to exempt a facility offering a 24-hour maternity service from having to obtain approval for termination of pregnancy services under certain circumstances; to provide for the recording of information and the submission of statistics; to enable a Member of the Executive Council to make regulations; and to provide for matters connected therewith.

3 Discussion

5.18 Comparing the long title of this Act to the long title of the 2004 Amendment Act, it is clear that both Amendment Acts have the same purpose. This Act was enacted after a process of public consultation in order to comply with the order of the Constitutional Court in *Doctors for Life International v Speaker of National Assembly and Others*,⁵⁴ which declared the CTOP Amendment Act of 2004 inconsistent with the Constitution due to a lack of public consultation.

E Sterilisation Act 44 of 1998

1 Recommendation

5.19 The following are recommended regarding the Sterilisation Act 44 of 1998:

⁵⁴ 2006 (6) SA 416 (CC).

- (a) Section 1: In the definition of “nurse”, refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
- (b) Section 1: In the definition of “social worker”, refer to the renamed Social Service Professions Act, 1978 (Act 110 of 1978) instead of the Social Work Act, 1978 (Act 110 of 1978).

Amendment of section 1 of Act 44 of 1998, as amended by section 1 of Act 3 of 2005

32. Section 1 of the Sterilisation Act, 1998 is hereby amended –

- (a) by the substitution for the definition of “nurse” of the following definition:

“ ‘nurse’ means a person registered as such in terms of the **[Nursing Act, 1978 (Act 50 of 1978),] Nursing Act, 2005 (Act 33 of 2005)**, and who holds a qualification in psychiatry;” and

- (b) by the substitution for the definition of “social worker” of the following definition:

“ ‘social worker’ means a person registered as such in terms of the **[Social Work Act,] Social Service Professions Act, 1978 (Act 110 of 1978)**”.

2 Purpose of Act

5.20 The Sterilisation Act 44 of 1998 was enacted to provide for the right to sterilisation; to determine the circumstances under which sterilisation may be performed and, in particular, the circumstances under which sterilisation may be performed on persons incapable of consenting or incompetent to consent due to mental disability; and to provide for matters connected therewith. It is meant to bring the laws regarding sterilisation in line with the Constitution. It therefore repeals those laws dealing with sterilisation prior to the commencement of this Act.

3 Discussion

5.21 The Sterilisation Act grants mentally competent individuals aged 18 years and above the right to make autonomous decisions about their own sterilisation⁵⁵ and prohibits the non-consensual sterilisation of individuals who are capable of giving

⁵⁵ Section 2(1) of the Sterilisation Act 44 of 1998

consent.⁵⁶ The Act prescribes the circumstances under which a person who is incapable of consenting may be sterilised, as well as when sterilisation may be performed on an individual who is under the age of 18 years.⁵⁷ These provisions affirm those constitutional rights that recognise and respect the autonomy of individuals in making important decisions about their physical and mental well-being.⁵⁸

5.22 The Sterilisation Act contains non-discriminatory, gender-neutral terminology and, in this respect, is in accordance with the right to equality enshrined in South Africa's Bill of Rights. The Sterilisation Act does not appear to contain any obviously unconstitutional provisions and actually supports section 12(2) of the Constitution in that it gives effect to a person's right to make decisions concerning reproduction. Apart from minor amendments to refer to current rather than repealed legislation, the Act does not appear to contain any redundant or obsolete provisions.

F Sterilisation Amendment Act 3 of 2005

1 Recommendation

5.23 There is no recommendation regarding the Sterilisation Amendment Act 3 of 2005. There is no apparent inconsistency with section 9 of the Constitution in this Act. There are no obsolete or redundant provisions.

2 Purpose of Act

5.24 The purpose of this Act was to amend the Sterilisation Act 44 of 1998 in order to substitute the definition of "sterilisation"; to make provision for a medical opinion in certain circumstances; to provide for additional information to be considered when contemplating sterilisation; and related matters.

⁵⁶ Section 2(2) of the Sterilisation Act 44 of 1998

⁵⁷ Section 3 of the Sterilisation Act 44 of 1998

⁵⁸ Singh JA, Govender M, Reddy N. South Africa a Decade after Apartheid: Realizing Health Through Human Rights. *Georgetown Journal on Poverty Law & Policy* Volume XII, Number 3 Fall 2005 on 355-388.

CHAPTER 6: HEALTH SERVICE STATUTES

A Health Service Statutes: Summary of Recommendations

Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**.

1. The following are recommended regarding the South African Medical Research Council Act 58 of 1991:
 - (a) Section 4(1)(o)(iii): Refer to an entity or enterprise contemplated in section 1 of the Public Finance Management Act, 1999 (Act 1 of 1999) instead of referring to a company or statutory body contemplated in section 1 of the Exchequer Act, 1975 (Act 66 of 1975) (see paragraph 6.12).
 - (b) Section 6(4)(f)(i): Refer to the Electoral Act, 1998 (Act 73 of 1998) instead of the repealed Electoral Act, 1979 (Act 45 of 1979) (see paragraph 6.12).
 - (c) Section 6(4)(f)(ii): Refer to the Constitution of the Republic of South Africa, 1996 instead of the repealed Constitution of the Republic of South Africa Constitution Act, 1983 (Act 110 of 1983) and delete the phrase “, or is appointed or designated as a member of the President's Council” (see paragraph 6.12).
 - (d) Section 9(2): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974) (see paragraph 6.12).
 - (e) Section 14(1): Refer to the Companies Act, 2008 (Act 71 of 2008) instead of the repealed Companies Act, 1973 (Act 61 of 1973) (see paragraph 6.12).
 - (f) Repeal section 21 subsections (2) to (5) as these subsections have become redundant (see paragraph 6.13).
2. The following are recommended about the Hospital Ordinance Amendment Act 111 of 1992 (see paragraphs 6.17 to 6.22):
 - (a) Engage with the departments of health of the provinces of Gauteng, Mpumalanga and North-West on the possible repeal of the Hospitals Ordinance 14 of 1958.
 - (b) If the Hospitals Ordinance 14 of 1958 is repealed, it is recommended that the national DOH repeal the Hospital Ordinance Amendment Act 111 of 1992.

3. The following are recommended for the National Health Laboratory Service Act 37 of 2000:
 - (a) Section 10(2)(c): Section 10(2)(c): Refer to a person becoming an involuntary mental health care user under the Mental Health Care Act, 2002 (Act 17 of 2002) instead a person being detained under the Mental Health Act, 1973 (Act 18 of 1973) (see paragraph 6.25).
 - (b) Section 16(1)(d): Refer to the National Health Act, 2003 (Act 61 of 2003) instead of the repealed Human Tissue Act, 1983 (Act 65 of 1983) and delete the expression “section 25 of” (see paragraph 6.25).
 - (c) Determine the reason for the delay in bringing the amendment to the Schedule to the NHLSA, effected by the NHLS Amendment Act 24 of 2001, into operation. Put the amendment into operation or amend the Schedule to the Act (see paragraph 6.29).
4. Determine the reason for the delay of more than 14 years in proclaiming the date of commencement of the National Health Laboratory Service Amendment Act 24 of 2001. The date of commencement of Act 24 of 2001 should be proclaimed, or, if it is not to be proclaimed, the Act should be repealed (see paragraph 6.29).
5. Determine the reason for the delay in bringing the amendment of the definition of “business of a medical scheme” in section 1 of the Medical Schemes Act 131 of 1998 by section 264 of the Financial Services Laws General Amendment Act 45 of 2013 into operation. Put the amendment into operation, amend the definition again if necessary or repeal section 264 of Act 45 of 2013 if no longer relevant (see paragraphs 6.39 to 6.44).
6. The following are recommended regarding the content of the Medical Schemes Act of 1998 (see paragraph 6.45):
 - (a) Section 5(2)(e): Refer to the Electoral Act, 1998 (Act 73 of 1998) instead of the repealed Electoral Act, 1993 (Act 202 of 1993).
 - (b) Section 36(3)(e): Refer to the requirements for the appointment of a person as an auditor as stipulated in section 90 of the Companies Act, 2008 (Act 71 of 2008) instead of referring to a person who is disqualified from acting as an auditor in terms of section 275 of the repealed Companies Act, 1973 (Act 61 of 1973).
 - (c) Section 36(4): Refer to the Auditing Professions Act, 2005 (Act 26 of 2005) instead of the repealed Public Accountants' and Auditors' Act, 1991 (Act 80 of 1991).
 - (d) Section 36(5)(a) and (c): Refer to section 45 of the Auditing Professions Act, 2005 (Act 26 of 2005) instead of section 20(5) of the repealed Public Accountants' and Auditors' Act, 1991 (Act 80 of 1991).
 - (e) Section 36(8)(a): Refer to section 44 of the Auditing Professions Act, 2005 (Act 26 of 2005) instead of section 20 of the repealed Public Accountants' and Auditors' Act, 1991 (Act 80 of 1991).

- (f) Section 37(3): Refer to the Auditing Professions Act, 2005 instead of the Public Accountants' and Auditors' Act, 1991.
 - (g) Section 44(2) and (3): Refer to the Inspection of Financial Institutions Act 80 of 1998 instead of the repealed Inspection of Financial Institutions Act 38 of 1984.
 - (h) Section 52: Refer to the procedure for business rescue in terms of Chapter 6 of the Companies Act, 2008 (Act 71 of 2008) instead of the procedure for judicial management in terms of Chapter XV of the Companies Act, 1973 (Act 61 of 1973).
 - (i) Section 53: Refer to the transitional arrangement as provided for by item 9 of Schedule 5 of the Companies Act, 2008 (Act 71 of 2008) in addition to the reference to the winding up of companies in terms of Chapter XIV of the repealed Companies Act, 1973 (Act 61 of 1973).
 - (j) Section 54: Refer to business rescue proceedings and the business rescue practitioner instead of a judicial management order and the judicial manager.
 - (k) Section 56(2), (3) and (3)(a): Refer to the Financial Institutions (Protection of Funds) Act 28 of 2001 instead of the Financial Institutions (Investment of Funds) Act 39 of 1984.
7. It is not part of the mandate for this review to make a recommendation on the establishment of a risk equalisation fund (REF). However, to the extent that the REF is necessary in order to facilitate access to health care services (through increasing access to medical schemes), then it is essential to reducing inequality in access to health care services. For this reason it would require the attention of the DOH (see paragraph 6.41).
 8. There is no recommendation regarding the Medical Schemes Amendment Acts 55 of 2001 and 62 of 2002 (see paragraph 6.46).
 9. There is no recommendation regarding the Council for Medical Schemes Levies Act 58 of 2000 (see paragraph 6.47).
 10. There is no recommendation regarding the Health Donations Fund Act Repeal Act 31 of 2002 (see paragraph 6.52).

B South African Medical Research Council Act 58 of 1991

1 Recommendation

6.1 The following are recommended regarding to the South African Medical Research Council Act 58 of 1991 (SAMRC Act):

- (a) Section 4(1)(o)(iii): Refer to an entity or enterprise contemplated in section 1 of the Public Finance Management Act, 1999 (Act 1 of 1999) instead of referring to a company or statutory body contemplated in section 1 of the repealed Exchequer Act, 1975 (Act 66 of 1975).
- (b) Section 6(4)(f)(i): Refer to the Electoral Act, 1998 (Act 73 of 1998) instead of the repealed Electoral Act, 1979 (Act 45 of 1979).
- (c) Section 6(4)(f)(ii): Refer to the Constitution of the Republic of South Africa, 1996 instead of the repealed Constitution of the Republic of South Africa Constitution Act, 1983 (Act 110 of 1983) and delete the phrase “, or is appointed or designated as a member of the President's Council”.
- (d) Section 9(2): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (e) Section 14(1): Refer to the Companies Act, 2008 (Act 71 of 2008) instead of the repealed Companies Act, 1973 (Act 61 of 1973).
- (f) Delete section 21 subsections (2) to (5) as these subsections have become redundant.

Amendment of section 4 of Act 58 of 1991

24. Section 4 of the South African Medical Research Council Act, 1991 is hereby amended by the substitution in subsection (1) for subparagraph (iii) of paragraph (o) of the following subparagraph:

- “(iii) on its own, or in association with any person, establish a company for the purpose of developing or exploiting in any manner any invention or technological expertise, and for this purpose acquire an interest in or control over **[a company or statutory body referred to in section 1 of the Exchequer Act, 1975 (Act 66 of 1975)]** an entity or enterprise contemplated in section 1 of the Public Finance Management Act, 1999 (Act 1 of 1999);”.

Amendment of section 6 of Act 58 of 1991

25. Section 6 of the South African Medical Research Council Act, 1991 is hereby amended –

- (a) by the substitution in subsection (4) for subparagraph (i) of paragraph (f) of the following subparagraph:

- “(i) he is in terms of the provisions of the **[Electoral Act, 1979 (Act 45 of 1979)]** Electoral Act, 1998 (Act 73 of 1998), nominated as a candidate for election as a member of Parliament; or”; and
- (b) by the substitution in subsection (4) for subparagraph (ii) of paragraph (f) of the following subparagraph:
- “(ii) he is in terms of the provisions of the **[Republic of South Africa Constitution Act, 1983 (Act 110 of 1983),]** Constitution of the Republic of South Africa, 1996 nominated as a member of Parliament [, **or is appointed or designated as a member of the President's Council**]; or”.

Amendment of section 9 of Act 58 of 1991

26. Section 9 of the South African Medical Research Council Act, 1991 is hereby amended by the substitution for subsection (2) of the following subsection:

“(2) The president shall be registered as a medical practitioner under the **[Medical, Dental and Supplementary Health Service Professions Act,]** Health Professions Act, 1974 (Act 56 of 1974).”.

Amendment of section 14 of Act 58 of 1991

27. Section 14 of the South African Medical Research Council Act, 1991 is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) The keeping and compilation of annual financial statements of a company referred to in section 4 (1) (o) (iii) shall be done in accordance with the provisions of the **[Companies Act, 1973 (Act 61 of 1973)]** Companies Act, 2008 (Act 71 of 2008).”.

Amendment of section 21 of Act 58 of 1991

28. Section 21 of the South African Medical Research Council Act, 1991 is hereby amended by the repeal of subsections (2) to (5).

2 Purpose of Act

6.2 The South African Medical Research Council Act 58 of 1991 was enacted to provide for the continued existence of the South African Medical Research Council (SAMRC), for the management thereof by a Board, and for matters connected therewith.

3 Discussion

6.3 The SAMRC Act delineates the functions, powers and duties of the SAMRC – one of a number of statutory bodies that undertake and support medical science and health research. The Minister of Health may request the SAMRC to undertake certain research and the SAMRC may advise the Minister on research policy and priorities.

(a) *Definition of “research”*

6.4 The SAMRC Act defines the term “research” as:

“research” means ‘the creation, preservation, accumulation and improvement of knowledge by means of scientific investigations and methods in the field of the medical and related sciences as well as those sciences the application of which is important for the promotion of health or the combating of disease, and includes the acquisition, development and transfer of expertise and technology.

6.5 The Scientific Research Council Act 46 of 1988 defines “research” as:

“research” means the augmentation and improvement of knowledge through scientific investigations and methods directed towards the scientific and technological requirements of the private and public sectors, including the solution of relevant problems in the national interest, and includes the development, acquisition and transfer of expertise and technology.

6.6 The Human Sciences Research Council Act 17 of 2008 defines “research” as:

“research” means the generation, preservation, augmentation and improvement of knowledge by means of scientific investigations and methods in the field of the human sciences.

6.7 The National Research Foundation Act 23 of 1998 defines “research” as:

“research” means the generation, preservation, augmentation and improvement of knowledge by means of scientific investigations and methods in the field of science and technology.

6.8 The National Health Act 61 of 2003 defines “health research” as:

“health research” includes any research which contributes to knowledge of –

- (a) the biological, clinical, psychological or social processes in human beings;
- (b) improved methods for the provision of health services;
- (c) human pathology;
- (d) the causes of disease;
- (e) the effects of the environment on the human body;
- (f) the development or new application of pharmaceuticals, medicines and related substances; and
- (g) the development of new applications of health technology.

6.9 The National Health Laboratory Service Act 37 of 2000 on the other hand, distinguishes between “basic research” and “operational research”. The Act defines “basic research” as:

“basic research” means ‘the creation, preservation and accumulation of knowledge by means of scientific investigations and methods in –

- (a) the field of medical and related sciences; and
- (b) those sciences the application of which is important for the promotion of health or the combating of disease,

and includes the acquisition, development and transfer of expertise and technology’.

6.10 The National Health Laboratory Service Act defines “operational research” as:

“operational research” means research conducted as a part of the process of improving quality, efficiency and effectiveness of the health laboratory services.

6.11 These varying definitions do not render the definitions in any Act redundant, obsolete or inconsistent, but reflect the specialised nature of research that is conducted under each respective governing Act. No amendments are therefore recommended in respect of the definition of “research” in the SAMRC Act.

(b) *References to outdated legislation*

6.12 The Act was adopted in 1991 and operationalized the same year, which means that the SAMRC Act has been on the statute book for nearly 25 years. It is therefore to be expected that the SAMRC Act contains several references to outdated legislation. Examples of references to outdated legislation are the Exchequer Act 66 of 1975 in section 4, the Electoral Act 45 of 1979 and the 1983 Constitution in section 6 and the Companies Act 61 of 1973 in section 14.

(c) *Obsolete provisions*

6.13 The predecessor of the current SAMRC Act of 1991 was the South African Medical Research Council Act 19 of 1969. Section 21 of the SAMRC Act of 1991 is a

savings clause, making provision for a smooth transition from the 1969 Act to the 1991 Act. Due to the lapse of time, the transitional arrangements are no longer necessary and have become redundant. For this reason, subsections (2), (4) and (5) can be repealed. Subsection (3), which provides for the saving of regulations, can also be repealed as there are no regulations under this Act.

(d) *Male-centric terminology*

6.14 The Act is replete with reference to the male pronoun only. This is inconsistent with section 9 of the Constitution. The following provisions in the SAMRC Act contain male-centric terms: sections 1(2), 2(2), 6(2)(b), 6(4) to (6), 6(8)(b), 9(3), 9(5) to (6), 10(2), 10(4), 11(1)(c), 11(3), 12(3), 13(1), 15(1)(c), 15(1)(e), 15(2), 15(5), 15(6)(a), 18(a), 19(1), 19(2)(a), 19(4), and 21(4). This should be noted in the event of the Act being replaced.

C Hospitals Ordinance Amendment Act 111 of 1992

1 Recommendation

6.15 It is recommended that the national DOH should:

- (a) Engage with the departments of health of the provinces of Gauteng, Limpopo, Mpumalanga and North-West on the possible repeal of the Hospitals Ordinance 14 of 1958.
- (b) If the Hospitals Ordinance 14 of 1958 is repealed, it is recommended that the national DOH should repeal the Hospital Ordinance Amendment Act 111 of 1992.

2 Purpose of Act

6.16 The Hospitals Ordinance Amendment Act 111 of 1992 (HO Amendment Act) was enacted to “amend the Hospitals Ordinance, 1958 (Transvaal) (in so far as it is applied as a law on own affairs of the White population group), so as to define a certain expression; to empower the Minister to transfer a provincial hospital to a local authority; and to provide for the consequences of such a transfer; and to provide for matters connected therewith.”

3 Discussion

6.17 Since the HO Amendment Act refers to the geographical areas that previously encompassed the province of Transvaal, it is uncertain in which areas the HO Amendment Act are applicable now as the borders of the provinces have been redrawn. The long title of the HO Amendment Act indicates that the aim of the Act is to “amend the Hospitals Ordinance, 1958 (Transvaal) (in so far as it is applied as a law on own affairs of the White population group).” It is therefore unclear whether the HO Amendment Act applies generally or specifically.

6.18 Although several ordinances of the former provinces of Transvaal, Natal, the Cape of Good Hope and the Free State and legislation of the former TBVC states and self-governing territories were assigned to the new post-1994 provinces, the HO Amendment Act was not assigned and therefore remains in the national sphere of government.

6.19 Several provisions in the HO Amendment Act are obsolete. The expression in the long title “as a law on own affairs of the White population group” contains references to apartheid racial terminology. The wording offends section 9 of the Constitution. In addition, since a distinction made on the basis of race is unconstitutional, the stated purpose of the HO Amendment Act also offends section 9 of the Constitution.

6.20 Reference to the province of “Transvaal” in the Act is obsolete as this province no longer exists, both in name and geographic boundaries. Reference in section 1 of the Act to the “Republic of South Africa Constitution Act, 110 of 1983” is no longer applicable as the 1983 Constitution has since been repealed and ultimately superseded by the Constitution of the Republic of South Africa, 1996.

6.21 In section 2 of the Act “Minister” is defined as meaning “the Minister of Health Services and Welfare: House of Assembly”. This portfolio is obsolete as the House of Assembly no longer exists and the equivalent post-apartheid portfolio is referred to as “Minister of Health”.

6.22 Chapter II of the Act,⁵⁹ which governs the transfer of provincial hospitals to local authorities, does not appear to have been superseded by subsequent legislation, but

⁵⁹ **Transfer of provincial hospital**

10. The Minister may, with the concurrence of a local authority and after consultation with the Administrator, on such conditions as the Minister may determine, by notice in the *Gazette*

contains references to obsolete definitions. In addition, it is not known if this chapter was implemented and whether any provincial hospitals were ever transferred to local authorities in terms of this provision. The provision for transferring provincial hospitals to local authorities does not appear to be in line with national health policy and the National Health Act 61 of 2003.

transfer a provincial hospital to the local authority concerned with effect from a date mentioned in the notice.

Consequences of transfer of provincial hospital to local authority

11. (1) As from the date on which a provincial hospital is transferred to a local authority under section 10-

- (a) the provisions of this Ordinance and a regulation made thereunder, exclusive of this Chapter, shall cease to be applicable to such provincial hospital;
- (b) the ownership and control of movable and immovable property and all rights which immediately prior to that date vested in the Minister and the Department of Health Services and Welfare, Administration: House of Assembly and which relate to the provincial hospital concerned, shall devolve upon the local authority concerned on such terms and conditions as the Minister with the concurrence of the Minister of the Budget may determine: Provided that the ownership of such property shall without payment of compensation by the State revert to the State if the property in the opinion of the Minister is not being utilized in the interest of national health;
- (c) the liabilities and obligations which immediately prior to that date vested in the Minister and the Department of Health Services and Welfare, Administration: House of Assembly, shall devolve upon the local authority concerned;
- (d) the administrative records and other documents relating to the provincial hospital concerned and which the Minister may determine shall be transferred to such local authority;
- (e) the management, care, control, executive power, regulation and superintendence of the provincial hospital shall vest in the council of the local authority concerned.

(2) If the immovable property of which the ownership reverts to the State as contemplated in the proviso to subsection (1) (b), was encumbered in any manner by the local authority concerned, that local authority shall indemnify the State in respect of any costs or expenses incurred in respect of such encumbrance and such costs or expenses shall constitute a debt which may be recovered in any competent court.

(3) Immovable property devolving upon the local authority or reverting to the State in terms of subsection (1) (b), shall be transferred to the local authority or the State, as the case may be, without payment of transfer duty, stamp duty or other moneys or costs, but subject to any term or condition referred to in subsection (1) (b) and any existing right, encumbrance, obligation or trust on or over that property.

(4) The officer in charge of a deeds office or other office where the immovable property referred to in subsection (3) is registered, shall, on submission to him of the title deed concerned, make such endorsements on that title deed and such entries in his registers as may be required to effect the transfer concerned.

D National Health Laboratory Service Act 37 of 2000

1 Recommendation

6.23 The following recommendations are made with regard to the National Health Laboratory Service Act 37 of 2000 (NHLSA):

- (a) Section 10(2)(c): Refer to a person becoming an involuntary mental health care user under the Mental Health Care Act, 2002 (Act 17 of 2002) instead a person being detained under the Mental Health Act, 1973 (Act 18 of 1973).
- (b) Section 16(1)(d): Refer to the National Health Act, 2003 (Act 61 of 2003) instead of the repealed Human Tissue Act, 1983 (Act 65 of 1983) and delete the expression “section 25 of”.
- (c) Determine the reason for the delay in bringing the amendment to the Schedule to the NHLS Act, effected by the NHLS Amendment Act 24 of 2001, into operation. Put the amendment into operation or amend the Schedule to the Act.

Amendment of section 10 of Act 37 of 2000

40. Section 10 of the National Health Laboratory Service Act 37 of 2000 is hereby amended by the substitution in subsection (2) for paragraph (c) of the following paragraph:

“(c) he or she is declared by the High Court to be of unsound mind or mentally disordered or **[is detained]** becomes an involuntary mental health care user under the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 16 of Act 37 of 2000

41. Section 16 of the National Health Laboratory Service Act 37 of 2000 is hereby amended by the substitution in subsection (1) for paragraph (d) of the following paragraph:

“(d) import any human tissue or any blood, blood product or gamete in terms of **[section 25 of the Human Tissue Act, 1983 (Act 65 of 1983)]** the National Health Act, 2003 (Act 61 of 2003), for the purposes contemplated in paragraph (a), (b) or (c); and”.

2 Purpose of Act

6.24 The NHLSA was enacted to provide for the establishment of a juristic person to be known as the National Health Laboratory Service; to provide for the abolition of the South African Institute for Medical Research, the National Institute for Virology, the National Centre for Occupational Health, certain forensic chemistry laboratories and all provincial health laboratory services; and to provide for matters connected therewith.

3 Discussion

6.25 The NHLSA still contains outdated references to legislation that has been repealed, such as the Mental Health Act 18 of 1973 and the Human Tissue Act 65 of 1983. Section 16(1)(d) refers specifically to section 25 of the repealed Human Tissue Act of 1983. It is recommended that section 16(1)(d) be amended to refer to the National Health Act, since Chapter 8 of the NHA now deals with the control of use of blood, blood products, tissue and gametes in humans; matters that the Human Tissue Act had dealt with in the past. In terms of section 25 of the Human Tissue Act only a person who had been issued with a permit by the Director-General could import or export any tissue or any blood, blood product or gamete. The NHA does not contain a similar provision, since the NHA determines in section 68 that the Minister may make regulations, among others, regarding the importation and exportation of tissue, human cells, blood, blood products or gametes. For this reason the words “section 25 of”, that precede the reference to the Human Tissue Act in section 16(1)(d), should be repealed.

6.26 The NHLS Act's provision on the composition of the National Health Laboratory's board is commendable in attempting to promote and uphold the right to equality. Section 7 states: “The Board consists of the following members appointed by the Minister, taking into account, among other things, the appropriate representation of race, gender and disability.” The Act contains gender-sensitive terminology and, apart from the references to outdated legislation referred in paragraph 6.25 above, does not appear to contain any redundant, obsolete, or unconstitutional provisions.

E National Health Laboratory Service Amendment Act 24 of 2001 and proposed National Health Laboratory Service Amendment Bill

1 Recommendation

6.27 Determine the reason for the delay of more than 14 years in proclaiming the date of commencement of the National Health Laboratory Service Amendment Act 24 of 2001 (NHLS Amendment Act). The date of commencement of Act 24 of 2001 should be proclaimed, or, if it is not to be proclaimed, the Act should be repealed.

2 Purpose of Act

6.28 The purpose of the NHLS Amendment Act is to amend the National Health Laboratory Service Act, 2000, so as to provide for pension options to employees of bodies that are to be replaced by the National Health Laboratory Service; and to provide for matters connected therewith.

3 Discussion

6.29 It has been more than 14 years since the NHLS Amendment Act was passed into law, but the Act has not been put into operation to date. The Amendment Act proposes to add item 8 to the Schedule to the NHLSA, providing for pension options for employees.⁶⁰ The reason for the delay in the implementation of the Amendment Act should be investigated and addressed. Alternatively, the Amendment Act should be repealed. As indicated in paragraph 1.22 above, the SALRC referred the consultation paper that preceded this discussion paper to DOH in February 2016. In August 2016 the DOH submitted its comments to the SALRC on the SALRC consultation paper. In its

⁶⁰ **Pension options**

- 8.** (1) An employee contemplated in item 2 who is a member of –
- (a) a pension scheme registered in terms of the Pension Funds Act, 1956 (Act No. 24 of 1956), must transfer to a pension scheme to be established by the Service and such a transfer takes place in terms of section 14 of that Act;
 - (b) the Government Employees Pension Fund may –
 - (i) become a dormant member of such Fund;
 - (ii) remain an active member of such Fund; or
 - (iii) become a member of a pension scheme to be established by the Service.
- (2) For the purposes of the Income Tax Act, 1962 (Act No. 58 of 1962), no change of employer is deemed to have taken place when an employee's pension choice changes in terms of this item.

comments, DOH indicated that they are working on a National Health Laboratory Service Amendment Bill. DOH indicated that the recommendations made in the consultation paper (which recommendations are duplicated in this discussion paper) regarding the National Health Laboratory Service Act, 2000 and the National Health Laboratory Service Amendment Act, 2001 will be attended to in the proposed National Health Laboratory Service Amendment Bill.

F Medical Schemes Act 131 of 1998

1 Recommendation

6.30 Determine the reason for the delay in bringing the amendment of the definition of “business of a medical scheme” in section 1 of the Medical Schemes Act 131 of 1998 (MSA) by section 264 of the Financial Services Laws General Amendment Act 45 of 2013 into operation. Put the amendment into operation, amend the definition again if necessary or repeal section 264 of Act 45 of 2013 if no longer relevant.

6.31 In addition, the following recommendations are made with regard to the content of the Medical Schemes Act of 1998:

- (a) Section 5(2)(e) : Refer to the Electoral Act, 1998 (Act 73 of 1998) instead of the repealed Electoral Act, 1993 (Act 202 of 1993).
- (b) Section 36(3)(e): Refer to the requirements for the appointment of a person as an auditor as stipulated in section 90 of the Companies Act, 2008 (Act 71 of 2008) instead of referring to a person who is disqualified from acting as an auditor in terms of section 275 of the repealed Companies Act , 1973 (Act 61 of 1973).
- (c) Section 36(4): Refer to the Auditing Professions Act, 2005 (Act 26 of 2005) instead of the repealed Public Accountants' and Auditors' Act, 1991 (Act 80 of 1991).
- (d) Section 36(5)(a) and (c): Refer to section 45 of the Auditing Professions Act, 2005 (Act 26 of 2005) instead of section 20(5) of the repealed Public Accountants' and Auditors' Act, 1991 (Act 80 of 1991).
- (e) Section 36(8)(a): Refer to section 44 of the Auditing Professions Act, 2005 (Act 26 of 2005) instead of section 20 of the repealed Public Accountants' and Auditors' Act, 1991 (Act 80 of 1991).
- (f) Section 37(3): Refer to the Auditing Professions Act, 2005 instead of the Public Accountants' and Auditors' Act, 1991.

- (g) Section 44(2) and (3): Refer to the Inspection of Financial Institutions Act, 1998 (Act 80 of 1998) instead of the repealed Inspection of Financial Institutions Act, 1984 (Act 38 of 1984).
- (h) Section 52: Refer to the procedure for business rescue in terms of Chapter 6 of the Companies Act, 2008 (Act 71 of 2008) instead of the procedure for judicial management in terms of Chapter XV of the repealed Companies Act, 1973 (Act 61 of 1973).
- (i) Section 53: Refer to the transitional arrangement as provided for by item 9 of Schedule 5 of the Companies Act, 2008 (Act 71 of 2008) in addition to the reference to the winding up of companies in terms of Chapter XIV of the repealed Companies Act, 1973 (Act 61 of 1973).
- (j) Section 54: Refer to business rescue proceedings and the business rescue practitioner instead of a judicial management order and the judicial manager.
- (k) Section 56(2), (3) and (3)(a): Refer to the Financial Institutions (Protection of Funds) Act, 2001 (Act 28 of 2001) instead of the repealed Financial Institutions (Investment of Funds) Act, 1984 (Act 39 of 1984).

6.32 It is not part of the mandate for this review to make a recommendation on the establishment of a risk equalisation fund (REF). However, to the extent that the REF is necessary in order to facilitate access to health care services (through increasing access to medical schemes), then it is essential to reducing inequality in access to health care services. For this reason it would require the attention of the DOH.

Amendment of section 5 of Act 131 of 1998 as amended by section 36 of Act 12 of 2005

32. Section 5 of the Medical Schemes Act, 1998 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

“(e) is in terms of the provisions of the **[Electoral Act, 1993 (Act 202 of 1993)]**, Electoral Act, 1998 (Act 73 of 1998) nominated as a candidate for election as a member of Parliament; or”.

Amendment of section 36 of Act 131 of 1998 as amended by section 13 of Act 55 of 2001

33. Section 36 of the Medical Schemes Act, 1998 is hereby amended –

- (a) by the substitution in subsection (3) for paragraph (e) of the following paragraph:

- “(e) a person who **[is disqualified from acting as an auditor in terms of section 275 of the Companies Act, 1973 (Act 61 of 1973)]** does not comply with the requirements for appointment as an auditor as stipulated in section 90 of the Companies Act, 2008 (Act 71 of 2008).”;
- (b) by the substitution for subsection (4) of the following subsection:
- “(4) The approval of an auditor of a medical scheme by the Registrar shall not lapse if an auditor of a medical scheme is a firm as contemplated in the **[Public Accountants' and Auditors' Act, 1991, (Act 80 of 1991)]** Auditing Professions Act, 2005 (Act 26 of 2005), whose membership of the firm has changed, if not fewer than half of the members after the change, were members when the appointment of the firm was last approved by the Registrar.”;
- (c) by the substitution in subsection (5) for paragraph (a) of the following paragraph:
- “(a) whenever he or she furnishes a report or other document of particulars as contemplated in section **[20 (5) (b) of the Public Accountants' and Auditors' Act, 1991]** 45 of the Auditing Professions Act, 2005 (Act 26 of 2005), also furnish a copy thereof to the Registrar;”;
- (d) by the substitution in subsection (5) for subparagraph (ii) of paragraph (c) of the following subparagraph:
- “(ii) if he or she would, but for that termination, have had reason to submit to the medical scheme a report as contemplated in section **[20 (5) (a) of the Public Accountants' and Auditors' Act, 1991]** 45 of the Auditing Professions Act, 2005 (Act 26 of 2005), submit such a report to the Registrar; and”;
- (e) by the substitution in subsection (8) for paragraph (a) of the following paragraph:
- “(a) in respect of a return or statement which he or she is required to examine in terms of this Chapter, certify whether that return or statement complies with the requirements of this Act and whether the return or statement, including any annexure thereto, presents fairly the matters dealt with therein as if such return or statement were a financial statement contemplated in section **[20 of the Public Accountants' and Auditors' Act, 1991]** 44 of the Auditing Professions Act, 2005 (Act 26 of 2005); and”.

Amendment of section 37 of Act 131 of 1998 as amended by section 14 of Act 55 of 2001

34. Section 37 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) The annual financial statements of a medical scheme shall, subject to the provisions of the **[Public Accountants' and Auditors' Act, 1991]** Auditing Professions Act, 2005, be audited by an accountant and auditor registered in terms of that Act except where such accounts are to be audited by the Auditor-General in terms of any law.”.

Amendment of section 44 of Act 131 of 1998 as amended by section 17 of Act 55 of 2001

35. Section 44 of the Medical Schemes Act, 1998 is hereby amended –

(a) by the substitution for subsection (2) of the following subsection:

“(2) The Registrar, or such other person authorised by him or her, shall in addition to the powers and duties conferred or imposed upon him or her by this Act, have all the powers and duties conferred or imposed upon an inspector appointed under section 2 of the **[Inspection of Financial Institutions Act, 1984 (Act 38 of 1984)]** Inspection of Financial Institutions Act, 1998 (Act 80 of 1998), as if he or she has been appointed an inspector under that Act.” and

(b) by the substitution for subsection (3) of the following subsection:

“(3) Any reference in this Act to an inspection made under this section shall also be construed as a reference to an inspection made under the **[Inspection of Financial Institutions Act, 1984]** Inspection of Financial Institutions Act, 1998.”.

Substitution of section 52 of Act 131 of 1998 as amended by section 20 of Act 55 of 2001

36. Section 52 of the Medical Schemes Act, 1998 is hereby substituted for the following section:

“Business rescue

52. (1) Chapter 6 of the Companies Act, 2008 (Act 71 of 2008), shall, subject to the provisions of this section and with the necessary changes, apply in relation to the business rescue of a medical scheme, and in such application the Registrar

shall be deemed to be an affected person as contemplated by section 131 of the Companies Act, 2008.

(2) The Registrar may, with the concurrence of the Council, make an application under section 131 of the Companies Act, 2008 for an order placing a medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme if he or she is satisfied that it is in the interests of the members of that medical scheme to do so.

(3) In the application of Chapter 6 of the Companies Act, 2008, as provided for by subsection (1) –

- (a) a reference which relates to the inability of a medical scheme to pay its debts or to meet its obligations shall be construed as relating also to its inability to comply with the requirements prescribed by section 35 (1) of this Act;
- (b) in addition to any question which relates to the nature of a medical scheme as a successful concern, there shall be considered also the question whether any course of action is in the interest of its members;
- (c) a reference to an affected person in Chapter 6 of the Companies Act, 2008 shall be construed as a reference also to a member of a medical scheme;
- (d) a reference in sections 131, 132 and 155 to the Companies and Intellectual Property Commission shall be construed as a reference also to the Registrar;
- (e) a reference in section 140(1A) to a relevant regulatory authority shall be construed as a reference also to the Registrar;
- (f) a reference to a contravention of any provision of that Act shall be construed as a reference also to a contravention of any provision of this Act; and
- (g) a reference to a director shall be construed as referring also to a member of the board of trustees.

(4) If an application is made to a court for an order placing a medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme by a person other than the Registrar –

- (a) it shall not be heard unless copies of the notice of motion and of all accompanying affidavits and other documents filed in support of the application are lodged with Registrar at least 15 days, or such shorter period as the court may allow on good cause shown, before the application is set down for hearing; and
- (b) the Registrar may, if he or she is satisfied that the application is contrary to the interests of the beneficiaries of the medical scheme concerned make application to the court to join the application as a party and file affidavits and

other documents in opposition to the application.

(5) As from the date on which an order placing a medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme is granted –

(a) any reference in this Act to a medical scheme shall, unless clearly inappropriate, be construed as a reference to the business rescue practitioner appointed for the medical scheme; and

(b) the business rescue practitioner appointed for a medical scheme shall not admit members unless he or she has been granted permission to do so by the court in the order placing the medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme, or any variation of the order.”.

Amendment of section 53 of Act 131 of 1998 as amended by section 21 of Act 55 of 2001

37. Section 53 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) Item 9 of Schedule 5 of the Companies Act, 2008 (Act 71 of 2008) and Chapter XIV of the Companies Act, 1973 (Act 61 of 1973), shall, subject to the provisions of this section and with the necessary changes, apply in relation to the winding-up of a medical scheme and in such application the Registrar shall be deemed to be a person authorised by section 346 of the Companies Act, 1973, to make an application to the High Court for the winding-up of the medical scheme.”.

Amendment of section 54 of Act 131 of 1998

38. Section 54 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) Where any compromise or arrangement is proposed between a medical scheme and its creditors or any class of them, or between a medical scheme and its members or any group of them, the High Court may, on the application of the medical scheme or any creditor or member thereof or, in the case of a medical scheme being wound up, of the liquidator, or **[if the medical scheme is subject to a judicial management order, of the judicial manager,]** during business rescue proceedings of a medical scheme placed under supervision, of the business rescue practitioner, or if the medical scheme is subject to a curatorship order, of the curator, order a meeting of the creditors or class of creditors, or of the members of

the medical scheme or a group of members, as the case may be, to be summoned in such manner as the High Court may direct.”.

Amendment of section 56 of Act 131 of 1998 as amended by section 22 of Act 55 of 2001

39. Section 56 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsections (2) and (3) of the following subsections, respectively:

“(2) The provisions of the **[Financial Institutions (Investment of Funds) Act, 1984 (Act 39 of 1984)]** Financial Institutions (Protection of Funds) Act, 2001 (Act 28 of 2001), insofar as those provisions relate to the appointment of a curator in terms of the said Act, and insofar as they are not inconsistent with the provisions of this Act, shall apply with the necessary changes to the appointment of a curator of a medical scheme in terms of this section.

(3) In the application of the **[Financial Institutions (Investment of Funds) Act, 1984]** Financial Institutions (Protection of Funds) Act, 2001 as provided for by subsection (1) –

- (a) a reference to a company and the registrar in section 1 of the **[Financial Institutions (Investment of Funds) Act, 1984]** Financial Institutions (Protection of Funds) Act, 2001, shall be construed as a reference also to a board of trustees and the Registrar, respectively;
- (b) a reference in that Act to a director, official, employee or agent shall be construed as a reference also to a member of the board of trustees or the principal officer, as the case may be; and
- (c) a reference in that Act to a financial institution shall be construed as a reference also to a medical scheme.”.

2 Purpose of Act

6.33 The MSA was enacted to consolidate the laws relating to registered medical schemes; to provide for the establishment of the Council for Medical Schemes as a juristic person; to provide for the appointment of the Registrar of Medical Schemes; to make provision for the registration and control of certain activities of medical schemes; to protect the interests of members of medical schemes; to provide for measures for the co-ordination of medical schemes; and to provide for incidental matters.

3 Discussion

6.34 The MSA created a significant departure from the manner in which medical schemes operated before 1994. It was a response to the earlier deregulation of medical schemes, which limited access to medical insurance on the grounds of health, age and race.⁶¹ Apart from the provisions that prohibit discrimination on these grounds, it also introduced a set of prescribed minimum benefits, to which all members are entitled, regardless of their level of cover.

6.35 Section 24(2)(e) affirms the values enshrined in South Africa's Bill of Rights in stating:

No medical scheme shall be registered under this section unless the Council is satisfied that –

- (e) the medical scheme does not or will not unfairly discriminate directly or indirectly against any person on one or more arbitrary grounds including race, gender, marital status, ethnic or social origin, sexual orientation, pregnancy, disability and state of health.

6.36 Notwithstanding the MSA's prohibition of discrimination on the above listed grounds, the Act allows medical schemes to charge members differential premiums based on their income and number of dependants. In this respect, section 29(1)(n) provides as follows:

The Registrar shall not register a medical scheme under section 24, and no medical scheme shall carry on any business, unless provision is made in its rules for the following matters:

- (n) The terms and conditions applicable to the admission of a person as a member and his or her dependants, which terms and conditions shall provide for the determination of contributions on the basis of income or the number of dependants or both the income and the number of dependants, and shall not provide for any other grounds, including age, sex, past or present state of health, of the applicant or one or more of the applicant's dependants, the frequency of rendering of relevant health services to an applicant or one or more of the applicant's dependants other than for the provisions as prescribed.

6.37 Certain provisions of the MSA have been tested before South Africa's highest courts. In the case of *Guardrisk Insurance Co Ltd v Registrar of Medical Schemes*⁶² the

⁶¹ Adila Hassim, Mark Heywood and Jonathan Berger (eds), *Health and Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa* (Siberink: Cape Town, 2007) at 178-181.

⁶² 2008 (4) SA 620 (SCA)

respondent, the Registrar of Medical Schemes, applied for an interdict prohibiting the appellant, Guardrisk Insurance Company, from marketing and selling two of its policies which offered cover for the difference between what a medical scheme pays towards medical bills and what healthcare providers charge, often referred to as “gap cover”. The respondent argued that the sale of these policies constituted the “business of a medical scheme” in terms of the Medical Schemes Act of 1998, and that the appellant was not registered in terms of this Act. The Supreme Court of Appeal (SCA) held in favour of the appellant, finding its activities did not constitute the business of a medical scheme.

6.38 The respondent took the matter on appeal to the Constitutional Court, arguing that the Medical Schemes Act functions to uphold the constitutional principles of promoting access to health care, non-discrimination and equality, and that these aims would be seriously compromised if the SCA’s interpretation of the MSA was allowed to stand. The respondent argued that young and healthy members would be attracted out of the medical schemes environment or to less comprehensive medical scheme products, thereby resulting in costs increasing rapidly for the older and less healthy who would lose the benefit of being cross-subsidised by the young and healthy. The short term insurance schemes that would provide cover to the younger clients would not be subject to regulation under the MSA – one consequence being that they will be able to discriminate on the basis of the age and health profile of their members. In May 2004, the Constitutional Court denied the Registrar leave to appeal in the matter, holding that the application bore “no prospects of success.”⁶³

6.39 The term “business of a medical scheme” in the MSA is currently defined as:

“business of a medical scheme” means the business of undertaking liability in return for a premium or contribution –

- (a) to make provision for the obtaining of any relevant health service;
- (b) to grant assistance in defraying expenditure incurred in connection with the rendering of any relevant health service; **and**
- (c) where applicable, to render a relevant health service, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme; (Emphasis added.)

6.40 A Medical Schemes Amendment Bill was promoted by DOH in 2008 that sought, amongst other things, to change the definition of the “business of a medical scheme” so as to remedy the consequences of the SCA decision. The Bill proposed inserting the

⁶³ Unreported case. See Laura du Preez “Law change may settle health cover row” published on 24 May 2008 available at <http://ftp.bhfglobal.com/> accessed 15 November 2016.

word “or” after paragraph (a) of the definition and substituting the word “and” at the end of paragraph (b) with the word “or”. Had the Bill been adopted as an Act, the definition of “business of a medical scheme” would have been:

“business of a medical scheme” means the business of undertaking liability in return for a premium or contribution –

- (a) to make provision for the obtaining of any relevant health service; **or**
- (b) to grant assistance in defraying expenditure incurred in connection with the rendering of any relevant health service; **or**
- (c) where applicable, to render a relevant health service, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme; (Emphasis added.)

6.41 The proposed Medical Schemes Amendment Bill was the subject of huge controversy among stakeholders in the health field, mainly in relation to the part of the Bill that sought to establish a risk equalisation fund (REF). Part of the controversy related to whether the Bill would undermine the implementation of a National Health Insurance (NHI) mechanism. NHI has been part of the health policy agenda since 1994, but the process of implementation has been slow. There is now a renewed commitment to operationalise a NHI system without undue delay.

6.42 As a result of the controversy, the Bill did not proceed and the definition was not amended. If the effect is a migration of young and healthier people to short term insurance schemes, this could threaten the sustainability of medical schemes with poorer and sicker members, resulting in a growth in inequality of access to health care services.

6.43 The matter raised in the *Guardrisk Insurance Co Ltd v Registrar of Medical Schemes* was addressed by the Financial Services Laws General Amendment Act 45 of 2013 (FSLG Amendment Act). Section 264 of the Amendment Act effects consequential and related amendments to certain laws, including the definition of “business of a medical scheme”. The date of commencement of section 264 in so far as it amends section 1 of the MSA however still stands to be determined.

6.44 After amendment by section 264, the definition of “business of a medical scheme” will read as follows:

“business of a medical scheme” means the business of undertaking, in return for a premium or contribution, the liability associated with one or more of the following activities:

- (a) Providing for the obtaining of any relevant health service;
- (b) granting assistance in defraying expenditure incurred in connection with the rendering of any relevant health service; or

- (c) rendering a relevant health service, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme.

6.45 The Department should therefore take note that the issue that arose as a result of *Guardrisk Insurance Co Ltd v Registrar of Medical Schemes* has been addressed by section 264 of Act 45 of 2013, but that the amendment of section 1 of the Medical Schemes Act by the FSLG Amendment Act must still be put into operation. In spite thereof, the Act does contain gender-sensitive terminology and does not appear to contain redundant, obsolete or unconstitutional provisions, apart from references to repealed legislation (see paragraph 6.31 for the complete list of references to repealed legislation).

G Medical Schemes Amendment Acts 55 of 2001 and 62 of 2002

6.46 There is no recommendation regarding the Medical Schemes Amendment Acts 55 of 2001 and 62 of 2002.

H Council for Medical Schemes Levies Act 58 of 2000

1 Recommendation

6.47 There is no recommendation regarding the Council for Medical Schemes Levies Act 58 of 2000.

2 Purpose of Act

6.48 The Council for Medical Schemes Levies Act 58 of 2000 was enacted to provide for the imposition of levies by the Council for Medical Schemes; and to provide for matters incidental thereto.

3 Discussion

6.49 The Act contains gender-neutral terminology and does not appear to contain any redundant, obsolete, or unconstitutional provisions. Consequently there is no recommendation regarding the Council for Medical Schemes Levies Act 58 of 2000.

I Health Donations Fund Act Repeal Act 31 of 2002

1 Recommendation

6.50 There is no recommendation in respect of the Health Donations Fund Act Repeal Act 31 of 2002.

2 Purpose of Act

6.51 The Health Donations Fund Act Repeal Act 31 of 2002 was enacted to provide for the disestablishment of the Health Donations Fund and for the repeal of the Health Donations Fund Act, 1978 and to provide for matters connected therewith.

3 Discussion

6.52 The Act does not appear to contain redundant, obsolete, or unconstitutional provisions. Consequently there is no recommendation regarding the Council for Medical Schemes Levies Act 58 of 2000.

CHAPTER 7: HEALTH PROFESSIONS STATUTES

A Health Professions Statutes: Summary of Recommendations

1. Refer to the proposed consolidated **Pharmacy Bill** in **Annexure E**. The following are recommended regarding the Pharmacy Act 53 of 1974 (see paragraph 7.3):
 - (a) Consider consolidating the Pharmacy Act and promulgating it afresh.
 - (b) Section 1: In the definition of “medicine”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965.
 - (c) Section 7(1)(c): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
 - (d) Section 29(3)(a): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965.
 - (e) Section 29(3)(e): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the Nursing Act, 2005 (Act 33 of 2005) instead of the Medicines and Related Substances Control Act, 1965 and the repealed Nursing Act, 1957 (Act 69 of 1957), respectively.
 - (f) Section 38(1)(c): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965.
2. There is no recommendation regarding the Pharmacy Amendment Acts 20 of 1979, 39 of 1982, 20 of 1983, 69 of 1985, 6 of 1995, 88 of 1997 and 1 of 2000.
3. Refer to the proposed consolidated **Health Professions Bill** in **Annexure F**. The following are recommended regarding the Health Professions Act 56 of 1974 (see paragraphs 7.8 to 7.12):
 - (a) Consider consolidating the Health Professions Act and promulgating it afresh.
 - (b) Section 1: In the definition of “medicine”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
 - (c) Section 15B: Put the amendment of section 15B by section 14 of the Health Professions Amendment Act 29 of 2007 into operation as soon as possible.
 - (d) Section 16: Put the amendment of section 16 by section 16 of the Health Professions Amendment Act 29 of 2007 into operation as soon as possible.
 - (e) Section 16(1): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the

repealed Nursing Act, 1978 (Act 50 of 1978) and delete the expression “or a technikon”. However, if the amendment of section 16 of this Act by section 16 of the Health Professions Amendment Act 29 of 2007 is put into operation, this amendment will not be necessary as these amendments have already been effected by Act 29 of 2007.

- (f) Section 16(6): The attention of the DOH is drawn thereto that the proposed section 16(6), added by section 16(f) (still not operational) of Act 29 of 2007 should refer to the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of the South African Qualifications Authority Act, 1995 (Act 58 of 1995).
- (g) Section 31: Put the amendment of section 31 by section 30 of the Health Professions Amendment Act 29 of 2007 into operation as soon as possible.
- (h) Heading of section 31: Delete the expression “, technikons”. However, this amendment has already been effected by section 30(a) of Act 29 of 2007, which must still be operationalized.
- (i) Section 31(1), (2), (3) and (5): Delete the expression “, technikon” wherever it occurs. However, these amendments to section 31(1), (2), (3) and (5) have already been effected by paragraphs (b), (c), (d) and (e) of section 30 of Act 29 of 2007, which must still be operationalized.
- (j) Section 39(1)(e): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
- (k) Section 55(g): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978.
- (l) Section 56: Refer to the Inquests Act 58 of 1959 instead of the Inquest Act, 1959 (Act 58 of 1959) and to the Births and Deaths Registration Act, 1992 (Act 51 of 1992) instead of the Births, Marriages and Deaths Registration Act, 1992 (Act 51 of 1992).

4. There are no recommendations with regard to the Medical, Dental and Supplementary Health Service Professions Amendment Acts 33 of 1976, 52 of 1978, 43 of 1980, 66 of 1981, 38 of 1982, 58 of 1984, 79 of 1990, 58 of 1992, 18 of 1995, 89 of 1997 and 1 of 1998.

5. Refer to the proposed consolidated **Health Professions Bill** in **Annexure F**. The following are recommended regarding the Health Professions Amendment Act 29 of 2007 (see paragraphs 7.17 and 7.18):

- (a) Put sections 14, 16 and 30 of HP Amendment Act 29 of 2007, which respectively amend sections 15B, 16 and 31 of the Health Professions Act, into operation as soon as possible.

(b) Section 16(f) (still to be put into operation), which adds the proposed subsection (6) to section 16 of the HP Act, should refer to the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of the repealed South African Qualifications Authority Act, 1995 (Act 58 of 1995).

6. Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**. The following are recommended regarding the Dental Technicians Act 19 of 1979 (see paragraph 7.21):

- (a) Section 1: In the definition of “clinical dental technologist”, refer to the Medical Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (b) Section 1: In the definition of “dentist”, refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (c) Section 1: In the definition of “scheduled substance”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (d) Section 5(1)(b)(iii): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (e) Section 6(1)(b): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (f) Section 6(1)(e): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (g) Section 24(4) and (5)(c): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (h) Section 27(7)(a) and (b): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (i) Section 29(2)(e): Refer to the Medical Schemes Act, 1998 (Act 131 of 1998) instead of the Medical Schemes Act, 1967 (Act 72 of 1967).

7. There is no recommendation on the Dental Technicians Amendment Act 43 of 1997.

8. Put sections 1, 2 and 5 of the Dental Technicians Amendment Act 24 of 2004 into operation or, if the amendments are not to be effected, repeal these sections (see section 7.25).

9. Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure**

B. The following are recommended about the Allied Health Professions Act 63 of 1982:

- (a) Insert definitions for the following: acupuncture, ayurveda, Chinese medicine, chiropractic, homeopathy, naturopathy, osteopathy, phytotherapy, therapeutic aromatherapy, therapeutic massage therapy and therapeutic reflexology (see paragraphs 7.29 to 7.30).
- (b) Section 1: In the definition of “scheduled substance”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (c) Section 6(2)(e): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (d) Section 10B(2)(e): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (e) Section 16(1): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
- (f) Section 16(3): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (g) Section 30(1)(b): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (h) Section 31(2)(a): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
- (i) Section 32A(f): Refer to the Nursing Act, 2005 (Act 33 of 2005) and the Nursing Act, 2005 instead of the repealed Nursing Act, 1978 (Act 50 of 1978) and the Nursing Act, 1978 respectively.
- (j) Section 38(3): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (k) Section 40: Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974). (See paragraph 7.28 regarding references to repealed legislation.)
- (l) Section 41: Amend section 41 in the following manner:
 - i. Refer to a “herbalist” and “traditional health practitioner” as contemplated in

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| <p>the Traditional Health Practitioners Act, 2007 (Act 22 of 2007) (see paragraph 7.32).</p> <p>ii. Refer to the KwaZulu Act on the Code of Zulu Law 19 of 1985 and the Natal Code of Zulu Law published under Proclamation R151 of 1987 instead of the Code of Zulu Law (see paragraph 7.31).</p> <p>(m) Refer to “medicine men” as contemplated in the KwaZulu Act on the Code of Zulu Law 19 of 1985 and the Natal Code of Zulu Law published under Proclamation R151 of 1987 in addition to the reference to “herbalist” in the content of section 41 (see paragraph 7.31).</p> |
| <p>10. There is no recommendation in respect of the Associated Health Service Professions Amendment Acts 108 of 1985, 10 of 1990 and 63 of 1993.</p> |
| <p>11. There is no recommendation in respect of the Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 40 of 1995.</p> |
| <p>12. Refer to the proposed Health and Related Matters Amendment Bill in Annexure B. It is recommended that the Chiropractors, Homeopaths and Allied Health Service Professions Amendment Acts 91 of 1997 and 6 of 2000 be repealed (see paragraph 7.37).</p> |
| <p>13. There is no recommendation in respect of the Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act 50 of 2000.</p> |
| <p>14. Refer to the proposed Health and Related Matters Amendment Bill in Annexure B. The following is recommended regarding the Nursing Act 33 of 2005: Section 4(1)(o): refer to section 13 of the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of section 5 of the repealed South African Qualifications Authority Act, 1995 (Act 58 of 1995) (see paragraph 7.42).</p> |
| <p>15. Refer to the proposed Health and Related Matters Amendment Bill in Annexure B. In view of the judgement of the Constitutional Court in <i>Doctors for Life International v Speaker of the National Assembly and others</i> 2006 (6) SA 416 (CC) and the subsequent passing of the Traditional Health Practitioners Act 22 of 2007, it is recommended that (see paragraphs 7.45 to 7.48):</p> <p>(a) The Traditional Health Practitioners Act 35 of 2004 be repealed.</p> <p>(b) After the repeal of Act 35 of 2004, the regulations made under that Act be promulgated afresh under the Traditional Health Practitioners Act 22 of 2007.</p> |
| <p>16. Refer to the proposed Health and Related Matters Amendment Bill in Annexure B. The following are recommended regarding the Traditional Health Practitioners Act 22 of 2007 (see paragraph 7.51):</p> |

- (a) Section 1: In the definition of “accredited institution”, refer to the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of the South African Qualifications Authority Act, 1995 (Act 58 of 1995).
- (b) Section 1: In paragraph (d) of the definition of “traditional health practice”, refer to the Nursing Act, 2005 (Act 33 of 2005), instead of the repealed Nursing Act, 1974 (Act 50 of 1974) (*sic*).

17. Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure**

- B.** It is recommended that the Extension of Terms of Office of Members of Certain Councils Act 45 of 1997 be repealed (see paragraphs 7.54 to 7.59).

B Pharmacy Act 53 of 1974

1 Recommendation

7.1 The following are recommended regarding the Pharmacy Act of 1974:

- (a) Consider consolidating the Pharmacy Act and promulgating it afresh.
- (b) Section 1: In the definition of “medicine”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965.
- (c) Section 7(1)(c): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (d) Section 29(3)(a): Refer to the Medicines and Related Substances Act, 1965 instead of the Medicines and Related Substances Control Act, 1965.
- (e) Section 29(3)(e): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the Nursing Act, 2005 (Act 33 of 2005) instead of the Medicines and Related Substances Control Act, 1965 and the repealed Nursing Act, 1957 (Act 69 of 1957), respectively.
- (f) Section 38(1)(c): Refer to the Medicines and Related Substances Act, 1965 instead of the Medicines and Related Substances Control Act, 1965.

2 Purpose of Act

7.2 The purpose of the Act is to provide for the establishment of the South African Pharmacy Council and for its objects and general powers; to extend the control of the

council to the public sector; and to provide for pharmacy education and training, requirements for registration, the practice of pharmacy, the ownership of pharmacies and the investigative and disciplinary powers of the council; and to provide for matters connected therewith.

3 Discussion

7.3 The Pharmacy Act was adopted in 1974 and came into operation on 21 February 1975, which means that the Pharmacy Act has been on the statute book for more than 40 years. Since the Act has been on the statute book for such a long time, the question is asked why this Act has not been consolidated and promulgated afresh. In addition, the Act contains several references to out-dated legislation. For example, section 7 refers to the Mental Health Act 18 of 1973, which was repealed by the Mental Health Care Act 17 of 2002. Section 29(3)(e) refers to the Nursing Act 69 of 1957, which was wholly repealed by the Nursing Act 50 of 1978, which in turn was repealed by the Nursing Act 33 of 2005. There are also several references to the Medicines and Related Substances Control Act 101 of 1965, the name of which has since been changed to “Medicines and Related Substances Act”.

C Pharmacy Amendment Acts

7.4 The Pharmacy Act 53 of 1974 was amended by the Pharmacy Amendment Acts listed below:

- (a) Pharmacy Amendment Act 20 of 1979
- (b) Pharmacy Amendment Act 39 of 1982
- (c) Pharmacy Amendment Act 20 of 1983
- (d) Pharmacy Amendment Act 69 of 1985
- (e) Pharmacy Amendment Act 6 of 1995
- (f) Pharmacy Amendment Act 88 of 1997
- (g) Pharmacy Amendment Act 1 of 2000

7.5 There is no recommendation regarding any of the Pharmacy Amendment Acts.

D Health Professions Act 56 of 1974

1 Recommendation

7.6 The following are recommended regarding the Health Professions Act 56 of 1974 (the HPA):

- (a) Consider consolidating the Health Professions Act and promulgating it afresh.
- (b) Section 1: In the definition of “medicine”, refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (c) Section 15B: Put the amendment of section 15B by section 14 of the Health Professions Amendment Act 29 of 2007 into operation as soon as possible.
- (d) Section 16: Put the amendment of section 16 by section 16 of the Health Professions Amendment Act 29 of 2007 into operation as soon as possible.
- (e) Section 16(1): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978) and delete the expression “or a technikon”. However, if the amendment of section 16 of this Act by section 16 of the Health Professions Amendment Act 29 of 2007 is put into operation, this amendment will not be necessary as these amendments have already been effected by Act 29 of 2007.
- (f) Section 16(6): The attention of the Department is drawn thereto that the proposed section 16(6), added by section 16(f) (still not operational) of Act 29 of 2007 should refer to the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of the South African Qualifications Authority Act, 1995 (Act 58 of 1995).
- (g) Section 31: Put the amendment of section 31 by section 30 of the Health Professions Amendment Act 29 of 2007 into operation as soon as possible.
- (h) Heading of section 31: Delete the expression “, technikons”. However, this amendment has already been effected by section 30(a) of Act 29 of 2007, which must still be operationalised.
- (i) Section 31(1), (2), (3) and (5): Delete the expression “, technikon” wherever it occurs. However, these amendments to subsections (1), (2), (3) and (5) of section 31 have already been effected by paragraphs (b), (c), (d) and (e) of section 30 of Act 29 of 2007, which must still be operationalized.
- (j) Section 39(1)(e): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).

- (k) Section 55(g): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978.
- (l) Section 56: Refer to the Inquests Act, 1959 (Act 58 of 1959) instead of the Inquest Act, 1959 (Act 58 of 1959) and to the Births and Deaths Registration Act, 1992 (Act 51 of 1992) instead of the Births, Marriages and Deaths Registration Act, 1992 (Act 51 of 1992).

2 Purpose of Act

7.7 The purpose of the Act is to establish the Health Professions Council of South Africa and professional boards; to provide for control over the education, training and registration for and practising of health professions registered under this Act; and to provide for matters incidental thereto.

3 Discussion

7.8 The original name of the Health Professions Act was the Medical, Dental and Supplementary Health Service Professions Act 56 of 1974. The name of the Act was amended by the Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997 and Act 56 of 1974 is now known as the Health Professions Act 56 of 1974.

7.9 This Act has been extensively amended by several subsequent Amendment Acts and most previous inconsistencies have been addressed by these amendments. There is nothing in the Act that is inconsistent with section 9 of the Constitution and the only amendments required are corrections to address the references to out-dated legislation referred to in paragraph 7.4 above.

7.10 However, in view thereof that this Act has been on the statute book for more than 40 years (the original date of commencement was 21 February 1975) and has been amended so often and so extensively, the question is asked why this Act has not been consolidated and promulgated afresh. A quick overview of the Act reveals that the name of the HP Act has been changed; out of about 40 definitions in section 1, only 15 have never been amended, substituted or repealed; and only 1 out of the current 60 sections has never been amended. Over time 13 of the original 60 sections were repealed, while 14 new sections were inserted, of which 7 have been repealed again. The last amendment of the Act, the Health Professions Amendment Act 29 of 2007, has not even been fully operationalized yet.

7.11 The Health Professions Amendment Act 29 of 2007 amended several sections of the HPA. Sections 14, 16 and 30 of Act 29 of 2007, respectively amending sections 15B, 16 and 31 of the HPA, have not been put into operation yet for unknown reasons. Such a long lapse between the adoption of an Act and the commencement thereof is undesirable and leads to legal uncertainty. The reason for the delay should be addressed; alternatively the amendments should be repealed. See paragraphs 7.17 and 7.18 below for a further discussion of the matter.

7.12 Some of the amendments to sections 16 and 31 pertain to the deletion of the expression “technikon”. Minister Kader Asmal, the Minister of Education at the time, announced in October 2003 that the term “technikon” will no longer be used.⁶⁴ Up to that time, the expression “technikon” formed part of the name of several higher education institutes. All the names have since been changed and the expression “University of Technology” is now used. The Higher Education Act 101 of 1997 however still provides in section 20 that the Minister of Higher Education and Training may “declare any education institution providing higher education as ... a university, technikon or college”.

E Health Professions Amendment Acts

7.13 Apart from the Health Professions Amendment Act 29 of 2007, the Health Professions Act was amended by the following Health Amendment Acts and Health Professions Amendment Acts:

- (a) Medical, Dental and Supplementary Health Service Professions Amendment Act 33 of 1976
- (b) Health Laws Amendment Act 36 of 1977
- (c) Medical, Dental and Supplementary Health Service Professions Amendment Act 52 of 1978
- (d) Medical, Dental and Supplementary Health Service Professions Amendment Act 43 of 1980
- (e) Medical, Dental and Supplementary Health Service Professions Amendment Act 66 of 1981
- (f) Medical, Dental and Supplementary Health Service Professions Amendment Act 38 of 1982

⁶⁴ World Education Services “Technikon label thrown out” *World Education News and Reviews* available at <https://www.wes.org> accessed on 15 November 2016.

- (g) Medical, Dental and Supplementary Health Service Professions Amendment Act 58 of 1984
- (h) Medical, Dental and Supplementary Health Service Professions Amendment Act 79 of 1990
- (i) Medical, Dental and Supplementary Health Service Professions Amendment Act 58 of 1992
- (j) Medical Schemes Amendment Act 23 of 1993
- (k) Medical, Dental and Supplementary Health Service Professions Amendment Act 18 of 1995
- (l) Extension of Terms of Office of Members of Certain Councils Act 45 of 1997
- (m) Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997
- (n) Medical, Dental and Supplementary Health Service Professions Amendment Act 1 of 1998.

7.14 There is no recommendation with regard to any of these Amendment Acts.

F Health Professions Amendment Act 29 of 2007

1 Recommendation

7.15 The following are recommended regarding the Health Professions Amendment Act 29 of 2007 (HP Amendment Act of 2007):

- (a) Put sections 14, 16 and 30 of HP Amendment Act, which respectively amend sections 15B, 16 and 31 of the Health Professions Act, into operation as soon as possible.
- (b) The attention of the Department is drawn thereto that section 16(f) (still to be put into operation), which adds the proposed subsection (6) to section 16 of the HP Act, should refer to the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of the repealed South African Qualifications Authority Act, 1995 (Act 58 of 1995).

2 Purpose of Act

7.16 The purpose of the Act is to amend the Health Professions Act, 1974, so as to amend and insert certain definitions; to provide for the requirements for removal of

members from office; to provide for the absence of the president from council meetings; to provide for the functions of registrar and staff; to provide for the investigation of members whose names have been removed from the register; to provide for the publication of the register by electronic means; to provide for the particulars to be contained in the certificate of status of registration to be issued by the registrar; to provide for qualifications prescribed for registration and for registration of persons holding qualifications not prescribed for registration; to provide for compliance with conditions as a prerequisite for continuing professional development; to provide for registration of professional categories and additional professional categories; to provide for inquiry by professional boards into charges of unprofessional conduct; to provide for the handling of cases relating to the death of a person undergoing a procedure of a therapeutic, diagnostic or palliative nature; to provide for regulations relating to professional boards, educational institutions and facilities; and to provide for the rules relating to fees payable; and to provide for matters connected therewith.

3 Discussion

7.17 All the provisions of the HP Amendment Act of 2007 have been put into operation, with the exception of sections 14, 16 and 30, which respectively amend sections 15B, 16 and 31 of the HPA. Section 15B of the HPA deals with the general powers of professional boards, while section 16 pertains to control over training. Section 30 requires universities, technikons and other training institutions to furnish the Health Professions Council with certain particulars. The relevant sections of the HP Amendment Act of 2007 amend sections 15B, 16 and 31 as follows (also see footnote):⁶⁵

Amendment of section 15B

14. Section 15B of the principal Act is hereby amended—

- (a) by the substitution in subsection (1) for paragraph (a) of the following paragraph:
 - "(a) in such circumstances as may be prescribed, or where otherwise authorised by this Act, remove any name from a register or, upon payment of **[the prescribed]** a fee, restore thereto, or suspend a registered person from practising his or her profession pending the institution of a formal inquiry in terms of section 41 or investigation in terms of section 51;"
- (b) by the substitution in subsection (1) for paragraph (b) of the following paragraph:

⁶⁵ **[Words in bold type in square brackets indicate omissions from existing enactments]** and words underlined with a solid line indicate insertions in existing enactments.

- "(b) appoint examiners and moderators, conduct examinations **[and]** or evaluations, grant certificates, and charge such fees in respect of **[such]** the examinations, evaluations or certificates as may be prescribed;"
- (c) by the substitution in subsection (1) for paragraph (c) of the following paragraph:
 "(c) subject to the prescribed accreditation process and prescribed conditions, [approve training schools] including the submission of reports by accreditation teams or evaluators appointed by the professional board, accredit teaching institutions and training facilities;"
- (d) by the substitution in subsection (1) for paragraph (d) of the following paragraph:
 "(d) consider any matter affecting any health profession falling within the ambit of the professional board and make representations or take such action in connection therewith as the professional board deems advisable;"
- (e) by the substitution in subsection (1) for paragraph (e) of the following paragraph:
 "(e) upon application by any person, recognise any qualification held by him or her (whether such qualification **[has been]** was obtained in the Republic or elsewhere) as being equal, either wholly or in part, to any prescribed qualification, whereupon such person shall, to the extent to which the qualification has **[so]** been so recognised, be deemed to hold such prescribed qualification and upon compliance with any other additional requirements as may be determined by the professional board, register such person;" and
- (f) by the substitution in subsection (1) for paragraph (g) of the following paragraph:
 "(g) perform such other functions as may be prescribed, and generally, do all such things as the professional board deems necessary or expedient to achieve the objects of this Act in relation to **[a]** the health profession or professions falling within the ambit of the professional board."

Amendment of section 16

16. Section 16 of the principal Act is hereby amended—

- (a) by the substitution for the heading of the following heading:
"Control over education and training";
- (b) by the substitution for subsection (1) of the following subsection:
 "(1) Notwithstanding anything to the contrary in any other law **[contained]** but subject to the provisions of the Nursing Act, **[1978 (Act No. 50 of 1978)]** 2005 (Act No. 33 of 2005), no person **[or]**, educational institution **[, excluding a university or technikon]** or training facility, may offer or provide any education or training having as its object to qualify any person for the practising of any health profession to which the provisions of

this Act apply or for the **[carrying on]** performance of any other activity directed to the mental or physical examining of any person or to the diagnosis, treatment or prevention of any mental or physical defect, illness or deficiency in **[man]** humankind, unless such education and training has been **[approved]** accredited by the professional board concerned as being appropriate education and training for such purposes.";

- (c) by the substitution for subsection (2) of the following subsection:
 "(2) Any person, **[or]** educational institution or training facility wishing to offer such education or training as is referred to in subsection (1) shall, before offering such education or training, apply to the professional board concerned in writing for **[its approval]** the accreditation of such education or training [and] shall furnish such particulars regarding such education or training as the professional board concerned may require and pay the prescribed accreditation and annual fees to remain accredited.";
- (d) by the substitution for subsection (3) of the following subsection:
 "(3) The professional board concerned may grant or refuse any application made in terms of subsection (2) and, having granted such application, may **[prescribe]** impose such conditions and requirements as it may deem fit subject to which the education or training in question may be provided.";
- (e) by the substitution for subsection (5) of the following subsection:
 "(5) Any person who contravenes or fails to comply with any provision of this section shall be guilty of an offence and on conviction be liable to a fine or to imprisonment for a period not exceeding **[six]** 12 months or both **[such]** a fine and such imprisonment."; and
- (f) by the addition of the following subsection:
 "(6) The council is the education and training quality assurer for the health professionals registered under this Act, in terms of the South African Qualifications Authority Act, 1995 (Act No. 58 of 1995).".

Amendment of section 31

30. Section 31 of the principal Act is hereby amended—

- (a) by the substitution for the heading of the following heading:
"Universities [, technikon] and other [training] educational institutions to furnish [council] professional board with certain particulars";
- (b) by the substitution for subsection (1) of the following subsection:
 "(1) Every university **[, technikon]** or other educational institution at which a qualification can be obtained which entitles any holder thereof to registration under this Act, shall furnish **[the council]** a professional board on its request with full particulars as to—
- (a) the minimum age and **[standard of general]** evidence of compliance with set standards of education and training required of students;

- (b) evidence of compliance with the set course of study, training and examinations or assessment methodologies required of a student before such qualification is granted;
- (c) the results of any examinations conducted by it, and **[such]** any other particulars relating to **[any of the matters specified in paragraph (a), (b) or (c)]** the education and training offered by such institution as the **[council]** professional board may from time to time require for the accreditation of the qualification or qualifications offered by that institution for the purpose of registration under this Act.";
- (c) by the substitution for subsection (2) of the following subsection:
 "(2) If any university **[, technikon]** or other educational institution referred to in subsection (1) fails or refuses to furnish any particulars requested by **[the council]** a professional board under that subsection, or if it appears to the **[council]** professional board that any provision of this Act is not being properly complied with by any such university **[, technikon]** or other educational institution and that such improper compliance is having or may have an adverse effect on the standards of education and training maintained at that university **[, technikon]** or other educational institution, the **[Minister may, on the recommendation of the council, by notice in the Gazette declare that any specified qualification granted by such university, technikon or educational institution after a date specified in the notice shall not entitle any holder thereof to registration under this Act]** professional board concerned may suspend accreditation of such university or other educational institution referred to in subsection (1) until such time as the concerned university or other educational institution has complied with the conditions and terms determined by the board.";
- (d) by the substitution for subsection (3) of the following subsection:
 "(3) The professional board may, when it has been made to appear to it upon representations made by the affected institution that satisfactory provision has been made for complying with the requirements of this Act by the said institution, reinstate, by notice in the Gazette, the accreditation of that institution."; and⁶⁶
- (e) by the substitution for subsection (5) of the following subsection:
 "(5) The **[council]** relevant professional board may appoint a person to be present whenever tests or examinations are being conducted by any university **[, technikon]** or other educational institution in respect of the academic progress made by students at such university **[, technikon]** or other educational institution and to

⁶⁶ Wording of subsection (3) of section 31 before amendment: "(3) The Minister may, when it has been made to appear to him or her upon representations made by the council that satisfactory provision has been made for complying with the requirements of this Act by any university, technikon or educational institution in respect of any qualification which is the subject of a notice issued under subsection (2), repeal the said notice."

report to the **[council upon such tests]** relevant professional board thereon."

7.18 The Amendment Act was originally assented to on 11 January 2008, and the rest of the Act commenced on 1 August 2008. It is unclear why these amendment provisions have not been put into operation yet, but in view of the time lapse from the date when the Act was assented to and the other provisions of the Act put into operation, it is important that a commencement date for sections 14, 16 and 30 of the HPA Act of 2007 be proclaimed as soon as possible. If the amendments to sections 15B, 16 and 31 of the HPA are no longer relevant and are not to be put into operation, sections 14, 16 and 30 of the Health Professions Amendment Act 29 of 2007 should be repealed.

G Dental Technicians Act 19 of 1979

1 Recommendation

7.19 The following recommendations are made with regard to the Dental Technicians Act 19 of 1979:

- (a) Section 1: In the definition of "clinical dental technologist", refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (b) Section 1: In the definition of "dentist", refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (c) Section 1: In the definition of "scheduled substance", refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (d) Section 5(1)(b)(iii): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (e) Section 6(1)(b): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (f) Section 6(2)(e): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).

- (g) Section 24(4) and (5)(c): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (h) Section 27(7)(a) and (b): Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (i) Section 29(2)(e): Refer to the Medical Schemes Act, 1998 (Act 131 of 1998) instead of the Medical Schemes Act, 1967 (Act 72 of 1967).

Amendment of section 1 of Act 19 of 1979, as amended by section 1 of Act 43 of 1997

8. Section 1 of the Dental Technicians Act, 1979 is hereby amended –
- (a) by the substitution in section 1 for the definition of “clinical dental technologist” of the following definition:
 - “ ‘clinical dental technologist’ means a person who has undergone training in treating patients requiring complete artificial dentures and who is registered as such under the **[Medical, Dental and Supplementary Health Service Professions Act]** Health Professions Act, 1974 (Act 56 of 1974);”;
 - (b) by the substitution in section 1 for the definition of “dentist” of the following definition:
 - “ ‘dentist’ means a person registered as such under the **[Medical, Dental and Supplementary Health Service Professions Act]** Health Professions Act, 1974 (Act 56 of 1974);”;
 - (c) by the substitution in section 1 for the definition of “scheduled substance” of the following definition:
 - “ ‘scheduled substance’ means a scheduled substance as defined in section 1 of the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965);”.

Amendment of section 5 of Act 19 of 1979, as amended by section 4 of Act 43 of 1997

9. Section 5 of the Dental Technicians Act, 1979 is hereby amended by the substitution in subsection (1) for subparagraph (iii) of paragraph (b) of the following subparagraph:
- “(iii) three shall be members of the public who shall be appointed after calling through the media for nominations by the public and who are not

registered in terms of this Act or the **[Medical, Dental and Supplementary Health Service Professions Act]** Health Professions Act, 1974 (Act 56 of 1974), of whom at least one shall be appointed on account of his or her knowledge of the law;”.

Amendment of section 6 of Act 19 of 1979, as amended by section 46 of Act 97 of 1986 and section 5 of Act 43 of 1997

10. Section 6 of the Dental Technicians Act, 1979 is hereby amended –

(a) by the substitution in subsection (1) for paragraph (b) of the following paragraph:

“(b) who in terms of this Act or the **[Medical, Dental and Supplementary Health Service Professions Act]** Health Professions Act, 1974 (Act 56 of 1974), is disqualified from practising his or her profession;”; and

(b) by the substitution in subsection (2) for paragraph (e) of the following paragraph:

“(e) he or she **[becomes a patient or a State patient]** suffers from a mental illness as defined in section 1 of the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 24 of Act 19 of 1979, as amended by sections 19 and 35 of Act 43 of 1997

11. Section 24 of the Dental Technicians Act, 1979 is hereby amended –

(a) by the substitution for subsection (4) of the following subsection:

“(4) If it appears to the judge concerned from the documents submitted to him or her in terms of the Mental Health Care Act, 2002 (Act 17 of 2002), or it is brought to his or her notice in any other manner, that the person to whom the documents relate is a person registered under this Act, he or she shall, if the said person is declared a mentally ill person as contemplated by the said Mental Health Care Act, direct that a copy of the order declaring such a person a mentally ill person be transmitted to the registrar and the registrar shall, on receipt of the said copy, remove the name of the person concerned from the register.”; and

(b) by the substitution in subsection (5) for paragraph (c) of the following paragraph:

“(c) if his or her name has been removed from the register in terms of

subsection (4), submits proof to the satisfaction of the council of his or her discharge in terms of the provisions of the **[Mental Health Act, 1973,] Mental Health Care Act, 2002**, from the institution at which he or she was detained; and”.

Amendment of section 27 of Act 19 of 1979, as amended by section 20 of Act 43 of 1997

12. Section 27 of the Dental Technicians Act, 1979 is hereby amended –

(a) by the substitution in subsection (7) for paragraph (a) of the following paragraph:

“(a) The prohibitions in subsections (1) and (2) shall not replace those contained in section 38 (1) of the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974 (Act 56 of 1974).”; and

(b) by the substitution in subsection (7) for paragraph (b) of the following paragraph:

“(b) The provisions of subsection (2) shall not imply that any dentist or clinical dental technologist who solicits, or allows any person to solicit on his or her behalf, any order referred to in that subsection, or accepts any such order so solicited, is not guilty of improper conduct, or that an inquiry under Chapter IV of the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974, may not be instituted against any such dentist or clinical dental technologist.”.

Amendment of section 29 of Act 19 of 1979, as amended by section 22 of Act 43 of 1997

13. Section 29 of the Dental Technicians Act, 1979 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

“(e) any medical **[benefit]** scheme registered in terms of the **[Medical Schemes Act, 1967 (Act 72 of 1967)] Medical Schemes Act, 1998 (Act 131 of 1998)**.”.

2 Purpose of Act

7.20 The purpose of the Dental Technicians Act 19 of 1979 is to consolidate and amend the laws relating to the profession of dental technician; to regulate the profession of dental technologist; and to provide for matters connected therewith.

3 Discussion

7.21 The Dental Technicians Act was adopted in 1979 and came into operation on 1 June 1979, which means that the DTA has been on the statute book for more than 35 years. It is therefore to be expected that the Act contains references to outdated legislation. For example, there are several references to the Mental Health Act 18 of 1973, instead of the Mental Health Care Act 17 of 2002; the Medical Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974) and even a reference to the long since repealed Medical Schemes Act, 1967 (Act 72 of 1967) instead of the Medical Schemes Act, 1998 (Act 131 of 1998).

H Dental Technicians Amendment Act 43 of 1997

7.22 There is no recommendation regarding the Dental Technicians Amendment Act 43 of 1997.

I Dental Technicians Amendment Act 24 of 2004

1 Recommendation

7.23 Put sections 1, 2 and 5 of the Dental Technicians Amendment Act 24 of 2004 into operation or, if the amendments are not to be effected, repeal these sections.

2 Purpose of Act

7.24 The purpose of Act 24 of 2004 is to amend the Dental Technicians Act, 1979, so as to define “informally trained person”; to provide for the restricted registration of informally trained persons as dental technicians; to make direct billing by a dental technician contractor discretionary; to restrict the performance of certain acts by members of certain juristic persons; and to make provision for the publication of draft regulations for comment; and to provide for matters connected therewith.

3 Discussion

7.25 This Amendment Act was assented to on 25 November 2004. Sections 3, 4 and 6 of the Act commenced on 28 February 2007. The rest of the Act's provisions, namely sections 1, 2 and 5 of Act 24 of 2004, have to date not been put into operation. It is unclear why these sections have not been operationalized yet. Section 1 of Act 24 of 2004 amends section 1 of the DTA by inserting a definition for "informally trained person". Section 2 of Act 24 of 2004 inserts section 23A, providing for the "Restricted registration of informally trained persons". Section 5 amends section 50 of the DTA to provide for the making of regulations relating to the conditions on which an informally trained person may be registered by the council as a dental technician in terms of section 23A and to provide for proposed regulations to be published in the *Government Gazette* for comment in certain instances before it is made. More than a decade has elapsed since Act 24 of 2004 was adopted. If sections 1, 2 and 5 of Act 24 of 2004 are no longer relevant, these sections should be repealed.

J Allied Health Professions Act 63 of 1982

1 Recommendation

7.26 The following are recommended regarding the Allied Health Professions Act 63 of 1982 (AHPA):

- (a) Insert definitions for the following: acupuncture, ayurveda, Chinese medicine, chiropractic, homeopathy, naturopathy, osteopathy, phytotherapy, therapeutic aromatherapy, therapeutic massage therapy and therapeutic reflexology.
- (b) Section 1: In the definition of "scheduled substance", refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (c) Section 6(2)(e): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (d) Section 10B(2)(e): Refer to the Mental Health Care Act, 2002 (Act 17 of 2002) instead of the Mental Health Act, 1973 (Act 18 of 1973).
- (e) Section 16(1): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).

- (f) Section 16(3): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (g) Section 30(1)(b): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (h) Section 31(2)(a): Refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
- (i) Section 32A(f): Refer to the Nursing Act, 2005 (Act 33 of 2005) and the Nursing Act, 2005 instead of the repealed Nursing Act, 1978 (Act 50 of 1978) and the Nursing Act, 1978 respectively.
- (j) Section 38(3): Refer to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) instead of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
- (k) Section 40: Refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
- (l) Section 41: Amend section 41 in the following manner:
 - i. Refer to a “herbalist” and “traditional health practitioner” as contemplated in the Traditional Health Practitioners Act, 2007 (Act 22 of 2007).
 - ii. Refer to the KwaZulu Act on the Code of Zulu Law 19 of 1985 and the Natal Code of Zulu Law published under Proclamation R151 of 1987 instead of the Code of Zulu Law.
 - iii. Refer to “medicine men” as contemplated in the KwaZulu Act on the Code of Zulu Law 19 of 1985 and the Natal Code of Zulu Law published under Proclamation R151 of 1987 in addition to the reference to “herbalist” in the content of section 41.

Amendment of section 1 of Act 63 of 1982, as amended by section 1 of Act 108 of 1985, section 1 of Act 10 of 1990, section 1 of Act 63 of 1993, section 1 of Act 40 of 1995 and section 1 of Act 50 of 2000

14. Section 1 of the Allied Health Professions Act, 1982 is hereby amended –

- (a) by the insertion before the definition of “acupuncturist” of the following definition:

“ ‘acupuncture’ means a system of complementary medicine in which fine needles are inserted in the skin at specific points along what are considered

to be lines of energy (meridians), used in the treatment of various physical and mental conditions.”;

- (b) by the insertion after the definition of “annual fees” of the following definition:
“‘ayurveda’ means the traditional Hindu system of medicine, incorporated in Atharva Veda, the last of the four Vedas, which is based on the balance in bodily systems and which uses diet, herbal treatment, and yogic breathing.”;
- (c) by the insertion after the definition of “chairperson” of the following definitions:
“‘Chinese medicine’ means the traditional Chinese medical system to prevent, diagnose, and treat disease, based on the belief that qi, the body's vital energy, flows along meridians (channels) in the body and keeps a person’s spiritual, emotional, mental, and physical health in balance.”; and
“‘chiropractic’ means a system of complementary medicine based on the diagnosis and manipulative treatment of misalignments of the joints, especially those of the spinal column, which are believed to cause other disorders by affecting the nerves, muscles, and organs.”;
- (d) by the insertion after the definition of “homeopath” of the following definition:
“‘homeopathy’ means a system of complementary medicine in which ailments are treated by minute doses of natural substances that in larger amounts would produce symptoms of the ailment.”;
- (e) by the insertion after the definition of “naturopath” of the following definition:
“‘naturopathy’ means a system of treatment of disease that avoids drugs and that emphasizes the use of natural agents, including air, water and herbs, and physical means, including tissue manipulation and electrotherapy.”;
- (f) by the insertion after the definition of “osteopath” of the following definition:
“‘osteopathy’ means a system of medical practice based on theory that diseases are due chiefly to loss of structural integrity which can be restored by manipulation of the parts, supplemented by therapeutic measures.”;
- (g) by the insertion after the definition of “phytotherapist” of the following definition:
“‘phytotherapy’ means a science-based medical practice based on the use of plant-derived medications in the treatment and prevention of disease.”;
- (h) by the substitution for the definition of “scheduled substance” of the following definition:
“‘scheduled substance’ means any scheduled substance as defined in section 1 of the Medicines and Related Substances **[Control]** Act, 1965 (Act

101 of 1965);”;

- (i) by the insertion after the definition of “therapeutic aromatherapist” of the following definition:

“ ‘therapeutic aromatherapy’ means the use of plant-derived, aromatic essential oils to promote physical and psychological well-being, sometimes used in combination with massage and other therapeutic techniques as part of a holistic treatment approach;”;

- (j) by the insertion after the definition of “therapeutic massage therapist” of the following definition:

“ ‘therapeutic massage therapy’ means the manual manipulation of soft body tissues, such as muscle, connective tissue, tendons and ligaments, to enhance a person's health and well-being;” and

- (k) by the insertion after the definition of “therapeutic reflexologist” of the following definition:

“ ‘therapeutic reflexology’ means the method of relieving pain by the application of pressure to stimulate predefined pressure points on the feet and hands to alleviate the source of the discomfort;”.

Amendment of section 6 of Act 63 of 1982, as amended by section 7 of Act 40 of 1995 and section 7 of Act 50 of 2000

15. Section 6 of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

- “(e) **[becomes a patient or State patient]** suffers from a mental illness as defined in section 1 of the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 10B of Act 63 of 1982, as inserted by section 10 of Act 50 of 2000

16. Section 10B of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

- “(e) **[becomes a patient or State patient]** suffers from a mental illness as defined in section 1 of the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 16 of Act 63 of 1982, as repealed by section 5 of Act 108 of 1985, inserted by section 7 of Act 63 of 1993 and substituted by section 14 of Act 50 of 2000

17. Section 16 of the Allied Health Professions Act, 1982 is hereby amended –

(a) by the substitution for subsection (1) of the following subsection:

“(1) The Minister may, at the request of the council, by notice in the *Gazette* declare the provisions of this Act to be applicable to any profession which has as its object the promotion of health, or the treatment, prevention or relief of physical or mental defects, illnesses or deficiencies in humans, excluding any profession referred to in subsection (1A) or any profession to which the provisions of the Pharmacy Act, 1974 (Act 53 of 1974), the Health Professions Act, 1974 (Act 56 of 1974), the **[Nursing Act, 1978 (Act 50 of 1978)]** Nursing Act, 2005 (Act 33 of 2005), or the Dental Technicians Act, 1979 (Act 19 of 1979), apply.”; and

(b) by the substitution for subsection (3) of the following subsection:

“(3) Subject to the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965), and subject to the approval of the Medicines Control Council, the Minister may, on the recommendation of the council, by regulation prescribe access to and availability of medicines relative to the professions registered in terms of this Act.”.

Amendment of section 30 of Act 63 of 1982, as substituted by section 17 of Act 108 of 1985 and amended by section 23 of Act 63 of 1993 and section 26 of Act 50 of 2000

18. Section 30 of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (1) for paragraph (b) of the following paragraph:

“(b) has become addicted to the use of any scheduled substance as defined in section 1 (1) of the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965),”.

Amendment of section 31 of Act 63 of 1982, as substituted by section 17 of Act 108 of 1985 and amended by section 23 of Act 63 of 1993 and section 26 of Act 50 of 2000

19. Section 31 of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (2) for paragraph (a) of the following paragraph:

“(a) any person exercising a profession to which the provisions of the Pharmacy Act, 1974 (Act 53 of 1974), the Health Professions Act, 1974 (Act 56 of 1974), the **[Nursing Act, 1978 (Act 50 of 1978)]** Nursing Act, 2005 (Act 33 of 2005), or the Dental Technicians Act, 1979 (Act 19 of 1979), apply, from performing any act pertaining to his or her profession, as contemplated in the appropriate Act, which may lawfully be performed by him or her;”.

Amendment of section 32A of Act 63 of 1982, as inserted by section 29 of Act 50 of 2000

20. Section 32A of the Allied Health Professions Act, 1982 is hereby amended by the substitution for paragraph (f) of the following paragraph:

“(f) supplies or offers to supply to any person not registered under this Act, the Health Professions Act, 1974 (Act 56 of 1974), or the **[Nursing Act, 1978 (Act 50 of 1978)]** Nursing Act, 2005 (Act 33 of 2005), any instrument or appliance which can be used, or is claimed to be effective, for the purpose of diagnosing, treating or preventing physical or mental defects, illnesses or deficiencies in man, knowing that such instrument or appliance will be used by such unregistered person for the purpose of performing for gain an act which such unregistered person is in terms of the provisions of this Act or the Health Professions Act, 1974, or **[Nursing Act, 1978]** Nursing Act, 2005, prohibited from performing for gain,”.

Amendment of section 38 of Act 63 of 1982, as amended by section 22 of Act 108 of 1985, section 27 of Act 94 of 1991, sections 21 and 23 of Act 63 of 1993 and section 33 of Act 50 of 2000

21. Section 38 of the Allied Health Professions Act, 1982 is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) The provisions of subsection (1) (l) and (m) shall not be applicable to a remedy which is a Scheduled substance as defined in section 1 of the Medicines and Related Substances **[Control]** Act, 1965.”.

Substitution of section 40 of Act 63 of 1982

22. The following section is hereby substituted for section 40 of the Allied Health Professions Act, 1982:

“Saving

40. The provisions of the [**Medical, Dental and Supplementary Health Service Professions Act,**] Health Professions Act, 1974 (Act 56 of 1974), shall not be construed as prohibiting any practitioner from performing for gain any act usually performed at the commencement of this Act by persons who practise the profession concerned in the Republic and the performance of which by any such practitioner is not prohibited by this Act.”.

Substitution of section 41 of Act 63 of 1982

23. The following section is hereby substituted for section 41 of the Allied Health Professions Act, 1982:

“Interpretation of laws in respect of certain traditional health practitioners, medicine men and herbalists

41. The provisions of this Act and the Health Professions Act, 1974 (Act 56 of 1974), shall not be construed as derogating from the right which a traditional health practitioner as defined in the Traditional Health Practitioners Act, 2007 (Act 22 of 2007), herbalist or medicine man as contemplated in the [**Code of Zulu Law**] KwaZulu Act on the Code of Zulu Law, 1985 (Act 19 of 1985) and the Natal Code of Zulu Law (Proclamation R151 of 1987) may have to practise his or her profession.”.

2 Purpose of Act

7.27 The purpose of the AHPA is to provide for the control of the practice of allied health professions and for that purpose to establish an Allied Health Professions Council of South Africa and to determine its functions.

3 Discussion

7.28 The original name of the Allied Health Professions Act was the Associated Health Service Professions Act. The short title of the Act was amended by Act 63 of 1993 and was changed to the Chiropractors, Homeopaths and Allied Health Service Professions Act 63 of 1982. The short title of the Act was amended again by Act 50 of 2000. The Act is now known as the Allied Health Professions Act.

7.29 The AHPA describes an “acupuncturist” as “a person registered as such under this Act in respect of the profession of Chinese medicine and acupuncture”. The definition of “allied health profession” refers to the professions: ayurveda, Chinese medicine and acupuncture, chiropractic, homeopathy, naturopathy, osteopathy, phytotherapy, therapeutic aromatherapy, therapeutic massage therapy and therapeutic reflexology. According to the HPA Act, an ayurveda practitioner, chiropractor, homeopath, naturopath, osteopath, phytotherapist, therapeutic aromatherapist, therapeutic massage therapist and therapeutic reflexologist are all described as “a person registered as such under this Act”. The term “therapist” is defined as “a person registered as a therapeutic aromatherapist, therapeutic massage therapist or therapeutic reflexologist in terms of this Act”. A therapist means a person registered as a therapeutic aromatherapist, therapeutic massage therapist or therapeutic reflexologist in terms of this Act.

7.30 The Act determines in section 16 that the Minister may, on the recommendation of the council, by regulation define the scope of any allied health profession by specifying the acts which shall for the purposes of the application of this Act be deemed to be acts pertaining to that profession. In essence, it means that the allied health professions are described by regulation. It is very poor legislative drafting practice to make an expression used in an Act, which is principal legislation, dependant on a description in a regulation, which is subordinate legislation. It would be more legally sound if the various allied health professions are defined in the Act.

7.31 Section 41 of the AHPA determines that the Act and the Health Professions Act shall not be construed as derogating from the right which a herbalist contemplated in the Code of Zulu Law may have to practise his or her profession. Firstly, the heading of section 41 does not correspond with the content thereof, as the heading refers to “medicine men” and “herbalists”, while the content of section 41 only refers to “herbalists”. In addition, the reference to the “Code of Zulu Law” is not quite correct. There are actually two codes, namely the KwaZulu Act on the Code of Zulu Law 19 of 1985 and the Natal Code of Zulu Law Published under Proclamation R151 of 1987.

7.32 The expression “herbalist” is also defined in the Traditional Health Practitioners Act, 2007 (Act 22 of 2007). If a “herbalist” as defined in Act 22 of 2007 should also be excluded from the AHPA, this should be stated in section 41 of the AHPA. In addition, reference should also be made to a “traditional health practitioner” as contemplated in the Traditional Health Practitioners Act, 2007 (Act 22 of 2007).

K Associated Health Service Professions Amendment Acts 108 of 1985, 10 of 1990 and 63 of 1993

7.33 There is no recommendation in respect of the Associated Health Service Professions Amendment Acts 108 of 1985, 10 of 1990 and 63 of 1993.

L Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 40 of 1995

7.34 There is no recommendation in respect of the Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 40 of 1995.

M Chiropractors, Homeopaths and Allied Health Service Professions Amendment Acts 91 of 1997 and 6 of 2000

1 Recommendation

7.35 It is recommended that the Chiropractors, Homeopaths and Allied Health Service Professions Amendment Acts 91 of 1997 and 6 of 2000 be repealed.

| No. and year of Act | Short title | Extent of repeal |
|----------------------------|---|-------------------------|
| Act 91 of 1997 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act, 1997 | The whole |
| Act 6 of 2000 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act, 2000 | The whole |

2 Purpose of Amendment Acts

7.36 The purpose of both the Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 91 of 1997 as well as Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act 6 of 2000 was to amend the Chiropractors, Homeopaths and Allied Health Service Professions Act, 1982, in order to extend the

terms of office of members of the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council; and to provide for matters connected therewith. In the case of Act 6 of 2000 the term of office of the members of the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council was extended retrospectively.

3 Discussion

7.37 Apart from the fact that Act 6 of 2000 applies retrospectively, Act 91 of 1997 and Act 6 of 2000 have the same objective. Both Amendment Acts amend sections 3(e) and 5(6) of the AHPA to achieve an extension of the term of office of the Chiropractors, Homeopaths and Allied Health Service Professions Interim Council. Sections 3 and 5 of the AHPA however have since been substituted in their entirety by sections 4 and 6 of the Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act 40 of 2000 respectively. For this reason Act 91 of 1997 and Act 6 of 2000 are now both obsolete and should be repealed.

N Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act 50 of 2000

7.38 There is no recommendation in respect of the Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act 50 of 2000.

O Nursing Act 33 of 2005

1 Recommendation

7.39 The following is recommended regarding the Nursing Act 33 of 2005: Section 4(1)(o): Refer to section 13 of the National Qualifications Framework Act 67 of 2008 instead of section 5 of the repealed South African Qualifications Authority Act 58 of 1995.

Amendment of section 4 of Act 33 of 2005

42. Section 4 of the Nursing Act, of 2005 is hereby amended by the substitution in subsection (1) for paragraph (o) of the following paragraph:

“(o) be regarded as an education and training quality assurer in terms of section [5 of the South African Qualifications Authority Act, 1995 (Act 58 of 1995)] 13 of the National Qualifications Framework Act, 2008 (Act 67 of 2008), for all nursing qualifications;”.

2 Purpose of Act

7.40 The purpose of the Act is to regulate the nursing profession.

3 Discussion

7.41 The Act was passed in 2005 and the sections were variously proclaimed in December 2006, August 2007 and March 2008. All sections have been proclaimed and are thus in operation. The Act repealed the Nursing Act 50 of 1978 as a whole, though section 2(1) provides that the South African Nursing Council established by section 2 of the Nursing Act 50 of 1978 continues to exist as a juristic person, notwithstanding the repeal of the 1978 Nursing Act by the 2005 Nursing Act.

7.42 The Act contains one reference to an outdated Act, namely a reference to section 5 of the repealed South African Qualifications Authority Act, 1995 (Act 58 of 1995) instead of referring to section 13 of the National Qualifications Framework Act 67 of 2008.

P Traditional Health Practitioners Act 35 of 2004

1 Recommendation

7.43 In view of the judgement of the Constitutional Court in *Doctors for Life International v Speaker of the National Assembly and others*⁶⁷ and the subsequent passing of the Traditional Health Practitioners Act 22 of 2007, it is recommended that:

1. The Traditional Health Practitioners Act 35 of 2004 be repealed.
2. After the repeal of Act 35 of 2004, the regulations made under Act 35 of 2004 be promulgated afresh in terms of the Traditional Health Practitioners Act 22 of 2007.

⁶⁷ 2006 (6) SA 416 (CC)

| No. and year of Act | Short title | Extent of repeal |
|---------------------|--|------------------|
| Act 35 of 2004 | Traditional Health Practitioners Act, 2004 | The whole |

2 Purpose of Act

7.44 The purpose of the Act is to establish the Interim Traditional Health Practitioners Council of South Africa; to provide for a regulatory framework to ensure the efficacy, safety and quality of traditional health care services; to provide for the management and control over the registration, training and conduct of practitioners, students and specified categories in the traditional health practitioners profession; and to provide for matters connected therewith.

3 Discussion

7.45 The Constitutional Court declared the Traditional Health Practitioners Act 35 of 2004 inconsistent with the Constitution in a judgement delivered on 17 August 2006 in *Doctors for Life International v Speaker of the National Assembly and others* 2006 (6) SA 416 (CC). The reason for the invalidity was the failure of the National Council of Provinces and provincial legislatures to fulfil their duty in terms of sections 72(1)(a) and 118(1)(a) of the Constitution to facilitate public involvement in the enactment of Act.

7.46 The order of invalidity was suspended for 18 months to enable Parliament to enact this statute afresh in accordance with the provisions of the Constitution. The Traditional Health Practitioners Act 22 of 2007 was promulgated on 10 January 2008. The Traditional Health Practitioners Act 35 of 2004, however, was not repealed.

7.47 Regulations, being subordinate legislation made under a provision authorising the making of regulations in an Act, will automatically lapse when the Act in terms of which the regulations were made, is repealed. This will be the case unless the regulations are retained by virtue of a transitional provision or a savings clause in subsequent legislation.

7.48 The Regulations relating to the appointment by the Minister as members of the Interim Traditional Health Practitioners Council of South Africa, published as Government Notice No. R. 689 of 21 July 2006, will lapse in the event of the repeal of the Traditional Health Practitioners Act 35 of 2004. The regulations in question will then have to be promulgated under the Traditional Health Practitioners Act 22 of 2007.

Q Traditional Health Practitioners Act 22 of 2007

1 Recommendation

7.49 The following are recommended regarding the Traditional Health Practitioners Act 22 of 2007:

- (a) Section 1: In the definition of “accredited institution”, refer to the National Qualifications Framework Act, 2008 (Act 67 of 2008) instead of the repealed South African Qualifications Authority Act, 1995 (Act 58 of 1995).
- (b) Section 1: In paragraph (d) of the definition of “traditional health practice”, refer to the Nursing Act, 2005 (Act 33 of 2005), instead of the repealed Nursing Act, 1974 (Act 50 of 1974) (*sic*).

Amendment of section 1 of Act 22 of 2007

43. Section 1 of the Traditional Health Practitioners Act, 2007 is hereby amended –

- (a) by the substitution in section 1 for the definition of “accredited institution” of the following definition:

“ ‘accredited institution’ 'accredited institution' means an institution, approved by the Council, which certifies that a person or body has the required capacity to perform the functions within the sphere of the **[National Quality Framework contemplated in the South African Qualifications Authority Act, 1995 (Act 58 of 1995)]** National Qualifications Framework contemplated in the National Qualifications Framework Act, 2008 (Act 67 of 2008);

- (b) by the substitution in the definition of “traditional health practice” for the words following paragraph (d) of the following words:

“but excludes the professional activities of a person practising any of the professions contemplated in the Pharmacy Act, 1974 (Act 53 of 1974), the Health Professions Act, 1974 (Act 56 of 1974), **[the Nursing Act, 1974 (Act 50 of 1974),]** the Allied Health Professions Act, 1982 (Act 63 of 1982), **[or]** the Dental Technicians Act, 1979 (Act 19 of 1979), or the Nursing Act, 2005 (Act 33 of 2005), and any other activity not based on traditional philosophy;”.

2 Purpose of Act

7.50 The purpose of the Traditional Health Practitioners Act 22 of 2007 is to establish the Interim Traditional Health Practitioners Council of South Africa; to provide for a regulatory framework to ensure the efficacy, safety and quality of traditional health care services; to provide for the management and control over the registration, training and conduct of practitioners, students and specified categories in the traditional health practitioners profession; and to provide for matters connected therewith.

3 Discussion

7.51 Sections 7, 10, 11(3), 12, 13, 14, 15, 47, 48 and 50 of the Act came into operation on 30 April 2008. The remaining sections of the Act, with the exception of sections 1, 2 3, 11(1) and (2), were put into operation on 1 May 2014. The date of commencement of sections 1 to 3 and section 11(1) and (2) is still to be proclaimed. Though section 1 is yet to be proclaimed, it is worth noting that the definition of “accredited institution” refers to the repealed South African Qualifications Authority Act, 1995 (Act 58 of 1995), instead of National Qualifications Framework Act, 2008 (Act 67 of 2008) and the definition of “traditional health practice” refers to the repealed Nursing Act 50 of 1978, instead of the current Nursing Act 33 of 2005.

R Extension of Terms of Office of Members of Certain Councils Act 45 of 1997

1 Recommendation

7.52 It is recommended that the Extension of Terms of Office of Members of Certain Councils Act 45 of 1997 (ETOMCCA) be repealed.

| No. and year of Act | Short title | Extent of repeal |
|---------------------|---|------------------|
| Act 45 of 1997 | Extension of Terms of Office of Members of Certain Councils Act, 1997 | The whole |

2 Purpose of Act

7.53 The purpose of the ETOMCCA is to amend the Pharmacy Act, 1974, the Medical, Dental and Supplementary Health Service Professions Act, 1974 and the Nursing Act, 1978 in order to respectively extend the terms of office of the members of the Interim Pharmacy Council of South Africa, the Interim National Medical and Dental Council of South Africa and the South African Interim Nursing Council.

3 Discussion

7.54 The ETOMCCA consists of 6 sections. Sections 1 and 2 amend the Pharmacy Act 53 of 1974, sections 3 and 4 amend the Medical, Dental and Supplementary Health Service Professions Act 56 of 1974 (renamed to the Health Professions Act 56 of 1974), section 5 amends the Nursing Act 50 of 1978 and sections 6 indicates the short title and determines the date of commencement of the ETOMCCA.

(a) Amendment to Pharmacy Act 53 of 1974

(i) Section 3

7.55 Section 1 of the ETOMCCA amended section 3 of the Pharmacy Act of 1974 by substituting paragraph (e). Section 3 deals with the objects of the Pharmacy Council. Section 3 was subsequently substituted by section 4 of the Pharmacy Amendment Act 88 of 1997. Section 1 of the ETOMCCA has therefore become redundant and may be repealed.

(ii) Section 5

7.56 Section 2 of the ETOMCCA amended section 5 of the Pharmacy Act of 1974 by substituting subsection (6). Section 5 deals with the constitution of the Pharmacy Council. Section 5 was subsequently substituted by section 6 of the Pharmacy Amendment Act 88 of 1997. Section 2 of the ETOMCCA has therefore become redundant and may be repealed.

(b) Amendment to Medical, Dental and Supplementary Health Service Professions Act 56 of 1974

(i) Section 3

7.57 Section 3 of the ETOMCCA amended section 3 of the Medical, Dental and Supplementary Health Service Professions Act 56 of 1974 (later renamed to the Health Professions Act 56 of 1974) by substituting paragraph (f). Section 3 deals with the objects of the Health Professions Council. Section 3 was subsequently substituted by section 4 of the Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997 and paragraph (f) was amended again by section 3(b) of the Health Professions Amendment Act 29 of 2007. Section 3 of the ETOMCCA has therefore become redundant and may be repealed.

(ii) Section 5

7.58 Section 4 of the ETOMCCA amended section 5 of the Medical, Dental and Supplementary Health Service Professions Act 56 of 1974 (renamed to the Health Professions Act 56 of 1974) by substituting subsection (6). Section 5 deals with the constitution of the Health Professions Council. Section 5 was subsequently substituted by section 6 of the Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997. Section 4 of the ETOMCCA has therefore become redundant and may be repealed.

(c) Amendment to Nursing Act 50 of 1978

7.59 Section 5 of the ETOMCCA amended section 3 of the Nursing Act 50 of 1978 by substituting paragraph (f). Section 3 deals with the objects of the Nursing Council. The whole of the Nursing Act of 1978 was subsequently repealed and replaced by the new Nursing Act 33 of 2005. Section 5 of the ETOMCCA has therefore become redundant and may be repealed.

CHAPTER 8: MEDICINES, SUBSTANCES AND PRODUCTS STATUTES

A Medicines, Substances and Products Statutes: Summary of Recommendations

1. Refer to the proposed consolidated **Medicines and Related Substances Bill** in **Annexure G**. The following are recommended regarding the Medicines and Related Substances Act 101 of 1965 (for out-dated references see paragraph 8.5):
 - (a) It is recommended that the Act be consolidated and promulgated afresh as it has been amended so often and to such an extent that the Act is becoming confusing (see paragraph 8.3).
 - (b) Section 1: In the definition of “nurse”, refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).
2. There is no recommendation regarding the Drugs Control Amendment Acts 29 of 1968, 88 of 1970, 95 of 1971 and 65 of 1974. If the MRSA is consolidated and promulgated afresh, these Amendment Acts can all be repealed.
3. There is no recommendation regarding the Medicines and Related Substances Control Amendment Acts 19 of 1976, 17 of 1979, 20 of 1981, 94 of 1991 and 90 of 1997. If the MRSA is consolidated and promulgated afresh, these Amendment Acts can all be repealed.
4. There is no recommendation regarding the Medicines and Related Substances Control Amendment Act 59 of 2002. If the MRSA is consolidated and promulgated afresh, this Amendment Act can be repealed.
5. It is recommended that the Medicines and Related Substances Amendment Acts 72 of 2008 and 14 of 2005 be put into operation as soon as possible. If the MRSA is consolidated and promulgated afresh, these Amendment Acts can both be repealed (see paragraph 8.13).
6. Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**. The following are recommended regarding the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (see paragraph 8.16):
 - (a) Section 3(2)(a): Refer to the Patents Act, 1978 (Act 57 of 1978) instead of the repealed Patents Act, 1952 (Act 37 of 1952).

- (b) Section 10(3): Repeal paragraph (e), unless the provision replacing section 28 of the Standards Act 29 of 1993 can be identified.
 - (c) Section 15A: Refer to the “members of Cabinet responsible for agriculture, environmental affairs, fisheries, and water” instead of the “Minister for Agriculture and Land Affairs, the Minister of Environmental Affairs and Tourism and the Minister of Water Affairs and Forestry”.
7. There is no recommendation in respect of the Foodstuffs, Cosmetics and Disinfectants Amendment Acts 32 of 1981 and 39 of 2007.
 8. Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**. The following are recommended regarding the Hazardous Substances Act 15 of 1973 (see paragraph 8.20):
 - (a) Section 1: In the definition of “Director-General”, refer to “Health” instead of “National Health and Population Development”.
 - (b) Section 1: Define “Minister” to mean “the member of Cabinet responsible for health”.
 - (c) Section 29(6): Refer to “the member of Cabinet responsible for labour”, instead of the Minister of Manpower.
 9. There is no recommendation regarding the Hazardous Substances Amendment Acts 16 of 1976, 31 of 1981 and 53 of 1992.
 10. Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**. The only recommendation regarding the Tobacco Products Control Act 83 of 1993 pertains to section 1 of the Act. In the definition of “Constitution, correct the reference to the Constitution (see paragraph 8.24).
 11. There is no recommendation regarding the Tobacco Products Control Amendment Act 12 of 1999 or the Tobacco Products Control Amendment Act 23 of 2007.

B Medicines and Related Substances Act 101 of 1965

1 Recommendation

8.1 The following are recommended regarding the Medicines and Related Substances Act 101 of 1965 (MRSA):

- (a) It is recommended that the Act be consolidated and promulgated afresh as it has been amended so often and to such an extent that the Act is becoming confusing.
- (b) Section 1: In the definition of “nurse”, refer to the Nursing Act, 2005 (Act 33 of 2005) instead of the repealed Nursing Act, 1978 (Act 50 of 1978).

2 Purpose of Act

8.2 The purpose of the MRSA is to provide for the registration of medicines intended for human and for animal use; for the registration of medical devices; for the establishment of a Medicines Control Council; for the control of medicines, scheduled substances and medical devices; for the control of manufacturers, wholesalers and distributors of medicines and medical devices; and for the control of persons who may compound and dispense medicines; and for matters incidental thereto.

3 Discussion

8.3 The MRSA, originally referred to as the Drugs Control Act, was put into operation on 1 April 1966, meaning that the Act has been on the statute book for more than 50 years. The Medicines and Related Substances Act 101 of 1965 has been amended so often and so extensively, especially by the last two amendments to the Act (Medicines and Related Substances Amendment Acts 72 of 2008 and 14 of 2015 – not yet operationalized), that it begs the question as to why the MRSA has not been consolidated and promulgated afresh. The name of the Act was changed to the “Medicines and Related Substances Control Act” by the Drugs Control Amendment Act 65 of 1974, which amendment was put into operation on 21 February 1975. The name of the Act was changed again to the “Medicines and Related Substances Act” by the Medicines and Related Substances Control Amendment Act 90 of 1997, which was only put into operation nearly six years later on 2 May 2003.

8.4 An overview of the Act reveals that, prior to the latest two Amendment Acts (72 of 2008 and 14 of 2015) and apart from the name of the Act having been changed twice, out of 54 definitions in section 1, only 14 have never been amended, substituted or repealed; and only 2 out of the current 52 sections have never been amended. Over time four out of the original 40 sections were repealed, while 16 new sections were inserted. The Medicines and Related Substances Amendment Act 72 of 2008, which had not been put into operation yet, will bring about a substantive change to medicines legislation as it will abolish the Medicines Control Council and establish a new body, the South African Health Products Regulatory Authority. Act 72 of 2008 effects an additional 11

amendments, deletions and insertions to definitions in section 1 of the MRSA, while 1 insertion, 12 amendments, 28 substitutions and 6 deletions are being made to the rest of the MRSA. In total, Act 72 of 2008 effects 11 changes to the definitions and 47 changes to the rest of the MRSA.

8.5 Parliament has since passed yet another Amendment Act, the Medicines and Related Substances Amendment Act 14 of 2015. Act 14 of 2015 has also not been put into operation yet. This Amendment Act effects another 10 amendments, deletions and insertions to the definitions in section 1 of the MRSA, and effects 10 insertions, 16 amendments, 3 substitutions and 1 deletion to the body of the MRSA. In total, Act 14 of 2015 effects an additional 10 changes to the definitions and an additional 30 changes to the rest of the MRSA. This brings unimplemented changes to the definitions of the MRSA to a total of 21, and unimplemented changes to the body of the MRSA to a total of 77 changes.

8.6 The Act contains 38 definitions and 54 sections at this stage. When the latest two Amendment Acts are put into operation, more changes will be effected to the Act than the total number of sections it currently contains. When such substantive amendments to an existing Act become necessary, it is advisable to replace the Act rather than to amend it. Yet it is ironic that, despite the many changes effected to the MRSA over the past few years, the definition of “nurse” in section 1 still refers to the repealed Nursing Act, 1978 (Act 50 of 1978), instead of the Nursing Act, 2005 (Act 33 of 2005).

C Drugs Control Amendment Acts 29 of 1968, 88 of 1970, 95 of 1971 and 65 of 1974

8.7 There is no recommendation regarding the Drugs Control Amendment Acts 29 of 1968, 88 of 1970, 95 of 1971 and 65 of 1974. However, if the MRSA is consolidated and promulgated afresh, these Amendment Acts can all be repealed.

D Medicines and Related Substances Control Amendment Acts 19 of 1976, 17 of 1979, 20 of 1981, 94 of 1991, 90 of 1997

8.8 There is no recommendation regarding the Medicines and Related Substances Control Amendment Acts 19 of 1976, 17 of 1979, 20 of 1981, 94 of 1991 and 90 of 1997. However, if the MRSA is consolidated and promulgated afresh, these Amendment Acts can all be repealed.

E Medicines and Related Substances Amendment Act 59 of 2002

8.9 There is no recommendation regarding the Medicines and Related Substances Control Amendment Act 59 of 2002. However, if the MRSA is consolidated and promulgated afresh, this Amendment Act can be repealed.

F Medicines and Related Substances Amendment Acts 72 of 2008 and 1 of 2015

1 Recommendation

8.10 It is recommended that the Medicines and Related Substances Amendment Acts 72 of 2008 and 14 of 2005 be put into operation as soon as possible. There is no recommendation in respect of the content of these Amendment Acts. However, if the MRSA is consolidated and promulgated afresh, both Amendment Acts can be repealed.

2 Purpose of Act

8.11 The purpose of Act 72 of 2008 is to amend the Medicines and Related Substances Act, 1965, so as to provide for the establishment of the South African Health Products Regulatory Authority; for the Chief Executive Officer and staff of the Authority; for the registration of medicines, medical devices, certain foodstuffs and cosmetics; for transitional measures; and for matters connected therewith. The date of commencement of the Act is still to be proclaimed.

8.12 The purpose of Act 14 of 2015 is to amend the Medicines and Related Substances Act, 1965, so as to define certain expressions and to delete or amend certain definitions; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to require the Minister to consult with the Pricing Committee when prescribing acceptable and prohibited acts in relation to bonusing; to replace the word “products” with the word “medicines” and expression “Scheduled substances” in order to correctly reflect the subject matter of the said Act; and to effect certain technical corrections; and to provide for matters connected therewith.

3 Discussion

8.13 In view of the time lapse since 19 April 2009 when the Medicines and Related Substances Amendment Act 72 of 2008 was assented to, it is important that a commencement date for this Amendment Act be proclaimed as soon as possible. However, if the MRSA is consolidated and promulgated afresh, the contents of Act 72 of 2008 and Act 14 of 2015 can be incorporated in the consolidated Act and these two Amendment Acts repealed.

G Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972

1 Recommendation

8.14 The following are recommended regarding the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (FCDA):

- (a) Section 3(2)(a): Refer to the Patents Act, 1978 (Act 57 of 1978) instead of the repealed Patents Act, 1952 (Act 37 of 1952).
- (b) Section 10(3): Repeal paragraph (e), unless the provision replacing section 28 of the Standards Act 29 of 1993 can be identified.
- (c) Section 15A: Refer to the “members of Cabinet responsible for agriculture, environmental affairs, fisheries, and water” instead of the “Minister for Agriculture and Land Affairs, the Minister of Environmental Affairs and Tourism and the Minister of Water Affairs and Forestry”.

Amendment of section 3 of Act 54 of 1972

3. Section 3 of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is hereby amended by the substitution in subsection (2) for paragraph (a) of the following paragraph:

“(a) which is the subject of a patent under the **[Patents Act, 1952 (Act 37 of 1952)]** Patents Act, 1978 (Act 57 of 1978), and which is sold in a condition complying with the specifications of the patent, and bears a label specifying the number under which the patent is registered in terms of that Act; or”

Amendment of section 10 of Act 54 of 1972, as amended by section 2 of Act 32 of 1981 and section 2 of Act 39 of 2007

4. Section 10 of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is hereby amended by the deletion in subsection (3) of paragraph (e).

Amendment of section 15A of Act 54 of 1972, as inserted by section 5 of Act 39 of 2007

5. Section 15A of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is hereby amended by the substitution for the words preceding paragraph (a) of the following words:

“The Minister may, after consultation with the **[Minister for Agriculture and Land Affairs, the Minister of Environmental Affairs and Tourism and the Minister of Water Affairs and Forestry]** members of Cabinet responsible for agriculture, environmental affairs, fisheries and water make regulations relating to –”

2 Purpose of Act

8.15 To control the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants; and to provide for incidental matters.

3 Discussion

8.16 Section 3(2)(a) refers to the repealed Patents Act 57 of 1978 instead of the Patents Act 37 of 1952 and should be corrected. Section 10(3)(e) refer to the Standards Act 29 of 1993 instead of the Standards Act 8 of 2008. However, there is no provision similar to section 28 of the Standards Act of 1993 in the new Standards Act of 2008.

Paragraph (e) of subsection (3) of section 10 can therefore be repealed, unless the provision replacing section 28 of Act 29 of 1993 can be identified. Section 15A refers to outdated ministerial portfolios. It would be an impossible task to amend all provisions referring to ministerial portfolios in all laws every time the portfolios change. The practice has therefore developed to refer to the member of Cabinet responsible for a specific branch of government rather than referring to ministerial portfolios by name.

H Foodstuffs, Cosmetics and Disinfectants

Amendment Acts 32 of 1981 and 39 of 2007

8.17 There is no recommendation about the Foodstuffs, Cosmetics and Disinfectants Amendment Acts 32 of 1981 and 39 of 2007.

I Hazardous Substances Act 15 of 1973

1 Recommendation

8.18 The following are recommended regarding the Hazardous Substances Act 15 of 1973 (HSA):

- (a) Section 1: In the definition of “Director-General”, refer to “Health” instead of National Health and Population Development”.
- (b) Section 1: In the definition of “Minister”, define “Minister” to mean “the member of Cabinet responsible for health”.
- (c) Section 29(6): Refer to “the member of Cabinet responsible for labour”, instead of the Minister of Manpower.

Amendment of section 1 of Act 15 of 1973, as amended by section 1 of Act 16 of 1976, section 1 of Act 31 of 1981, section 1 of Act 53 of 1992, section 84 of Act 131 of 1993 and section 58 of Act 46 of 1999

6. Section 1 of the Hazardous Substances Act, 1973, is hereby amended –

- (a) by the substitution for the definition of “Director-General” of the following definition:

“ ‘Director-General’ means the Director-General: **[National Health and**

Population Development] Health;; and

(b) by the substitution for the definition of “Minister” of the following definition:

“ ‘Minister’ means the **[Minister of National Health] member of Cabinet responsible for health;**”.

Amendment of section 29 of Act 15 of 1973, as amended by section 6 of Act 16 of 1976, section 7 of Act 31 of 1981 and section 12 of 1992

7. Section 29 of the Hazardous Substances Act, 1973, is hereby amended by the substitution for subsection (6) of the following subsection:

“(6) No regulation under subsection (1) (e) shall be made except after consultation with the **[Minister of Manpower] member of Cabinet responsible for labour.**”.

2 Purpose of Act

8.19 This Act provides for the control of substances which may cause injury or ill-health to or death of human beings by reason of their toxic, corrosive, irritant, strongly sensitising or flammable nature or the generation of pressure thereby in certain circumstances, and for the control of certain electronic products, to provide for the division of such substances or products into groups in relation to the degree of danger; to provide for the prohibition and control of the importation, manufacture, sale, use, operation, application, modification, disposal or dumping of such substances and products; and to provide for matters connected therewith.

3 Discussion

8.20 The Act contains references to outdated designations for government officials and Ministers. It would be an impossible task to amend all provisions referring to ministerial portfolios in all laws every time the portfolios change. The practice has therefore developed to refer to the member of Cabinet responsible for a specific branch of government rather than referring to ministerial portfolios by name.

J Hazardous Substances Amendment Acts 16 of 1976, 31 of 1981 and 53 of 1992

8.21 There is no recommendation regarding the Hazardous Substances Amendment Acts 16 of 1976, 31 of 1981 and 53 of 1992.

K Tobacco Products Control Act 83 of 1993

1 Recommendation

8.22 The only recommendation regarding the Tobacco Products Control Act 83 of 1993 pertains to section 1 of the Act. In the definition of “Constitution, correct the reference to the Constitution.

Amendment of section 1 of Act 83 of 1993

29. Section 1 of the Tobacco Products Control Act 83 of 1993 is hereby amended by the substitution in section 1 for the definition of “Constitution” of the following definition:

“ ‘Constitution’ means the Constitution of the Republic of South Africa, 1996 [(Act 108 of 1996)];”.

2 Purpose of Act

8.23 The purpose of this Act is to prohibit smoking in public places; to regulate the sale and advertising of tobacco products in certain respects and to prescribe what is to be reflected on packages; and to provide for matters connected therewith.

3 Discussion

8.24 According to Sections 1 and 2 of the Citation of Constitutional Laws Act, 2005 (Act No. 5 of 2005), no Act number is to be associated with the Constitution of the Republic of South Africa. Any reference to the Constitution, contained in any law in force immediately prior to the commencement of the Act, must be construed as a reference to the Constitution of the Republic of South Africa, 1996. It is therefore proposed that the definition of “Constitution” in section 1 of the Act should be amended.

L Tobacco Products Control Amendment Acts 12 of 1999, 23 of 2007 and 63 of 2008

8.25 There is no recommendation about the Tobacco Products Control Amendment Acts 12 of 1999, 23 of 2007 and 63 of 2008.

CHAPTER 9: OCCUPATIONAL HEALTH STATUTES

A Occupational Health Statutes: Summary of Recommendations

Note

The DOH indicated that there is a Ministerial Task Team working on the consolidation of health compensation as provided for in the Occupational Diseases in Mines and Works Act 78 of 1973 (ODMWA) and labour compensation as provided for in the Compensation for Occupational Injuries and Diseases Act 130 of 1993 (COIDA). It is envisaged that a single compensation system will result in the ODMWA being merged with COIDA and the repeal of ODMWA.

Subject to the outcome of the process referred to above, the following are recommended regarding the Occupational Diseases in Mines and Works Act 78 of 1973:

1. Give consideration to consolidating the Act and promulgating it afresh as it has been amended so often and to such an extent that the Act is becoming confusing (see paragraph 9.4).
2. Amend the definition of “Director-General” to refer to “Health” instead of “National Health and Population Development” (see paragraph 9.6).
3. Amend the definition of “medical practitioner” to refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974) (see paragraph 9.7).
4. Amend the definition of “Minister” to refer to “the member of Cabinet responsible for Health”, instead of the “Minister for National Health and Welfare” (see paragraph 9.8).
5. Amend paragraph (g) of the definition of “works” to refer to the Nuclear Energy Act, 1999 (Act 46 of 1999) instead of the Nuclear Energy Act, 1993 (Act 131 of 1993) (see paragraph 9.9).
6. Amend section 1(2)(b) to refer to “the member of Cabinet responsible for Labour” instead of the “Minister of Manpower” (see paragraph 9.9).
7. Amend the heading of sections 24 and 96 to delete the expression “White or Coloured” (see paragraph 9.10).

8. Provide for the giving of consent by persons who are required to undergo medical examination in terms of section 24, 25, 26, 29, 31 or 32, and the confidentiality of the results of these medical examinations as well as any information that may arise out of the questioning processes (see paragraph 9.11).
9. Amend section 27 to provide for counselling of persons as part of the procedure where the presence of a compensatable disease is suspected (see paragraph 9.12).
10. Amend section 34 so as to take cognisance of the fact that certain post-mortem procedures may be against the cultural and religious practices of some persons, and that these cultural and religious practices need to be respected as far as is possible (see paragraph 9.13).
11. Amend section 58 to reflect the current divisions and structure of the courts (see paragraph 9.14).
12. Amend section 63 subsection (1) by adding the expression “by notice in the Gazette from time to time” to subsection (1) and repealing subsection (2) (see paragraphs 9.15 to 9.16).
13. Amend section 64 to refer to the interest rate determined in terms 80(1) of the Public Finance Management Act 1 of 1999 instead of the interest rate determined in terms of section 26(1) of the repealed Exchequer Act, 1975 (Act 66 of 1975) (see paragraph 9.17).
14. Delete references to specific amounts in sections 79, 80 and 83 and replace it with references to amounts determined in terms of section 105A (see paragraph 9.18).
15. Amend section 122 to refer to the current structure of Parliament.
16. Amend section 123 to refer to the Department of Health instead of the Department of Mines (see paragraphs 9.19).
17. Amend the Act to refer to “surviving spouse” instead of “widow” throughout the Act (sections 34(3); 79 (heading), 79(1) and (3); 81(1); 83 (heading) and 83(1) and (2) and 95 (heading), words preceding paragraph (a) and paragraphs (a), (b) and (c); 96(2); 98 (heading and content); 133(3)(a) and (b) and 133(6)(a) and (b)) (see paragraphs 9.20 to 9.21).

18. Amend the Act to refer to the Minister of Finance instead of the Minister of State Expenditure throughout the Act (sections 37(1)(b)(i) and (ii) and (2)(b)(i) and (3); 41(1); 59(6); 60(2); 69(2); 75(2)(a); 105A(1) and 121(2)) (see paragraph 9.22).
19. Amend the Act to refer to the National Revenue Fund instead of the State Revenue Fund throughout the Act (sections 69(3)(c); 105A(1) and 121(2)) (see paragraph 9.23).
20. Review the amounts of fines and penalties to reflect changes in economic realities or leave out specific amounts to allow fines to be determined in accordance with the Adjustment of Fines Act 101 of 1991 (see paragraph 9.24).
21. Should the Occupational Diseases in Mines and Works Act 78 of 1973 come up for amendment in the future any gender specific terminology should be replaced with gender neutral terminology (see paragraphs 9.20 to 9.21).

Refer to the proposed **Health and Related Matters Amendment Bill** in **Annexure B**.

The following recommendations are made with regard to Occupational Diseases in Mines and Works Amendment Acts:

1. Repeal sections 3, 4, 7 and 8 of the Occupational Diseases in Mines and Works Amendment Act 27 of 1974 (see paragraph 9.27).
2. Repeal the Occupational Diseases in Mines and Works Amendment Act 67 of 1974 as it has become obsolete (see paragraph 9.30).
3. Repeal sections 1, 4, 5, 6, 8, 9, 10 and 11(b) of Act 45 of 1975 (see paragraphs 9.33 and 9.24).
4. Repeal the Occupational Diseases in Mines and Works Amendment Act 117 of 1977 as it has become obsolete (see paragraph 9.37).
5. Repeal sections 2, 3 and 4 of the Occupational Diseases in Mines and Works Amendment Act 30 of 1978 as it has become obsolete (see paragraph 9.40).
6. Repeal section 1 of the Occupational Diseases in Mines and Works Amendment Act 83 of 1979 as it has become obsolete (see paragraph 9.43).
7. Repeal the Occupational Diseases in Mines and Works Amendment Act 83 of 1980, the Occupational Diseases in Mines and Works Amendment Act 85 of 1981 and the Occupational Diseases in Mines and Works Amendment Act 106 of 1983 as these Amendment Acts have become obsolete (see paragraph 9.46).
8. Repeal section 2 of the Occupational Diseases in Mines and Works Amendment Act 137 of 1991 as it has become obsolete (see paragraph 9.49).

9. Regarding the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 (see paragraphs 9.53 to 9.55):
- Either put section 13 of Act 208 of 1993, which repeals section 43 of the ODMWA, into operation; or repeal section 13 of Act 208 of 1993.
 - Either put section 15 of Act 208 of 1996, which repeals section 46 of the ODMWA, into operation; or repeal section 15 of Act 208 of 1993.
10. There is no recommendation with regard to the Occupational Diseases in Mines and Works Amendment Act 60 of 2002 (see paragraph 9.58).

B Occupational Diseases in Mines and Works Act 78 of 1973

1 Recommendations

9.1 The following are recommended regarding the Occupational Diseases in Mines and Works Act 78 of 1973 (ODMWA):

1. Give consideration to consolidating the Act and promulgating it afresh as it has been amended so often and to such an extent that the Act is becoming confusing.
2. Amend the definition of “Director-General” to refer to “Health” instead of “National Health and Population Development”.
3. Amend the definition of “medical practitioner” to refer to the Health Professions Act, 1974 (Act 56 of 1974) instead of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974).
4. Amend the definition of “Minister” to refer to “the member of Cabinet responsible for Health”, instead of the “Minister for National Health and Welfare”.
5. Amend paragraph (g) of the definition of “works” to refer to the Nuclear Energy Act, 1999 (Act 46 of 1999) instead of the repealed Nuclear Energy Act, 1993 (Act 131 of 1993).
6. Amend section 1(2)(b) to refer to “the member of Cabinet responsible for Labour” instead of the “Minister of Manpower”.
7. Amend the heading of sections 24 and 96 to delete the expression “White or Coloured”.

8. Provide for the giving of consent by persons who are required to undergo medical examination in terms of section 24, 25, 26, 29, 31 or 32, and the confidentiality of the results of these medical examinations as well as any information that may arise out of the questioning processes.
9. Amend section 27 to provide for counselling of persons as part of the procedure where the presence of a compensatable disease is suspected.
10. Amend section 34 so as to take cognisance of the fact that certain post-mortem procedures may be against the cultural and religious practices of some persons, and that these cultural and religious practices need to be respected as far as is possible.
11. Amend section 58 to reflect the current divisions and structure of the courts.
12. Amend section 63 subsection (1) by adding the expression “by notice in the Gazette from time to time” to subsection (1) and repealing subsection (2).
13. Amend section 64 to refer to the interest rate determined in terms 80(1) of the Public Finance Management Act 1 of 1999 instead of the interest rate determined in terms of section 26(1) of the repealed Exchequer Act, 1975 (Act 66 of 1975).
14. Delete references to specific amounts in sections 79, 80 and 83 and replace it with references to amounts determined in terms of section 105A.
15. Amend section 122 to refer to the current structure of Parliament.
16. Amend section 123 to refer to the Department of Health instead of the Department of Mines.
17. Amend the Act to refer to “surviving spouse” instead of “widow” throughout the Act (sections 34(3); 79 (heading), 79(1) and (3); 81(1); 83 (heading) and 81(1) and (2) and 95 (heading), words preceding paragraph (a) and paragraphs (a), (b) and (c); 96(2); 98 (heading and content); 133(3)(a) and (b) and 133(6)(a) and (b)).
18. Amend the Act to refer to the Minister of Finance instead of the Minister of State Expenditure throughout the Act (sections 37(1)(b)(i) and (ii) and (2)(b)(i) and (3); 41(1); 59(6); 60(2); 69(2); 75(2)(a); 105A(1) and 121(2)).
19. Amend the Act to refer to the National Revenue Fund instead of the State Revenue Fund throughout the Act (sections 69(3)(c); 105A(1) and 121(2)).
20. Review the amounts of fines and penalties to reflect changes in economic realities or leave out specific amounts to allow fines to be determined in accordance with the Adjustment of Fines Act 101 of 1991.

21. Should the Occupational Diseases in Mines and Works Act 78 of 1973 come up for amendment in the future any gender specific terminology should be replaced with gender neutral terminology.

2 Purpose of Act

9.2 The purpose of this Act is to consolidate and amend the law relating to the payment of compensation in respect of diseases contracted by persons in mines and works as well as incidental matters.

3 Discussion

9.3 The Occupational Diseases in Mines and Works Act remains the primary piece of legislation that governs compensation for occupational diseases in mines and works. This Act has been amended several times. As such, the Occupational Diseases in Mines and Works Act has already, to some extent, been reviewed to bring it in line with constitutional equality jurisprudence. However, there remain a number of issues that are recommended for further amendment as discussed below.

9.4 The ODMW Act has been on the statute book for more than 40 years (the original date of commencement was 1 October 1973) and has been amended extensively over that time. The question is therefore asked why this Act has not been consolidated and promulgated afresh. A quick overview of the Act reveals that, out of the current 33 definitions in section 1, 11 definitions were inserted later, 10 were amended, and 11 had been repealed. The ODMW Act originally consisted of 137 sections. Only 19 of the sections remained unchanged, while 83 were amended, 33 of the original 137 had been repealed and 7 were inserted additionally. Two of the amendments effected by the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 had not been put into operation to date.

(a) Section 1

9.5 The Occupational Diseases in Mines and Works Amendment Act 208 of 1993 has already repealed the definitions of certain terms that offend section 9 of the Constitution, for example the definitions Black affairs authority, Black person, Coloured person, Coloured female and White person.

9.6 “Director-General”: the national state department responsible for health is now simply referred to as the Department of Health; hence the Director-General would be referred to as the Director-General: Health.

9.7 “Medical practitioner”: The Health Professions Act 56 of 1974 was known as the Medical, Dental and Supplementary Health Service Professions Act 56 of 1974 before the name was changed by the Medical, Dental and Supplementary Health Service Professions Amendment Act 89 of 1997.

9.8 “Minister”: In the Act this refers to the Minister of National Health and Welfare, which is an outdated ministerial portfolio reference. The modern trend is to refer to the Cabinet member responsible for the relevant portfolio, in this case “Health”.

9.9 The reference to in paragraph (g) of the definition of “works” should be amended to refer to the Nuclear Energy Act 46 of 1999, as the Nuclear Energy Act, 1993 (Act 131 of 1993) has been repealed. Section 1(2)(b) refers to the “Minister of Manpower”. Since this portfolio is now called “Labour”, the reference to “Manpower” is outdated.

(b) *References to outdated racial terminology*

9.10 Although the ODMWA has been amended to remove racial terminology such as “Black person”, “Coloured person” and “White person”, the headings of sections 24 and 96 were overlooked and still contain the expression “White or Coloured”. This offends section 9 of the Constitution.

(c) *Consent and confidentiality*

9.11 There are various provisions in the Act that require persons to undergo medical examinations and be subjected to questioning on their medical conditions, for example: sections 24, 25, 26, 29, 31, 32 and 42. No provision is made for the giving of consent by persons who are required to undergo medical examination or for the confidentiality of the results of these medical examinations and any information that may arise out of the questioning processes.

(d) *Lack of provision for counselling*

9.12 The Act provides for various circumstances under which persons may be medically tested and examined. No provision however is made for the counselling of persons to be medically tested and examined so as to help prepare these persons for the impact of the results of the medical tests and examinations on their lives.

(e) *Post mortem examinations*

9.13 Section 34 allows for the post-mortem examination and removal of organs of deceased persons without the consent of his surviving spouse (see below for the discussion of gender specific terms) or a relative. This means that the post-mortem procedures may nevertheless be carried out if this consent is not obtained. Provisions such as this should take cognisance of the fact that these post-mortem procedures may be against the cultural and religious practices of certain persons, and these cultural and religious practices need to be respected as far as is possible. The provision should also be amended to contain gender-neutral terminology.

(f) *Structure of courts and Parliament*

9.14 Section 58 still refers to the Appellate Division and provincial and local division of the Supreme Court. The structure and names of the courts have been changed and the ODMWA should reflect those changes. In a similar vein, the structure of Parliament has also been changed, meaning that the Senate and the House of Assembly no longer exist. Section 122 still refers to the “Table of Senate” and “House of Assembly”. It is recommended that this provision be amended to correctly reflect the new structure of Parliament.

(g) *Amounts payable for research*

9.15 Section 63 provides for payment of an amount by the owner of a controlled mine or a controlled works to the commissioner for research contemplated in section 120. Although subsection (1) indicates that the Minister may determine the amount, subsection (2) limits the amount to a maximum of two cents per shift. This amount was last amended in 1993 by section 20 of the ODMW Amendment Act 208 of 1993.

9.16 It is not advisable to fix amounts of this nature in a principal Act, as a change to the amount would require an amendment of the Act. In addition, it would be necessary to amend such amounts from time to time to reflect changes in economic realities. At present day, these amounts are now nominal and defeat the objective of serving as a source of funding for research. It is therefore proposed that the Minister be authorised to determine the amount by notice in the Gazette from time to time, which would allow for flexibility in the determination of the amount, while ensuring openness and transparency. Subsection (2) would then become redundant and should be repealed.

(h) References to repealed legislation

9.17 Section 64 pertains to interest on amounts in arrears. Because the Exchequer Act of 1975 has been repealed, the ODMWA should refer to the Public Finance Management Act, 1999, which is the Act in terms of which interest rates for these purposes are now determined.

(i) Benefits payable

9.18 The Act makes provision for the payment of certain benefits as determined in sections 79, 80, and 83. Initially, the amounts payable for these benefits had to be increased by means of Amendment Acts. Section 105A was then inserted in the ODMWA to enable the Minister to amend the amounts appearing in sections 79, 80 and 83 by notice in the *Government Gazette*. Sections 79, 80 and 83 should therefore be amended to refer to section 105A and the references to specific amounts should be deleted.

(j) Delegation of powers by Minister

9.19 Section 123 allows the Minister to delegate functions to the Director-General and any other officer in his or her department. The reference to the Department of Mines, however, is clearly wrong, as the administration of the ODMWA falls under the portfolio of the Minister of Health. In addition, the Director-General is defined to mean the Director-General of the Department of Health. The Department referred to for purposes of the delegation of powers should therefore be the Department of Health, not the Department of Mines or the Department of Mineral Affairs, the current equivalent of the Department of Mines.

(k) Gender neutral terminology

9.20 Section 4 of the Occupational Diseases in Mines and Works Amendment Act 60 of 2002 amended the ODMWA by:

- (a) the addition of “or she” after the expression “he”;
- (b) the addition of “or her” after the expression “him”; and
- (c) the addition of “or herself” after the expression “himself”.

9.21 However, a number of references to the male or female pronoun only still remain. There are also a number of provisions that make reference to “widow”, which assumes that a deceased miner will always be a male person, for example: sections 34, 79, 81, 83, 95, 96; 98 and 133. This is inconsistent with the Constitution and the manner of drafting

legislation post-1994. Should the Occupational Diseases in Mines and Works Act 78 of 1973 come up for amendment in the future any gender specific terminology should be replaced with gender neutral terminology.

(l) Reference to “Minister of State Expenditure”

9.22 The Act refers to the Minister of State Expenditure, for example: sections 37, 41, 59, 60, 69, 75, 105A and 121. The correct ministerial portfolio at present is the Minister of Finance.

(m) Reference to “State Revenue Fund”

9.23 The Act refers to the “State Revenue Fund”, for example: sections 69, 105A and 121. Section 213 of the Constitution provides for the National Revenue Fund and the ODMWA should be amended accordingly.

(n) Fines and penalties

9.24 The ODMWA makes provision for the payment of fines and penalties in the event of an offence being committed in terms of the Act. At present day, these amounts are now nominal and defeat the objective of serving as a form of deterrent. It is recommended that these amounts be deleted. If no amount is determined in respect of a fine, the fine is then determined in terms of the Adjustment of Fines Act 101 of 1991.

C Occupational Diseases in Mines and Works Amendment Act 27 of 1974

1 Recommendations

9.25 Repeal sections 3, 4, 7 and 8 of the Occupational Diseases in Mines and Works Amendment Act 27 of 1974 (ODMW Amendment Act 27 of 1974).

2 Purpose of Act

9.26 To amend the Occupational Diseases in Mines and Works Act, 1973, so as to effect an alteration to the definition of 'compensatable disease'; to empower the Minister to make regulations prescribing or providing for the repatriation or return of Black persons

recruited also by or for a contractor; to increase the amounts payable by the owner of a controlled mine or a controlled works for the purposes of research; to make new provision for the liability of the Minister to make good payments from the compensation fund in connection with work performed at certain mines or works; to further regulate the benefits to be awarded in respect of certain diseases; and to effect textual improvements in sections 37 and 127 of the said Act; and to provide for incidental matters.

3 Discussion

9.27 Sections 1, 2, 5, 6, 9 and 10 of the ODMW Amendment Act 27 of 1974 are still valid and should remain on the statute book. Sections 3, 4, 7 and 8 of however can be repealed for the reasons set out below:

- (a) Section 3 of Act 27 of 1974 amended section 38 of the ODMWA. Section 38 was subsequently repealed by section 12 of the ODMW Amendment Act of 208 of 1993, meaning that this section is now obsolete.
- (b) Section 4 of Act 27 of 1974 amended section 63 of the ODMWA, but was superseded by section 20 of Act 208 of 1993, making section 4 obsolete.
- (c) Section 7 of Act 27 of 1974 amended section 82 of the ODMWA. Section 82 was subsequently repealed by section 29 of the ODMW Amendment Act of 1993, rendering section 7 obsolete.
- (d) Section 8 of Act 27 of 1974 substituted section 90 of the ODMWA. Section 90 was then repealed by section 31 of the ODMW Amendment Act of 1993, causing section 8 to become obsolete.

D Occupational Diseases in Mines and Works Amendment Act 67 of 1974

1 Recommendation

9.28 Repeal the Occupational Diseases in Mines and Works Amendment Act 67 of 1974 as it has become obsolete.

2 Purpose of Act

9.29 This Act amended the Occupational Diseases in Mines and Works Act, 1973 to increase pensions payable under the said Act to certain beneficiaries.

3 Discussion

9.30 Section 1 of Act 67 of 1974 amended section 79 of the ODMW Act to increase the amount of the benefits paid out under section 79. The amount of these benefits have however been increased several times since, meaning that section 1 has become obsolete. In addition, the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 inserted section 105A in the ODMWA, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the *Government Gazette* so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above. Sections 2, 3 and 4 of Act 67 of 1974 respectively amended sections 84, 86 and 92 of the ODMWA, but since all three these provisions have since been repealed by Act 208 of 1993, these sections have also become obsolete, rendering the whole Act 67 of 1974 obsolete. Section 5 deals with the short title and commencement of this Act.

E Occupational Diseases in Mines and Works Amendment Act 45 of 1975

1 Recommendations

9.31 Repeal sections 1, 4, 5, 6, 8, 9, 10 and 11(b) of Act 45 of 1975.

2 Purpose of Act

9.32 The ODMW Amendment Act 45 of 1975 provides for the increase of benefits and special awards payable in terms of the Occupational Diseases in Mines and Works Act, 1973; to amend that Act, so as to effect an alteration to the definition of “compensatable disease”; to make new provision for the investment of moneys in the Research Account; to further regulate the disposal of unpaid benefits at the death of certain beneficiaries; and to further regulate the awarding of benefits to certain beneficiaries, and the cessation of pensions awarded to certain dependants; and to provide for incidental matters.

3 Discussion

9.33 Section 1 of Act 45 of 1975 amended section 79 of the ODMW Act to increase the amount of the benefits paid out under section 79. The amount of these benefits have however been increased several times since, meaning that section 1 has become obsolete. In addition, the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 inserted section 105A in the ODMWA, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the *Government Gazette* so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above. Section 4, which substituted section 81, was superseded by section 28 of the ODMW Amendment Act 208 of 1993, rendering section 4 obsolete. Section 5 of Act 45 of 1975 amended section 82 of the ODMWA. Section 82 was later repealed by section 29 of Act 208 of 1993, so section 5 has also become obsolete.

9.34 Section 6 substituted section 83 of Act 45 of 1975, but since section 83 was substituted again by section 30 of Act 203 of 1993, section 6 is now obsolete. Section 8 amended section 98 of the ODMWA, which section was subsequently repealed, therefore section 8 is obsolete. Section 9 amended section 101(4). After subsection 4 was repealed by section 34 of Act 208 of 1993, section 9 has become obsolete. Section 10 amended section 106, which was later repealed by section 37 of Act 208 of 1993, rendering section 10 obsolete. Paragraph (b) of section 11 substituted section 133(4). Subsection (4) was later substituted by section 4(a) of the ODMW Amendment Act 60 of 2002; hence section 11(b) is obsolete. Sections 2, 3, 7, 11(a) and 12 of this Act are still valid and should remain in the statute book.

F Occupational Diseases in Mines and Works Amendment Act 117 of 1977

1 Recommendation

9.35 Repeal the Occupational Diseases in Mines and Works Amendment Act 117 of 1977 as it has become obsolete.

2 Purpose of Act

9.36 To provide for the further increase of certain benefits, special awards and assistance payable in terms of the Occupational Diseases in Mines and Works Act, 1973.

3 Discussion

9.37 Section 1 of Act 117 of 1977 amended section 79 of the ODMWA to increase the amount of the benefits paid out under section 79. The amount of these benefits have however been increased several times since, meaning that section 1 has become obsolete. In addition, the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 inserted section 105A in the ODMWA, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the *Government Gazette* so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above. Section 2 amended section 102, which was later repealed by section 35 of Act 208 of 1993, rendering section 2 obsolete. Section 3 amended section 115, but since section 115 was subsequently repealed by section 12(1) of the Pension Laws Amendment Act 89 of 1988, section 3 has also become obsolete. Section 4 deals with the short title and commencement of this Amendment Act.

G Occupational Diseases in Mines and Works Amendment Act 30 of 1978

1 Recommendations

9.38 Repeal sections 2, 3 and 4 of the Occupational Diseases in Mines and Works Amendment Act 30 of 1978 as it has become obsolete.

2 Purpose of Act

9.39 Act 30 of 1978 aims to amend the provisions of the ODMWA, so as to effect an alteration to the definition of “compensatable disease” and to the definition of “pneumoconiosis”; to abolish compulsory consultation with an actuary while determining certain amounts payable for the benefit of the compensation fund and while determining certain interest rates; to further regulate the cessation of pensions awarded to certain dependants; to effect a textual improvement; and to further regulate the making of

payments by post to the Compensation Commissioner for Occupational Diseases; and to provide for incidental matters.

3 Discussion

9.40 Section 2 amended section 62 by substituting subsection (1), but since subsection (1) was later substituted by section 19 of Act 208 of 1993, section 2 has become obsolete. Section 3 amended section 94 by substituting subsection (4), but section 3 of this Act was superseded by section 10 of the Pension Laws Amendment Act 89 of 1988. Section 4 amended section 98, which was superseded by section 33 of Act 208 of 1993. Sections 1, 5, 6 and 7 of this Act are still valid and should remain in the statute book.

H Occupational Diseases in Mines and Works Amendment Act 83 of 1979

1 Recommendation

9.41 Repeal section 1 of the Occupational Diseases in Mines and Works Amendment Act 83 of 1979 as it has become obsolete.

2 Purpose of Act

9.42 The purpose of the Act is to amend the provisions of the Occupational Diseases in Mines and Works Act, 1973, so as to provide for the further increase of benefits and special awards; to make different provisions regarding the restrictions relating to the performance of work subject to which certain certificates of fitness may be issued; and to provide for matters incidental thereto.

3 Discussion

9.43 Section 1 of Act 83 of 1979 amended section 79 of the ODMWA to increase the amount of the benefits paid out under section 79. The amount of these benefits have however been increased several times since, meaning that section 1 has become obsolete. In addition, the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 inserted section 105A in the ODMWA, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the Government

Gazette so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above. Sections 2 and 3 of this Act are still valid and should remain in the statute book.

I Occupational Diseases in Mines and Works Amendment Acts of 1980, 1981 and 1983

1 Recommendations

9.44 Repeal the Occupational Diseases in Mines and Works Amendment Act 83 of 1980, the Occupational Diseases in Mines and Works Amendment Act 85 of 1981 and the Occupational Diseases in Mines and Works Amendment Act 106 of 1983 as these Amendment Acts have become obsolete.

2 Purpose of Act

9.45 All three the Amendment Acts aim to amend the provisions of the Occupational Diseases in Mines and Works Act, 1973, so as to provide for the further increase of benefits and special awards.

3 Discussion

9.46 Section 1 of Act 83 of 1980, section 1 of Act 85 of 1981 and section 1 of Act 106 of 1983 all amended section 79 of the ODMWA to increase the amount of the benefits paid out under section 79. The amount of these benefits have however been increased several times since, meaning that section 1 of each Act has become obsolete. In addition, the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 inserted section 105A in the ODMWA, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the *Government Gazette* so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above. All three these Amendment Acts only consist of two sections, section 2 indicating the short title of the Act.

J Occupational Diseases in Mines and Works Amendment Act 137 of 1991

1 Recommendations

9.47 Repeal section 2 of the Occupational Diseases in Mines and Works Amendment Act 137 of 1991.

2 Purpose of Act

9.48 The Act aims to amend the Occupational Diseases in Mines and Works Act, 1973, so as to do away with the limitation on the amount of a special award; and to increase certain benefits payable in terms of the said Act; and to provide for matters connected therewith.

3 Discussion

9.49 Section 2 of Act 137 of 1991 amended section 79 of the ODMWA to increase the amount of the benefits paid out under section 79. The amount of these benefits have however been increased since, meaning that section 2 has become obsolete. In addition, the Occupational Diseases in Mines and Works Amendment Act 208 of 1993 inserted section 105A in the ODMWA, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the *Government Gazette* so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above. Sections 1 and 3 of this Act are still valid and should remain in the statute book.

K Occupational Diseases in Mines and Works Amendment Act 208 of 1993

1 Recommendations

9.50 Either put section 13 of the Occupational Diseases in Mines and Works Amendment Act 208 of 1993, which repeals section 43 of the ODMWA, into operation; or repeal section 13 of Act 208 of 1993.

9.51 Either put section 15 of the Occupational Diseases in Mines and Works Amendment Act 208 of 1996, which repeals section 46 of the ODMWA, into operation; or repeal section 15 of Act 208 of 1993.

2 Purpose of Act

9.52 The Act aims to amend the Occupational Diseases in Mines and Works Act, 1973, so as to do away with all provisions which differentiate between persons on the ground of their sex or population group; to define or further define certain expressions; to empower the director to authorize owners of mines and works to issue certificates of fitness on his behalf and subject to his directions; to do away with the office of medical adviser; to regulate differently the expression of a risk; to make the possession of a certificate of fitness by all persons performing risk work in controlled mines and works compulsory; to regulate differently the issuing of certificates of fitness; to repeal provisions which seek to preclude the jurisdiction of the courts; to further regulate the certification of compensatable diseases; to increase the number of members of the advisory committee; to change the basis on which interest on amounts indebted to the commissioner is levied; to provide for the actuarial valuation of the fund; to change the basis on which benefits are calculated; to do away with assistance in connection with training; to empower the Minister to amend the Act so as to increase benefits; and to extend the Minister's powers to make regulations; and to provide for matters connected therewith.

3 Discussion

9.53 The Occupational Diseases in Mines and Works Amendment Act 208 of 1996 amended the ODMWA extensively. The Act aimed to do away with all provisions which differentiate between persons on the ground of their sex or population group. Although Act 208 of 1993 failed to do away with all the provisions in the ODMWA which offend the right to equality entrenched in section 9 of the Constitution, it went a long way towards achieving this aim.

9.54 Sections 13 of this Amendment Act repeals section 43 of the ODMWA, while section 15 of this Act amends section 46 of the ODMWA. Sections 13 and 15 however have not been put into operation to date. The reason for the delay is unclear, as 22 years have elapsed since the adoption of Act 208 of 1993. In addition, both section 43 as well as section 46 has since been amended by the Occupational Diseases in Mines and Works Amendment Act 60 of 2002. It therefore appears that section 13 and 15 of Act 208

of 1993 will never be put into operation. These two sections of this Amendment Act should therefore rather be repealed.

9.55 This Amendment Act inserted other important provisions, such as section 105A, which authorises the Minister to amend the amounts determined in sections 79, 80 and 83 by notice in the Government *Gazette* so as to increase any benefit. See the discussion regarding the amendment of these sections in paragraph 9.18 above.

L Occupational Diseases in Mines and Works Amendment Act 60 of 2002

1 Recommendation

9.56 There is no recommendation with regard to the Occupational Diseases in Mines and Works Amendment Act 60 of 2002.

2 Purpose of Act

9.57 The purpose of the Act is to amend the Occupational Diseases in Mines and Works Act, 1973, so as to provide that if a person was medically examined within a period of 24 months immediately preceding an application for medical examination, the Director of the Medical Bureau for Occupational Diseases may refuse that person's application for medical examination; and to provide for matters incidental thereto.

3 Discussion

9.58 This Amendment Act attempted to achieve gender equality in the ODWMA by inserting the words "or she" after the word "he" wherever it occurs; the words "or her" after the word "him" wherever it occurs; and the words "or herself" after the word "himself" wherever it occurs in the text of the ODMW Act. Gender equality was not achieved totally by this amendment, but it did advance the Act towards that goal. See the discussion on gender neutral terminology in paragraphs 9.20 and 9.21 above.

CHAPTER 10: PROVINCIAL LEGISLATION

A Recommendation

It is recommended that the National Health Act is fully implemented and that provincial legislation is revised in order to be consistent with the NHA as soon as possible. Refer to **Annexure H** for the list of legislation administered by the provincial Departments of Health.

B Constitutional provisions

10.1 Even prior to 1994, health matters in South Africa were dealt with at national as well as at provincial level. The Union of South Africa was created by the South Africa Act, 1909, an Act of the Parliament of the United Kingdom (the British Parliament), which came into force on 31 May 1910.⁶⁸ Sections 85 to 91 of the South Africa Act dealt with the powers of provincial councils. Section 85 determined in part as follows:

Subject to the provisions of this Act and the assent of the Governor-General in Council as hereinafter provided, the provincial council may make ordinances in relation to matters coming within the following classes of subjects (that is to say):

- ...
- (v) The establishment, maintenance, and management of hospitals and charitable institutions:

10.2 In 1961, when South Africa became a Republic, the Public Health Act 36 of 1919 was in force. Its purpose was to protect public health, prevent the spread of infectious diseases, provide for environmental sanitation and to set up a Ministry and department dedicated to public health. The history of the Public Health Act, 1919 is discussed in paragraphs 3.1 to 3.3 above.

10.3 Although the Public Health Act regulated health matters on a national level, the provinces still had a fair amount of autonomy with regard to some health matters. As was the case with the South Africa Act of 1909, the Republic of South Africa Constitution Act 32 of 1961 provided for powers of provincial councils. Section 84 of the 1961 Constitution

⁶⁸ South African History Online *The Union of South Africa Act, 2 December 1909* South African History Online available at www.sahistory.org.za accessed on 15 November 2016.

(which resembled section 85 of the 1909 South Africa Act to a large extent) contained a list of matters that provincial councils could make ordinances on. The list included hospitals and charitable organisations. Section 84 determined, in part, as follows:

(1) Subject to the provisions of this Act, the Financial Relations Consolidation and Amendment Act, 1945 (Act No. 88 of 1945), and the assent of the State President as hereinafter provided, a provincial council may make ordinances in relation to matters coming within the following classes of subjects, namely:

...

(e) the establishment, maintenance and management of hospitals and charitable institutions;

10.4 The Republic of South Africa Constitution Act 110 of 1983 moved away from the distinction between national and provincial matters. The 1983 Constitution introduced the concept of own affairs and general affairs along racial lines. Section 14 stated:

(1) Matters which specially or differentially affect a population group in relation to the maintenance of its identity and the upholding and furtherance of its way of life, culture, traditions and customs, are, subject to the provisions of section 16, own affairs in relation to such population group.

(2) Matters coming within the classes of subjects described in Schedule 1 are, subject to the provisions of section 16, own affairs in relation to each population group.

10.5 The classes of subjects that are own affairs in relation to each population group are described in Schedule 1 of the 1983 Constitution. "Health matters" is described in item 4 of Schedule 1:

Health matters, comprising the following, namely-

- (1) hospitals, clinics and similar or related institutions;
 - (2) medical services at schools and for indigent persons;
 - (3) health and nutritional guidance; and
 - (4) the registration of and control over private hospitals,
- but subject to any general law in relation to such matters.

10.6 The interim Constitution, the Constitution of the Republic of South Africa 200 of 1993, returned to the principle of provincial powers. Section 126(1) that dealt with the legislative competence of provinces, provided as follows:

(1) A provincial legislature shall, subject to subsections (3) and (4), have concurrent competence with Parliament to make laws for the province with regard to all matters which fall within the functional areas specified in Schedule 6.

10.7 Schedule 6 lists the matters that provincial legislatures may legislate on. Included in this list is "health services".

10.8 The Constitution of the Republic of South Africa, 1996 retained the legislative competence of provinces. Section 104, dealing with the legislative authority of provinces, states in part that:

(1) The legislative authority of a province is vested in its provincial legislature, and confers on the provincial legislature the power –

...
(b) to pass legislation for its province with regard to-
(i) any matter within a functional area listed in Schedule 4;

10.9 “Health services” is listed in Schedule 4 as a functional area of concurrent national and provincial legislative competence, meaning that the provinces can still, as they could from 1910 (when the original Union of South Africa was first established) to 3 September 1984 (when the Republic of South Africa Constitution Act 110 of 1983 came into operation), pass legislation on health matters. In terms of section 44 of the 1996 Constitution however, Parliament, as the national legislative authority, may still pass legislation with regard to any matter, including a matter within a functional area listed in Schedule 4.

10.10 According to the long title of the National Health Act 2003, the purpose of the NHA is to provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith. In the memorandum on the objects of the National Health Bill, which was published as part of the Bill while the Bill was in the Parliamentary process, it is indicated that the Bill holds implications for provinces. It is stated that:⁶⁹

Provincial health legislation will have to be revised in order to be consistent with the provisions of the Bill insofar as the Bill prevails over such legislation in terms of the Constitution.

10.11 From the overview of current provincial legislation below, it seems that the envisaged revision of provincial health legislation has not been completed yet. Provincial health legislation is a labyrinth of old provincial health ordinances, assigned national and former TBVC states Acts and provincial statutes adopted post-1994. There can hardly be any notion of a “structured uniform health system” (as indicated in the long title to the NHA) or the ideal to “consistently improve the health care delivery system by focusing on access, equity, efficiency, quality and sustainability” (vision statement of DOH) as long as

⁶⁹ Item 5 of the Memorandum of Objectives of the National Health Bill [B32B—2003]

this situation prevails. It has therefore become imperative that the NHA is fully implemented and provincial legislation brought in line with the NHA as soon as possible.

C Provincial health legislation

10.12 Health issues in the provinces are currently regulated by a variety of post-1994 provincial legislation and pre-1994 laws and provincial ordinances that had been assigned to provinces. It is not clear how many of these pieces are still utilised and to what extent.

10.13 In addition, the President assigned the administration of the Health Act 63 of 1977, excluding certain sections, to the provinces by Proclamation No. 152 of 1994 (published on 31 October 1994) as authorised by section 235(8) of the interim 1993 Constitution. In spite of the repeal of Act 63 of 1977 by the NHA, the assigned sections of Act 63 of 1977 remain in force in the provinces, as Parliament cannot repeal provincial legislation. For the sake of uniformity and legal certainty, the national DOH should engage with the provincial departments of health on the repeal by the provinces of the sections of Act 63 of 1977 assigned to them. An exposition of provincial legislation by province appears below.

1 Eastern Cape

10.14 The health laws of the Province of the Eastern Cape consist of ordinances of the former Province of the Cape of Good Hope, the parts of the Health Act 63 of 1977 that have been assigned to the Eastern Cape and two post-1994 provincial statutes.

(a) *Hospitals Ordinance No. 18 of 1946 [Cape of Good Hope]*

10.15 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of the Eastern Cape in terms of Proclamation No. 111 of 17 June 1994. The purpose of this Ordinance is to amend the law relating to hospitals in order to provide for hospital services and for matters incidental thereto.

(b) *Hospitals Amendment Ordinance No. 15 of 1955 [Cape of Good Hope]*

10.16 Administration of sections 3 and 4 of Ordinance No. 15 of 1955, ordinance of the former Province of the Cape of Good Hope, assigned to the Province of the Eastern

Cape in terms of Proclamation No. 111 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946.

(c) *Hospitals Amendment Ordinance 3 of 1956 [Cape of Good Hope]*

10.17 Administration of sections 1, 4(2) and 6 of Ordinance No. 3 of 1956, ordinance of the former Province of the Cape of Good Hope, assigned to the Province of the Eastern Cape in terms of Proclamation No. 111 of 17 June, 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946.

(d) *Health Act 63 of 1977 (as assigned)*

10.18 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to sec 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to the Province of Eastern Cape with effect from 31 October 1994.

10.19 The whole of this Act, excluding sections 14, 15, 16(b) to (d) inclusive, 17, 18, 20, 24, 30, 31, 32 to 40, 44, 45 to 49, 50, 51, 53, 55, 56, 57 and 58 in so far as they are applicable to sections 32 to 40, 45 to 49 and 55, has been repealed by section 43(1) of the Eastern Cape Provincial Health Act 10 of 1999 with effect from 1 March 2000.

(e) *Eastern Cape Provincial Health Act 10 of 1999*

10.20 Date of commencement: 1 March 2000 [Assented to on 24 January 1999]. The purpose of this Act is to provide for the determination of provincial health policy; structure health service delivery in the Province of the Eastern Cape; develop and implement provincial health policy, norms and standards; define the provision and delivery of health care services, within the available resources in the Province of the Eastern Cape; facilitate comprehensive provincial and district health system management, in accordance with national and provincial health policies and procedures; provide for transparency of provincial government in the development and implementation of health

policies and practices; provide for health service user rights and obligations; provide for health care provider obligations and rights and provide for community participation.

(f) *Application of Health Standards in Traditional Circumcision Act (Eastern Cape) 6 of 2001*

10.21 Date of commencement: 22 November 2001 [Assented to on 15 November 2001]. The purpose of this Act is to provide for the observation of health standards in traditional circumcision; to provide for issuing of permission for the performance of a circumcision operation and the holding of circumcision school; and for incidental matters.

2 Free State

10.22 The Province of the Free State administers the following relevant legislation:

(a) *Health Act 63 of 1977 (as assigned)*

10.23 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to Free State Province with effect from 31 October 1994.

(b) *Free State Hospitals Act 13 of 1996*

10.24 Date of commencement: 24 January 1997 [Assented to by the Premier on 22 January 1997]. The purpose of the Act is to provide for the establishment, maintenance and management of hospitals in the Province, and matters connected therewith.

(c) *Free State School Health Services Act 11 of 1998*

10.25 Date of commencement: 18 June 1998 [Assented to on 10 June 1998]. The purpose of the Act is to provide for the establishment of health services for schools and matters connected therewith.

(d) Free State Nursing Education Act 15 of 1998

10.26 Date of commencement: 19 June 1998 [Assented to on 15 June 1998]. The purpose of the Act is to consolidate the laws providing for the regulation of nursing education in the Free State and for matters incidental thereto.

(e) Free State Initiation School Health Act 1 of 2004

10.27 Date of commencement: 5 March 2004. The purpose of the Act is to provide for the observation of health standards in traditional initiation schools; to provide for the giving of permission for the performance of a circumcision operation and the holding of initiation school; and to provide for matters incidental thereto.

(f) Provincial Health Act 3 of 2009 [Free State]

10.28 Date of commencement: 30 March 2009 [Assented to on 30 March 2009]. The purpose of the Act is to provide for the establishment of a health system that is compatible with the structured uniform national standards; to establish health governance structures; to bring the provincial health legislation in line with Chapter 2 of the National Health Act, 2003 (Act No. 61 of 2003) and to replace Chapter 4 of the National Act in as far as it deals with health issues that are dealt with in this Act; to repeal the Free State Health Act, 1999 (Act No. 8 of 1999); and to provide for matters incidental thereto.

3 Gauteng

10.29 The Province of Gauteng administers the following relevant legislation:

(a) Transvaal Board for the Development of Peri-Urban Areas Ordinance No. 20 of 1943 [Transvaal]

10.30 Ordinance of the former Transvaal Province assigned to the Province of Gauteng in terms of Proclamation No. 114 of 17 June 1994. The purpose of this Ordinance is to provide for the Constitution of a Board for the Management, Regulation and Control of Matters Affecting the Public Health in Certain Areas not Controlled by Local Authorities, to prescribe the powers and duties of the Board, and to provide for incidental matters.

(b) Hospitals Ordinance No. 14 of 1958 [Transvaal]

10.31 Ordinance of the former Transvaal Province assigned to the Province of Gauteng in terms of Proclamation No. 114 of 17 June 1994. The purpose of this Ordinance is to

consolidate and amend the laws relating to hospitals and to provide for matters incidental thereto.

(c) Health Act 63 of 1977 (as assigned)

10.32 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to the Province of Gauteng with effect from 31 October 1994.

(d) Hospitals Ordinance Amendment Act 4 of 1999 [Gauteng]

10.33 Date of commencement: 15 July 1999. The purpose of this Act is to amend the Hospitals Ordinance, 1958 (Ordinance 14 of 1958) so as to make provision for the substitution of superintendent for Chief Executive Officer; and to give certain powers to the Member of the Executive Council responsible for Health in the Province of Gauteng to appoint such Chief Executive Officers for managing provincial hospitals; and to provide for matters incidental thereto.

(e) The Gauteng District Health Services Act 8 of 2000

10.34 The Act was assented to on 27 October 2000, but has not been put into operation to date. The purpose of the Act is to provide for the delivery of primary health care services through a district health system in the Gauteng Province; to devolve primary health care services to municipalities; to provide for the establishment of relevant institutions; to define the responsibilities of Provincial and Local Government; and to provide for matters in connection therewith.

(f) Gauteng Ambulance Services Act 6 of 2002

10.35 Date of commencement: 28 November 2002 [Assented to on 24 November 2002]. The purpose of the Act is to provide for the regulation of the delivery of ambulance

services in the Province; to establish the Gauteng Ambulance Services Board; to provide for the accreditation, registration and licensing of ambulance services; and to provide for matters connected therewith.

4 KwaZulu-Natal

10.36 The Province of KwaZulu-Natal administers the following relevant legislation:

**(a) Section 9 of the Provincial Hospitals Ordinances No. 13 of 1938
[Natal]**

10.37 Ordinance of the former Natal Province assigned to the Province of KwaZulu-Natal in terms of Proclamation No. 107 of 17 June 1994. The purpose of this Ordinance is to provide for the establishment, maintenance, management and control by the Natal Provincial Administration of public hospitals, for grants-in-aid or loans to be given or made to certain other hospitals, for the constitution of hospital boards of management and for other incidental matters.

(b) Provincial Hospitals Service Ordinance 22 of 1955 [Natal]

10.38 Ordinance of the former Natal Province assigned to the Province of KwaZulu-Natal in terms of Proclamation No. 107 of 17 June 1994. The purpose of this Ordinance is to provide for the organisation of and conditions of employment and discipline in the hospital service of the Natal Provincial Administration, and matters incidental thereto.

(c) Provincial Hospitals Ordinance 13 of 1961 [Natal]

10.39 Ordinance of the former Natal Province assigned to the Province of KwaZulu-Natal in terms of Proclamation No. 107 of 17 June 1994. The purpose of this Ordinance is to consolidate and amend the laws relating to the establishment, maintenance, management and control of provincial hospitals, services and institutions, the control of private hospitals, grants-in-aid and loans to certain hospitals, the constitution of hospital boards, and to provide for matters incidental thereto.

(d) Health Act 63 of 1977 (as assigned)

10.40 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;

- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to the Province of KwaZulu-Natal with effect from 31 October 1994.

**(e) *Provincial Hospitals Service Appointment of Dr. G. P. Wilson
Ordinance 3 of 1979 [Natal]***

10.41 Ordinance of the former Natal Province assigned to the Province of KwaZulu-Natal in terms of Proclamation No. 107 of 17 June 1994. The purpose of this Ordinance is to provide for the retrospective appointment of Dr Glenn Patrick Wilson (identity number 190 102 5007 10 3) with effect from 1 June 1961 on the permanent staff of the hospital service as defined in the Provincial Hospitals Service Ordinance, 1955.

(f) *KwaZulu-Natal Health Act 1 of 2009*

10.42 Date of commencement: 6 September 2012 [Assented to on 5 April 2009]. The purpose of this Act is to provide for the restructuring of the provincial health care service delivery system; to provide a framework for the development and implementation of provincial health policy, provincial norms and standards; to provide for the achievement of the progressive realisation of the right of access to health care services through the provision of accessible comprehensive provincial health care services within the available resources of the Province; to create an enabling environment for the realisation of mutually respectful rights and duties for health care users and personnel; to provide for the establishment of an integrated provincial health care system to be managed by appropriate structures in accordance with constitutional principles; to provide for the facilitation of improved management in the provision of public sector health care service delivery; to provide for community participation in the formulation of provincial policy, legislation and provincial health priorities; to provide for accreditation, licences, permits and authorisations for health care providers; to provide for the establishment of an Inspectorate for Health Establishments; to provide for the powers, duties and functions of the Inspectorate for Health Establishments; to provide for the establishment of a complaints and dispute resolution mechanism; to provide for an appeal mechanism; to

provide for transparency and accountability in the development and implementation of health policies and practices; and to provide for matters connected therewith.

5 Limpopo

10.43 The Province of Limpopo administers the following relevant legislation:

(a) *Health Act 63 of 1977 (as assigned)*

10.44 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to Limpopo Province with effect from 31 October 1994.

(b) *Health Act (Venda) 13 of 1984*

10.45 Act of the former Venda assigned to the Province of Limpopo in terms of Proclamation No. 140 of 9 September 1994, as amended by the Limpopo Health Services Act 5 of 1998. The purpose of this Act is to provide for measures for the promotion of the health of the inhabitants of Venda; to that end to provide for the rendering of health services; to define the duties, powers and responsibilities of the authorities which render health services in Venda; to provide for the establishment of a Health Advisory Board and to repeal the Health Act, 1977 (in Venda); and to provide for incidental matters.

(c) *Limpopo College of Nursing Act 3 of 1996*

10.46 Date of commencement: 25 July 1997 [Assented to on 10 July 1996]. The purpose of this Act is to consolidate the laws providing for the establishment of the Limpopo College of Nursing and for matters incidental thereto.

(d) Limpopo Province Health Services Act 5 of 1998

10.47 Date of commencement: 30 September 1999 [Assented to on 4 January 1999]. The purpose of this Act is to consolidate the laws relating to health services facilities of Limpopo and to provide for matters incidental thereto.

6 Mpumalanga

10.48 The Province of Mpumalanga administers the following relevant legislation:

(a) Transvaal Board for the Development of Peri-Urban Areas Ordinance No. 20 of 1943 [Transvaal]

10.49 Ordinance of the former Transvaal Province assigned to the Province of Mpumalanga in terms of Proclamation No. 112 of 17 June 1994. The purpose of this Ordinance is to provide for the Constitution of a Board for the Management, Regulation and Control of Matters Affecting the Public Health in Certain Areas not Controlled by Local Authorities, to prescribe the powers and duties of the Board, and to provide for incidental matters.

(b) Hospitals Ordinance No. 14 of 1958 [Transvaal]

10.50 Ordinance of the former Transvaal Province assigned to the Province of Mpumalanga in terms of Proclamation No. 112 of 17 June 1994. The purpose of this Ordinance is to consolidate and amend the laws relating to hospitals and to provide for matters incidental thereto.

(c) Health Act 63 of 1977 (as assigned)

10.51 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to the Province of Mpumalanga with effect from 31 October 1994.

(d) *Health Act 12 of 1983 [Bophuthatswana] (as assigned)*

10.52 Act of the former Bophuthatswana assigned to the Province of Mpumalanga in terms of Proclamation No. 144 of 23 September 1994. The purpose of the Act is to provide for measures to promote and protect the health of the inhabitants of Bophuthatswana; to that end to provide for comprehensive health services for Bophuthatswana; to define the powers, functions, duties and responsibilities of the various authorities rendering health services in Bophuthatswana; to establish a Health Matters Advisory Committee and a National Health Policy Council; to repeal the Public Health Act 36 of 1919 (in Bophuthatswana), the Health Act 63 of 1977 (in Bophuthatswana), and certain other laws in so far as they are still applicable; and to provide for incidental matters.

7 Northern Cape

10.53 The Province of the Northern Cape administers the following relevant legislation:

(a) *Kimberley Board of Health Pension Ordinance 3 of 1946 [Cape of Good Hope]*

10.54 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of the Northern Cape in terms of Proclamation No. 108 of 17 June 1994. The purpose of this Ordinance is to provide for the payment of a pension by the Kimberley Board of Health to Ellen Francis Horn.

(b) *Hospitals Ordinance 18 of 1946 [Cape of Good Hope]*

10.55 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of the Northern Cape in terms of Proclamation No. 108 of 17 June 1994. The purpose of this Ordinance is to amend the law relating to hospitals in order to provide for hospital services and for matters incidental thereto.

**(c) *Ambulance Personnel Transfer and Pensions Ordinance 11 of 1955*
*[Cape of Good Hope]***

10.56 Ordinance of former Province of the Cape of Good Hope assigned to the Province of the Northern Cape with effect from 17 June 1994 in terms of Proclamation 108 of 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to authorise the transfer of the personnel of the ambulance service conducted by the Provincial Administration in the Cape Peninsula and vicinity to the service of the local authority controlling any joint ambulance service established by local authorities in the division of the Cape, to make special provision in regard to the pension and superannuation benefits of the personnel so transferred, and to provide for matters incidental thereto.

(d) *Hospitals Amendment Ordinance 15 of 1955 [Cape of Good Hope]*

10.57 Administration of sections 3 and 4 of Ordinance No. 15 of 1955, ordinance of the former Province of the Cape of Good Hope, assigned to the Province of the Northern Cape in terms of Proclamation No. 108 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946.

(e) *Hospitals Amendment Ordinance 3 of 1956 [Cape of Good Hope]*

10.58 Administration of sections 1, 4(2) and 6 of Ordinance No. 3 of 1956, Ordinance of the former Province of the Cape of Good Hope, assigned to the Province of the Northern Cape in terms of Proclamation No. 108 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946.

(f) *Health Act 63 of 1977 (as assigned)*

10.59 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in Government *Gazette* 16049 of 31 October 1994, been assigned to the Province of Northern Cape with effect from 31 October 1994.

(g) *Training of Nurses and Midwives Ordinance 4 of 1984 [Cape of Good Hope]*

10.60 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of the Northern Cape with effect from 17 June 1994 in terms of Proclamation 108 of 1994 published in Government *Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to provide for the establishment and control of nursing colleges for the training of nurses and midwives, and for matters incidental thereto.

8 North-West

10.61 The schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is therefore unclear whether the following provincial ordinances of the Transvaal Province and the Province of the Cape of Good Hope Province assigned to the Province of North-West with effect from 17 June 1994 in terms of Proclamation 110 of 1994 published in Government *Gazette* 15813 of 17 June 1994 are still in operation in the North-West Province:

Ordinances of the former Transvaal Province assigned to the Province of North-West

- Transvaal Board for the Development of Peri-Urban Areas Ordinance 20 of 1943
- Hospitals Ordinance 14 of 1958

Ordinance of the former Province of the Cape of Good Hope assigned to the Province of North-West

- Hospitals Ordinance 18 of 1946
- Ambulance Personnel Transfer and Pensions Ordinance 11 of 1955
- Hospitals Amendment Ordinance 15 of 1955
- Hospitals Amendment Ordinance 3 of 1956
- Training of Nurses and Midwives Ordinance 4 of 1984

10.62 The Province of North-West administers the following relevant legislation:

(a) *Transvaal Board for the Development of Peri-Urban Areas Ordinance 20 of 1943 [Transvaal]*

10.63 Ordinance of the former Transvaal Province assigned to the Province of North-West with effect from 17 June 1994 in terms of Proclamation 110 of 1994 published in *Government Gazette* 15813 of 17 June 1994. It is unclear whether the Transvaal Board for the Development of Peri-Urban Areas Ordinance 20 of 1943 is still in operation in the North West Province. See the discussion in paragraph 10.61 above.

(b) *Hospitals Ordinance 18 of 1946 [Cape of Good Hope]*

10.64 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of North-West with effect from 17 June 1994 in terms of Proclamation 110 of 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to amend the law relating to hospitals in order to provide for hospital services and for matters incidental thereto. It is unclear whether this Ordinance is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(c) *Ambulance Personnel Transfer and Pensions Ordinance 11 of 1955 [Cape of Good Hope]*

10.65 Ordinance of former Province of the Cape of Good Hope assigned to the North-West Province with effect from 17 June 1994 in terms of Proclamation 110 of 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to authorise the transfer of the personnel of the ambulance service conducted by the Provincial Administration in the Cape Peninsula and vicinity to the service of the local authority controlling any joint ambulance service established by local authorities in the division of the Cape, to make special provision in regard to the pension and superannuation benefits of the personnel so transferred, and to provide for matters incidental thereto. It is unclear whether this Ordinance is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(d) *Hospitals Amendment Ordinance 15 of 1955 [Cape of Good Hope]*

10.66 Administration of sections 3 and 4 of Ordinance 15 of 1955, Ordinance of the former Province of the Cape of Good, assigned to the Province of North-West with effect from 17 June 1994 in terms of Proclamation 110 of 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals

Ordinance, 1946. It is unclear whether this Ordinance is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(e) *Hospitals Amendment Ordinance 3 of 1956 [Cape of Good Hope]*

10.67 Administration of sections 1, 4(2) and 6 of Ordinance 3 of 1956, Ordinance of the Province of the Cape of Good Hope, has been assigned to North-West Province with effect from 17 June 1994 in terms of Proclamation 110 of 1994, published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946. It is unclear whether this Ordinance is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(f) *Hospitals Ordinance 14 of 1958 [Transvaal]*

10.68 Ordinance of the former Transvaal assigned to the Province of North-West with effect from 17 June 1994 in terms of Proclamation 110 of 1994 published in *Government Gazette* 15813 of 17 June 1994. It is unclear whether this Ordinance is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(g) *Health Act 63 of 1977 (as assigned)*

10.69 The administration of the whole of this Act, excluding –

- (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;
- (b) section 30(4), in so far as it is applicable to section 30(2)(b);
- (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;
- (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government,

has under Proclamation R152 of 1994, promulgated in *Government Gazette* 16049 of 31 October 1994, been assigned to North-West Province with effect from 31 October 1994. It is unclear whether this Act is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(h) *Training of Nurses and Midwives Ordinance 4 of 1984 [Cape of Good Hope]*

10.70 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of North-West with effect from 17 June 1994 in terms of Proclamation 110 of

1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to provide for the establishment and control of nursing colleges for the training of nurses and midwives, and for matters incidental thereto. It is unclear whether this Ordinance is still in operation in the North-West Province. See the discussion in paragraph 10.61 above.

(i) *Health Laws Rationalisation Act 11 of 1995 [North-West]*

10.71 Date of commencement: 7 April, 2003 [Assented to on 8 September, 1995]. The purpose of this Act is to provide for the rationalisation of certain laws relating to health matters as applicable in and administered by the North West Province; the extension of the laws mentioned in section 2 to the whole of the territory of the Province of the North West as defined in Part 1 of Schedule 1 to the Constitution of the Republic of South Africa 1993 (Act No 200 of 1993); to provide for powers of regulation to regulate certain transitional matters; and to provide for incidental matters.

(j) *North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997*

10.72 Date of commencement: 7 April 2003 [Assented to on 24 March, 1997]. The purpose of this Act is to create health, developmental social welfare and hospital governance institutions in the North-West Province; to define the composition, powers, functions of such institutions; the appointment of members of those institutions and their remuneration; to repeal certain laws and to provide for incidental matters.

9 Western Cape

10.73 The Province of the Western Cape administers the following relevant legislation:

(a) *Hospitals Ordinance No. 18 of 1946 [Cape of Good Hope]*

10.74 Ordinance of the former Province of the Cape of Good Hope assigned to the Province of the Western Cape with effect from 17 June 1994 in terms of Proclamation No. 115 of 17 June 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to amend the law relating to hospitals in order to provide for hospital services and for matters incidental thereto. This Ordinance was been repealed by section 7 of the Western Cape Health Service Fees Act 5 of 2008, however Act 5 of 2008 did not repeal the Hospitals Amendment Ordinance No. 15 of 1955 or the Hospitals

Amendment Ordinance No. 3 of 1956. See the discussion of the Western Cape Health Service Fees Act 5 of 2008 in paragraph 10.77 below.

(b) *Hospitals Amendment Ordinance No. 15 of 1955 [Cape of Good Hope]*

10.75 Administration of sections 3 and 4 of Ordinance No. 15 of 1955, ordinance of the former Province of the Cape of Good Hope, assigned to the Province of the Western Cape with effect from 17 June 1994 in terms of Proclamation No. 115 of 17 June 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946.

(c) *Hospitals Amendment Ordinance No. 3 of 1956 [Cape of Good Hope]*

10.76 Administration of sections 1, 4 (2) and 6 of Ordinance No. 3 of 1956, ordinance of the former Province of the Cape of Good Hope, assigned to the Province of the Western Cape with effect from 17 June 1994 in terms of Proclamation No. 115 of 17 June 1994 published in *Government Gazette* 15813 of 17 June 1994. The purpose of this Ordinance is to amend the Hospitals Ordinance, 1946.

(d) *Western Cape Health Facility Boards Act 7 of 2001*

10.77 Date of commencement: 1 December 2001 [Assented to on 2 October 2001] as amended by Western Cape Health Facility Boards Amendment Act, No. 7 of 2012. The purpose of this Act is to provide for the establishment, functions, powers and procedures of Health Facility Boards; to amend and repeal certain laws relating to Hospital Boards; and to provide for matters incidental thereto.

(e) *Western Cape Health Amendment Act 6 of 2002*

10.78 Date of commencement: 18 June 2002 [Assented to on 14 June, 2002]. The purpose of this Act is to amend the Health Act, 1977, in so far as it applies in the Province, to extend the powers of the Minister of Health to make regulations regarding private health establishments, and for matters incidental thereto.

(f) *Western Cape Health Care Waste Management Act 7 of 2007*

10.79 Date of commencement: Date of commencement: 15 March 2013 [Assented to on 14 December 2007]. The purpose of this Act is to provide for the effective handling, storage, collection, transportation, treatment and disposal of health care waste by all

persons in the Province of the Western Cape; and to provide for matters incidental thereto.

(g) *Western Cape Health Service Fees Act 5 of 2008*

10.80 Date of commencement: 19 December 2008 [Assented to on 15 December 2008]. The purpose of this Act is to provide for a schedule of fees to be prescribed for health services rendered in the Western Cape Province by the Department; to repeal the Hospital Ordinance, 1946; and to provide for incidental matters. See the discussion of the Hospitals Ordinance No. 18 of 1946 in paragraph 10.71 above.

(h) *Western Cape Ambulance Personnel Transfer and Pensions Ordinance Repeal Act 6 of 2008*

10.81 Date of Commencement: 19 December 2008 [Assented to on 15 December 2008]. The purpose of this Act is to repeal the Ambulance Personnel Transfer and Pensions Ordinance, 1955, and to provide for matters incidental thereto.

(i) *Western Cape Ambulance Services Act 3 of 2010*

10.82 Date of commencement: 1 July 2012 [Assented to on 1 November 2010]. The purpose of this Act is to provide for the licensing of ambulance services in the Province; and for matters connected therewith.

(j) *Western Cape District Health Councils Act 5 of 2010*

10.83 Date of commencement: 24 August 2011 [Assented to on 15 December 2008]. The purpose of this Act is to provide for certain matters relating to district health councils so as to give effect to section 31 of the National Health Act, 2003; and to provide for matters connected therewith.

(k) *Western Cape Health Care Waste Management Amendment Act 6 of 2010*

10.84 Date of commencement: 15 March 2013 [Assented to on 6 December 2010]. The purpose of this Act is to amend the Western Cape Health Care Waste Management Act, 2007, so as to align the terminology with that used in the National Environmental Management: Waste Act, 2008; to define or redefine certain expressions; to delete certain unnecessary definitions; to provide for the issuing of compliance notices; to amend the provisions relating to offences and penalties; to make further provision

regarding regulations; to effect certain textual changes; and to provide for matters incidental thereto.

(l) Western Cape Health Facility Boards Amendment Act 7 of 2012

10.85 Date of commencement: 1 April 2012 [Assented to on 5 December 2012]. The purpose of this Act is to amend the Western Cape Health Facility Boards Act, 2001, so as to regulate the manner in which the Provincial Department of Health monitors the financial affairs of Health Facility Boards; to provide for a procedure that will ensure sound financial governance of the Boards; and to provide for matters connected therewith.

(m) Western Cape District Health Councils Amendment Act 9 of 2013

10.86 Date of commencement: 13 September 2013 [Assented to on 11 September 2013]. The purpose of this Act is to amend the Western Cape District Health Councils Act, 2010, so as to include members of health subdistricts in a district health council; and to provide for matters connected therewith.

(n) Western Cape Independent Health Complaints Committee Act 2 of 2014

10.87 Date of commencement: 1 August 2014 [Assented to on 31 March 2014]. The purpose of this Act is to provide for the establishment of the Independent Health Complaints Committee; to make provision for a system for the referral of complaints to the Committee for consideration; and to provide for matters incidental thereto.

(o) Western Cape Health Facility Boards and Committees Act 4 of 2016

10.88 Date of commencement: to be proclaimed [Assented to on 30 June 2016]. The purpose of this Act is to provide for the establishment, functions and procedures of boards established for hospitals and committees established for primary health care facilities; and to provide for matters incidental thereto.

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Proclamation No. 19 of 2003 National Health Act 61 of 2003: Commencement GG 27503 of 18 April 2005

Proclamation No. 11 of 2012 Commencement of certain sections of the National Health Act 61 of 2003 GG 35081 of 27 February 2012

Proclamation No. 21 of 2014 Commencement of Certain Sections of the National Health Act 61 of 2003 GG 37501 of 31 March 2014

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Annexure A

Statutes administered by Department of Health

| | No and year | Short title | Provisions in force |
|-----------|--------------------|--|--|
| 1. | 36 of 1919 | Public Health Act | Sections 16, 48, 50(1)(d) and 66(d) |
| 1.1 | 57 of 1935 | Public Health Amendment Act | Section 14 <i>bis</i> |
| 1.2 | 51 of 1946 | Public Health Amendment Act | Section 17(2), (3) and (4) |
| 1.3 | 44 of 1952 | Public Health Amendment Act | Section 32 |
| 2. | 101 of 1965 | Medicines and Related Substances Act | The whole |
| 2.1 | 29 of 1968 | Drugs Control Amendment Act | The whole |
| 2.2 | 88 of 1970 | Drugs Control Amendment Act | The whole |
| 2.3 | 95 of 1971 | Drugs Control Amendment Act | The whole |
| 2.4 | 65 of 1974 | Drugs Control Amendment Act | The whole |
| 2.5 | 19 of 1976 | Medicines and Related Substances Control Amendment Act | The whole |
| 2.6 | 17 of 1979 | Medicines and Related Substances Control Amendment Act | The whole |
| 2.7 | 20 of 1981 | Medicines and Related Substances Control Amendment Act | The whole |
| 2.8 | 94 of 1991 | Medicines and Related Substances Control Amendment Act | The whole |
| 2.9 | 90 of 1997 | Medicines and Related Substances Control Amendment Act | The whole |
| 2.10 | 59 of 2002 | Medicines and Related Substances Control Amendment Act | The whole |
| 2.11 | 72 of 2008 | Medicines and Related Substances Amendment Act | Date of commencement to be proclaimed. |
| 2.12 | 14 of 2015 | Medicines and Related Substances Amendment Act | Date of commencement to be proclaimed. |
| 3. | 54 of 1972 | Foodstuffs, Cosmetics and Disinfectants Act | The whole |
| 3.1 | 32 of 1981 | Foodstuffs, Cosmetics and Disinfectants Amendment Act | The whole |
| 3.2 | 39 of 2007 | Foodstuffs, Cosmetics and Disinfectants Amendment Act | The whole |
| 4. | 15 of 1973 | Hazardous Substances Act | The whole |
| 4.1 | 16 of 1976 | Hazardous Substances Amendment Act | The whole |
| 4.2 | 31 of 1981 | Hazardous Substances Amendment Act | The whole |
| 4.3 | 53 of 1992 | Hazardous Substances Amendment Act | The whole |

| | No and year | Short title | Provisions in force |
|-----------|--------------------|--|---|
| 5. | 18 of 1973 | Mental Health Act | Sections 47 to 54 (Repealed by section 2 of the Mental Health Care Amendment Act 12 of 2014, to come into operation on a date to be fixed by the President by proclamation in the <i>Gazette</i> .) |
| 5.1 | 48 of 1976 | Mental Health Amendment Act | The whole |
| 5.2 | 10 of 1978 | Mental Health Amendment Act | The whole |
| 5.3 | 38 of 1981 | Mental Health Amendment Act | The whole |
| 5.4 | 3 of 1984 | Mental Health Amendment Act | The whole |
| 5.5 | 16 of 1985 | Mental Health Amendment Act | The whole |
| 5.6 | 55 of 1987 | Mental Health Amendment Act | The whole |
| 5.7 | 52 of 1988 | Mental Health Amendment Act | The whole |
| 5.8 | 19 of 1992 | Mental Health Amendment Act | Date of commencement was never proclaimed |
| 6. | 78 of 1973 | Occupational Diseases in Mines and Works Act | The whole |
| 6.1 | 27 of 1974 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.2 | 67 of 1974 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.3 | 45 of 1975 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.4 | 117 of 1977 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.5 | 30 of 1978 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.6 | 83 of 1979 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.7 | 83 of 1980 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.8 | 85 of 1981 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.9 | 106 of 1983 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.10 | 137 of 1991 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 6.11 | 208 of 1993 | Occupational Diseases in Mines and Works Amendment Act | The whole, except sections 13 and 15. Date of commencement of sections 13 and 15 to be proclaimed. |

| | No and year | Short title | Provisions in force |
|-----------|--------------------|--|----------------------------|
| 6.12 | 60 of 2002 | Occupational Diseases in Mines and Works Amendment Act | The whole |
| 7. | 28 of 1974 | International Health Regulations Act | The whole |
| 8. | 53 of 1974 | Pharmacy Act | The whole |
| 8.1 | 20 of 1979 | Pharmacy Amendment Act | The whole |
| 8.2 | 39 of 1982 | Pharmacy Amendment Act | The whole |
| 8.3 | 20 of 1983 | Pharmacy Amendment Act | The whole |
| 8.4 | 69 of 1985 | Pharmacy Amendment Act | The whole |
| 8.5 | 6 of 1995 | Pharmacy Amendment Act | The whole |
| 8.6 | 88 of 1997 | Pharmacy Amendment Act | The whole |
| 8.7 | 1 of 2000 | Pharmacy Amendment Act | The whole |
| 9. | 56 of 1974 | Health Professions Act | The whole |
| 9.1 | 33 of 1976 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.2 | 52 of 1978 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.3 | 43 of 1980 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.4 | 66 of 1981 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.5 | 38 of 1982 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.6 | 58 of 1984 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.7 | 79 of 1990 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.8 | 58 of 1992 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.9 | 18 of 1995 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.10 | 89 of 1997 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |

| | No and year | Short title | Provisions in force |
|------------|--------------------|--|--|
| 9.11 | 1 of 1998 | Medical, Dental and Supplementary Health Service Professions Amendment Act | The whole |
| 9.12 | 29 of 2007 | Health Professions Amendment Act | The whole, except sections 14, 16 and 30. Date of commencement of sections 14, 16 and 30 to be proclaimed. |
| 10. | 36 of 1977 | Health Laws Amendment Act | The whole |
| 11. | 19 of 1979 | Dental Technicians Act | The whole |
| 11.1 | 43 of 1997 | Dental Technicians Amendment Act | The whole |
| 11.2 | 24 of 2004 | Dental Technicians Amendment Act | The whole, except sections 1, 2 and 5. Date of commencement of sections 1, 2 and 5 to be proclaimed. |
| 12. | 63 of 1982 | Allied Health Professions Act | The whole |
| 12.1 | 108 of 1985 | Associated Health Service Professions Amendment Act | The whole |
| 12.2 | 10 of 1990 | Associated Health Service Professions Amendment Act | The whole |
| 12.3 | 63 of 1993 | Associated Health Service Professions Amendment Act | The whole |
| 12.4 | 40 of 1995 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act | The whole |
| 12.5 | 91 of 1997 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act | The whole |
| 12.6 | 6 of 2000 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act | The whole |
| 12.7 | 50 of 2000 | Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act | The whole |
| 13. | 108 of 1990 | Mentally Ill Persons' Legal Interests Amendment Act | The whole |
| 14. | 58 of 1991 | South African Medical Research Council Act | The whole |
| 15. | 111 of 1992 | Hospitals Ordinance Amendment Act | The whole |
| 16. | 83 of 1993 | Tobacco Products Control Act | The whole |
| 16.1 | 12 of 1999 | Tobacco Products Control Amendment Act | The whole |

| | No and year | Short title | Provisions in force |
|------------|--------------------|--|---------------------------------------|
| 16.2 | 23 of 2007 | Tobacco Products Control Amendment Act | The whole |
| 16.3 | 63 of 2008 | Tobacco Products Control Amendment Act | The whole |
| 17. | 118 of 1993 | Health and Welfare Matters Amendment Act | The whole |
| 18. | 92 of 1996 | Choice on Termination of Pregnancy Act | The whole |
| 18.1 | 38 of 2004 | Choice on Termination of Pregnancy Amendment Act | The whole |
| 18.2 | 1 of 2008 | Choice on Termination of Pregnancy Amendment Act | The whole |
| 19. | 45 of 1997 | Extension of Terms of Office of Members of Certain Councils Act | The whole |
| 20. | 44 of 1998 | Sterilisation Act | The whole |
| 20.1 | 3 of 2005 | Sterilisation Amendment Act | The whole |
| 21. | 131 of 1998 | Medical Schemes Act | The whole |
| 21.1 | 55 of 2001 | Medical Schemes Amendment Act | The whole |
| 21.2 | 62 of 2002 | Medical Schemes Amendment Act | The whole |
| 22. | 37 of 2000 | National Health Laboratory Service Act | The whole |
| 22.1 | 24 of 2001 | National Health Laboratory Service Amendment Act | Date of commencement to be proclaimed |
| 23. | 58 of 2000 | Council for Medical Schemes Levies Act | The whole |
| 24. | 17 of 2002 | Mental Health Care Act | The whole |
| 24.1 | 12 of 2014 | Mental Health Care Amendment Act | The whole |
| 25. | 31 of 2002 | Health Donations Fund Act Repeal Act | The whole |
| 26. | 61 of 2003 | National Health Act | The whole |
| 26.1 | 12 of 2013 | National Health Amendment Act | The whole |
| 27. | 33 of 2005 | Nursing Act | The whole |
| 28. | 35 of 2004 | Traditional Health Practitioners Act | The whole |
| 29. | 22 of 2007 | Traditional Health Practitioners Act | The whole |

Annexure B

Health and Related Matters Repeal and Amendment Bill

[]

Words in bold type in square brackets indicate omissions from existing enactments.

Words underlined with a solid line indicate insertions in existing enactments.

ACT

To amend the Administration of Estates Act 66 of 1965; Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972; Hazardous Substances Act 15 of 1973; Pharmacy Act 53 of 1974; Dental Technicians Act 19 of 1979; Allied Health Professions Act 63 of 1982; South African Medical Research Council Act 58 of 1991; Choice on Termination of Pregnancy Act 92 of 1996; Sterilisation Act 44 of 1998; Medical Schemes Act 131 of 1998; National Health Laboratory Service Act 37 of 2000; Nursing Act 33 of 2005; Traditional Health Practitioners Act 22 of 2007 in order to correct references to other legislation and members of the executive; to repeal redundant and obsolete legislation and for matters connected therewith.

Be it enacted by the Parliament of the Republic of South Africa, as follows:-

Amendment of section 73 of Act 66 of 1965

1. Section 73 of the Administration of Estates Act, 1966 is hereby amended by the deletion in subsection (1) of paragraph (b).

Amendment of section 77 of Act 66 of 1965

2. Section 77 of the Administration of Estates Act, 1966 is hereby amended by the substitution for subsection (1) of the following subsection:

“Every person appointed or to be appointed tutor or curator as provided in section 72 (1) (d) or (2) or under section 73 or 74, shall, **[subject to the proviso to**

section 57 (3) of the Mental Health Act, 1973 (Act 18 of 1973),] before letters of tutorship or curatorship are granted or signed and sealed, or any endorsement is made, as the case may be, and at any time thereafter when called upon by the Master to do so, find security or additional security to the satisfaction of the Master in an amount determined by the Master, for the proper performance of his functions.”.

Amendment of section 3 of Act 54 of 1972

3. Section 3 of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is hereby amended by the substitution in subsection (2) for paragraph (a) of the following paragraph:

“(a) which is the subject of a patent under the **[Patents Act, 1952 (Act 37 of 1952)]** Patents Act, 1978 (Act 57 of 1978), and which is sold in a condition complying with the specifications of the patent, and bears a label specifying the number under which the patent is registered in terms of that Act; or”

Amendment of section 10 of Act 54 of 1972, as amended by section 2 of Act 32 of 1981 and section 2 of Act 39 of 2007

4. Section 10 of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is hereby amended by the deletion in subsection (3) of paragraph (e).

Amendment of section 15A of Act 54 of 1972, as inserted by section 5 of Act 39 of 2007

5. Section 15A of the Foodstuffs, Cosmetics and Disinfectants Act, 1972, is hereby amended by the substitution for the words preceding paragraph (a) of the following words:

“The Minister may, after consultation with the **[Minister for Agriculture and Land Affairs, the Minister of Environmental Affairs and Tourism and the Minister of Water Affairs and Forestry]** members of Cabinet responsible for agriculture, environmental affairs, fisheries and water make regulations relating to –”

Amendment of section 1 of Act 15 of 1973, as amended by section 1 of Act 16 of 1976, section 1 of Act 31 of 1981, section 1 of Act 53 of 1992, section 84 of Act 131 of 1993 and section 58 of Act 46 of 1999

6. Section 1 of the Hazardous Substances Act, 1973, is hereby amended –

(a) by the substitution for the definition of “Director-General” of the following definition:

“ ‘Director-General’ means the Director-General: **[National Health and Population Development] Health;**”; and

(b) by the substitution for the definition of “Minister” of the following definition:

“ ‘Minister’ means the **[Minister of National Health] member of Cabinet responsible for health;**”.

Amendment of section 29 of Act 15 of 1973, as amended by section 6 of Act 16 of 1976, section 7 of Act 31 of 1981 and section 12 of 1992

7. Section 29 of the Hazardous Substances Act, 1973, is hereby amended by the substitution for subsection (6) of the following subsection:

“(6) No regulation under subsection (1) (e) shall be made except after consultation with the **[Minister of Manpower] member of Cabinet responsible for labour.**”.

Amendment of section 1 of Act 19 of 1979, as amended by section 1 of Act 43 of 1997

8. Section 1 of the Dental Technicians Act, 1979 is hereby amended –

(a) by the substitution in section 1 for the definition of “clinical dental technologist” of the following definition:

“ ‘clinical dental technologist’ means a person who has undergone training in treating patients requiring complete artificial dentures and who is registered as such under the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act, 1974 (Act 56 of 1974);**”;

(b) by the substitution in section 1 for the definition of “dentist” of the following definition:

“ ‘dentist’ means a person registered as such under the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974 (Act 56 of 1974);”;

- (c) by the substitution in section 1 for the definition of “scheduled substance” of the following definition:

“ ‘scheduled substance’ means a scheduled substance as defined in section 1 of the Medicines and Related Substances **[Control] Act**, 1965 (Act 101 of 1965);”.

Amendment of section 5 of Act 19 of 1979, as amended by section 4 of Act 43 of 1997

9. Section 5 of the Dental Technicians Act, 1979 is hereby amended by the substitution in subsection (1) for subparagraph (iii) of paragraph (b) of the following subparagraph:

- “(iii) three shall be members of the public who shall be appointed after calling through the media for nominations by the public and who are not registered in terms of this Act or the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974 (Act 56 of 1974), of whom at least one shall be appointed on account of his or her knowledge of the law;”.

Amendment of section 6 of Act 19 of 1979, as amended by section 46 of Act 97 of 1986 and section 5 of Act 43 of 1997

10. Section 6 of the Dental Technicians Act, 1979 is hereby amended –

- (a) by the substitution in subsection (1) for paragraph (b) of the following paragraph:

“(b) who in terms of this Act or the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974 (Act 56 of 1974), is disqualified from practising his or her profession;”;

- (b) by the substitution in subsection (2) for paragraph (e) of the following paragraph:

“(e) he or she **[becomes a patient or a State patient]** suffers from a mental illness as defined in section 1 of the **[Mental Health Act, 1973 (Act 18 of 1973)] Mental Health Care Act, 2002 (Act 17 of 2002)**;”.

Amendment of section 24 of Act 19 of 1979, as amended by sections 19 and 35 of Act 43 of 1997

11. Section 24 of the Dental Technicians Act, 1979 is hereby amended –

(a) by the substitution for subsection (4) of the following subsection:

“(4) If it appears to the judge concerned from the documents submitted to him or her in terms of the Mental Health Care Act, 2002 (Act 17 of 2002), or it is brought to his or her notice in any other manner, that the person to whom the documents relate is a person registered under this Act, he or she shall, if the said person is declared a mentally ill person as contemplated by the said Mental Health Care Act, direct that a copy of the order declaring such a person a mentally ill person be transmitted to the registrar and the registrar shall, on receipt of the said copy, remove the name of the person concerned from the register.”; and

(b) by the substitution in subsection (5) for paragraph (c) of the following paragraph:

“(c) if his or her name has been removed from the register in terms of subsection (4), submits proof to the satisfaction of the council of his or her discharge in terms of the provisions of the **[Mental Health Act, 1973,] Mental Health Care Act, 2002**, from the institution at which he or she was detained; and”.

Amendment of section 27 of Act 19 of 1979, as amended by section 20 of Act 43 of 1997

12. Section 27 of the Dental Technicians Act, 1979 is hereby amended –

(a) by the substitution in subsection (7) for paragraph (a) of the following paragraph:

“(a) The prohibitions in subsections (1) and (2) shall not replace those contained in section 38 (1) of the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974 (Act 56 of 1974).”; and

(b) by the substitution in subsection (7) for paragraph (b) of the following paragraph:

“(b) The provisions of subsection (2) shall not imply that any dentist or clinical dental technologist who solicits, or allows any person to solicit on his

or her behalf, any order referred to in that subsection, or accepts any such order so solicited, is not guilty of improper conduct, or that an inquiry under Chapter IV of the **[Medical, Dental and Supplementary Health Service Professions Act] Health Professions Act**, 1974, may not be instituted against any such dentist or clinical dental technologist.”.

Amendment of section 29 of Act 19 of 1979, as amended by section 22 of Act 43 of 1997

13. Section 29 of the Dental Technicians Act, 1979 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

- “(e) any medical **[benefit]** scheme registered in terms of the **[Medical Schemes Act, 1967 (Act 72 of 1967)] Medical Schemes Act, 1998 (Act 131 of 1998)**,”.

Amendment of section 1 of Act 63 of 1982, as amended by section 1 of Act 108 of 1985, section 1 of Act 10 of 1990, section 1 of Act 63 of 1993, section 1 of Act 40 of 1995 and section 1 of Act 50 of 2000

14. Section 1 of the Allied Health Professions Act, 1982 is hereby amended –

- (a) by the insertion before the definition of “acupuncturist” of the following definition:
- “‘acupuncture’ means a system of complementary medicine in which fine needles are inserted in the skin at specific points along what are considered to be lines of energy (meridians), used in the treatment of various physical and mental conditions;”;
- (b) by the insertion after the definition of “annual fees” of the following definition:
- “‘ayurveda’ means the traditional Hindu system of medicine, incorporated in Atharva Veda, the last of the four Vedas, which is based on the balance in bodily systems and which uses diet, herbal treatment, and yogic breathing;”;
- (c) by the insertion after the definition of “chairperson” of the following definitions:
- “‘Chinese medicine’ means the traditional Chinese medical system to prevent, diagnose, and treat disease, based on the belief that qi, the body's vital energy, flows along meridians (channels) in the body and keeps a person’s spiritual, emotional, mental, and physical health in balance;” and
- “‘chiropractic’ means a system of complementary medicine based on the diagnosis and manipulative treatment of misalignments of the joints,

especially those of the spinal column, which are believed to cause other disorders by affecting the nerves, muscles, and organs;”;

- (d) by the insertion after the definition of “homeopath” of the following definition:

“ ‘homeopathy’ means a system of complementary medicine in which ailments are treated by minute doses of natural substances that in larger amounts would produce symptoms of the ailment;”;

- (e) by the insertion after the definition of “naturopath” of the following definition:

“ ‘naturopathy’ means a system of treatment of disease that avoids drugs and that emphasizes the use of natural agents, including air, water and herbs, and physical means, including tissue manipulation and electrotherapy;”;

- (f) by the insertion after the definition of “osteopath” of the following definition:

“ ‘osteopathy’ means a system of medical practice based on theory that diseases are due chiefly to loss of structural integrity which can be restored by manipulation of the parts, supplemented by therapeutic measures;”;

- (g) by the insertion after the definition of “phytotherapist” of the following definition:

“ ‘phytotherapy’ means a science-based medical practice based on the use of plant-derived medications in the treatment and prevention of disease;”;

- (h) by the substitution for the definition of “scheduled substance” of the following definition:

“ ‘scheduled substance’ means any scheduled substance as defined in section 1 of the Medicines and Related Substances [Control] Act, 1965 (Act 101 of 1965);”;

- (i) by the insertion after the definition of “therapeutic aromatherapist” of the following definition:

“ ‘therapeutic aromatherapy’ means the use of plant-derived, aromatic essential oils to promote physical and psychological well-being, sometimes used in combination with massage and other therapeutic techniques as part of a holistic treatment approach;”;

- (j) by the insertion after the definition of “therapeutic massage therapist” of the following definition:

“ ‘therapeutic massage therapy’ means the manual manipulation of soft body tissues, such as muscle, connective tissue, tendons and ligaments, to enhance a person's health and well-being;”; and

- (l) by the insertion after the definition of “therapeutic reflexologist” of the following definition:

“‘therapeutic reflexology’ means the method of relieving pain by the application of pressure to stimulate predefined pressure points on the feet and hands to alleviate the source of the discomfort;”.

Amendment of section 6 of Act 63 of 1982, as amended by section 7 of Act 40 of 1995 and section 7 of Act 50 of 2000

15. Section 6 of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

- “(e) **[becomes a patient or State patient]** suffers from a mental illness as defined in section 1 of the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 10B of Act 63 of 1982, as inserted by section 10 of Act 50 of 2000

16. Section 10B of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

- “(e) **[becomes a patient or State patient]** suffers from a mental illness as defined in section 1 of the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 16 of Act 63 of 1982, as repealed by section 5 of Act 108 of 1985, inserted by section 7 of Act 63 of 1993 and substituted by section 14 of Act 50 of 2000

17. Section 16 of the Allied Health Professions Act, 1982 is hereby amended –

- (a) by the substitution for subsection (1) of the following subsection:

“(1) The Minister may, at the request of the council, by notice in the *Gazette* declare the provisions of this Act to be applicable to any profession which has as its object the promotion of health, or the treatment, prevention or relief of physical or mental defects, illnesses or deficiencies in humans, excluding any profession referred to in subsection (1A) or any profession to which the provisions of the Pharmacy Act, 1974 (Act 53 of 1974), the Health

Professions Act, 1974 (Act 56 of 1974), the **[Nursing Act, 1978 (Act 50 of 1978)]** Nursing Act, 2005 (Act 33 of 2005), or the Dental Technicians Act, 1979 (Act 19 of 1979), apply.”; and

(b) by the substitution for subsection (3) of the following subsection:

“(3) Subject to the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965), and subject to the approval of the Medicines Control Council, the Minister may, on the recommendation of the council, by regulation prescribe access to and availability of medicines relative to the professions registered in terms of this Act.”.

Amendment of section 30 of Act 63 of 1982, as substituted by section 17 of Act 108 of 1985 and amended by section 23 of Act 63 of 1993 and section 26 of Act 50 of 2000

18. Section 30 of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (1) for paragraph (b) of the following paragraph:

“(b) has become addicted to the use of any scheduled substance as defined in section 1 (1) of the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965),”.

Amendment of section 31 of Act 63 of 1982, as substituted by section 17 of Act 108 of 1985 and amended by section 23 of Act 63 of 1993 and section 26 of Act 50 of 2000

19. Section 31 of the Allied Health Professions Act, 1982 is hereby amended by the substitution in subsection (2) for paragraph (a) of the following paragraph:

“(a) any person exercising a profession to which the provisions of the Pharmacy Act, 1974 (Act 53 of 1974), the Health Professions Act, 1974 (Act 56 of 1974), the **[Nursing Act, 1978 (Act 50 of 1978)]** Nursing Act, 2005 (Act 33 of 2005), or the Dental Technicians Act, 1979 (Act 19 of 1979), apply, from performing any act pertaining to his or her profession, as contemplated in the appropriate Act, which may lawfully be performed by him or her;”.

Amendment of section 32A of Act 63 of 1982, as inserted by section 29 of Act 50 of 2000

20. Section 32A of the Allied Health Professions Act, 1982 is hereby amended by the substitution for paragraph (f) of the following paragraph:

“(f) supplies or offers to supply to any person not registered under this Act, the Health Professions Act, 1974 (Act 56 of 1974), or the **[Nursing Act, 1978 (Act 50 of 1978)]** Nursing Act, 2005 (Act 33 of 2005), any instrument or appliance which can be used, or is claimed to be effective, for the purpose of diagnosing, treating or preventing physical or mental defects, illnesses or deficiencies in man, knowing that such instrument or appliance will be used by such unregistered person for the purpose of performing for gain an act which such unregistered person is in terms of the provisions of this Act or the Health Professions Act, 1974, or **[Nursing Act, 1978]** Nursing Act, 2005, prohibited from performing for gain.”.

Amendment of section 38 of Act 63 of 1982, as amended by section 22 of Act 108 of 1985, section 27 of Act 94 of 1991, sections 21 and 23 of Act 63 of 1993 and section 33 of Act 50 of 2000

21. Section 38 of the Allied Health Professions Act, 1982 is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) The provisions of subsection (1) (l) and (m) shall not be applicable to a remedy which is a Scheduled substance as defined in section 1 of the Medicines and Related Substances **[Control]** Act, 1965.”.

Substitution of section 40 of Act 63 of 1982

22. The following section is hereby substituted for section 40 of the Allied Health Professions Act, 1982:

“Saving

40. The provisions of the **[Medical, Dental and Supplementary Health Service Professions Act,]** Health Professions Act, 1974 (Act 56 of 1974), shall not be construed as prohibiting any practitioner from performing for gain any act usually performed at the commencement of this Act by persons who practise the profession

concerned in the Republic and the performance of which by any such practitioner is not prohibited by this Act.”.

Substitution of section 41 of Act 63 of 1982

23. The following section is hereby substituted for section 41 of the Allied Health Professions Act, 1982:

“Interpretation of laws in respect of certain traditional health practitioners, medicine men and herbalists

41. The provisions of this Act and the Health Professions Act, 1974 (Act 56 of 1974), shall not be construed as derogating from the right which a traditional health practitioner as defined in the Traditional Health Practitioners Act, 2007 (Act 22 of 2007), herbalist or medicine man as contemplated in the [Code of Zulu Law] KwaZulu Act on the Code of Zulu Law, 1985 (Act 19 of 1985) and the Natal Code of Zulu Law (Proclamation R151 of 1987) may have to practise his or her profession.”.

Amendment of section 4 of Act 58 of 1991

24. Section 4 of the South African Medical Research Council Act, 1991 is hereby amended by the substitution in subsection (1) for subparagraph (iii) of paragraph (o) of the following subparagraph:

- “(iii) on its own, or in association with any person, establish a company for the purpose of developing or exploiting in any manner any invention or technological expertise, and for this purpose acquire an interest in or control over **[a company or statutory body referred to in section 1 of the Exchequer Act, 1975 (Act 66 of 1975)]** an entity or enterprise contemplated in section 1 of the Public Finance Management Act, 1999 (Act 1 of 1999);”.

Amendment of section 6 of Act 58 of 1991

25. Section 6 of the South African Medical Research Council Act, 1991 is hereby amended –

- (a) by the substitution in subsection (4) for subparagraph (i) of paragraph (f) of the following subparagraph:

- “(i) he is in terms of the provisions of the **[Electoral Act, 1979 (Act 45 of 1979)]** Electoral Act, 1998 (Act 73 of 1998), nominated as a candidate for election as a member of Parliament; or”; and
- (b) by the substitution in subsection (4) for subparagraph (ii) of paragraph (f) of the following subparagraph:
- “(ii) he is in terms of the provisions of the **[Republic of South Africa Constitution Act, 1983 (Act 110 of 1983),]** Constitution of the Republic of South Africa, 1996 nominated as a member of Parliament [, or is appointed or designated as a member of the President's Council]; or”.

Amendment of section 9 of Act 58 of 1991

26. Section 9 of the South African Medical Research Council Act, 1991 is hereby amended by the substitution for subsection (2) of the following subsection:

“(2) The president shall be registered as a medical practitioner under the **[Medical, Dental and Supplementary Health Service Professions Act,]** Health Professions Act, 1974 (Act 56 of 1974).”.

Amendment of section 14 of Act 58 of 1991

27. Section 14 of the South African Medical Research Council Act, 1991 is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) The keeping and compilation of annual financial statements of a company referred to in section 4 (1) (o) (iii) shall be done in accordance with the provisions of the **[Companies Act, 1973 (Act 61 of 1973)]** Companies Act, 2008 (Act 71 of 2008).”.

Amendment of section 21 of Act 58 of 1991

28. Section 21 of the South African Medical Research Council Act, 1991 is hereby amended by the repeal of subsections (2) to (5).

Amendment of section 1 of Act 83 of 1993

29. Section 1 of the Tobacco Products Control Act 83 of 1993 is hereby amended by the substitution in section 1 for the definition of “Constitution” of the following definition:

“ ‘Constitution’ means the Constitution of the Republic of South Africa, 1996 **[(Act 108 of 1996)]**”.

Amendment of section 1 of Act 92 of 1996, as amended by section 68 of Act 32 of 2007 and section 1 of Act 1 of 2008

30. Section 1 of the Choice on Termination of Pregnancy Act, 1996 is hereby amended by the substitution for the definition of “medical practitioner” of the following definition.

“ ‘medical practitioner’ means a person registered as such under the **[Medical, Dental and Supplementary Health Service Professions Act,] Health Professions Act**, 1974 (Act 56 of 1974);

Amendment of section 2 of Act 92 of 1996

31. Section 2 of the Choice on Termination of Pregnancy Act, 1996 is hereby amended by the substitution in subsection (1) for the words preceding subparagraph (i) of paragraph (c) of the following words:

“after the 20th week of the gestation period if a medical practitioner, after consultation with another medical practitioner or a registered midwife, is of the opinion that the continued pregnancy – ”

Amendment of section 1 of Act 44 of 1998, as amended by section 1 of Act 3 of 2005

32. Section 1 of the Sterilisation Act, 1998 is hereby amended –

(a) by the substitution for the definition of “nurse” of the following definition:

“ ‘nurse’ means a person registered as such in terms of the **[Nursing Act, 1978 (Act 50 of 1978),] Nursing Act, 2005 (Act 33 of 2005)**, and who holds a qualification in psychiatry;” and

(b) by the substitution for the definition of “social worker” of the following definition:

“ ‘social worker’ means a person registered as such in terms of the **[Social Work Act,] Social Service Professions Act, 1978 (Act 110 of 1978);**”.

Amendment of section 5 of Act 131 of 1998 as amended by section 36 of Act 12 of 2005

33. Section 5 of the Medical Schemes Act, 1998 is hereby amended by the substitution in subsection (2) for paragraph (e) of the following paragraph:

“(e) is in terms of the provisions of the **[Electoral Act, 1993 (Act 202 of 1993)], Electoral Act, 1998 (Act 73 of 1998)** nominated as a candidate for election as a member of Parliament; or”.

Amendment of section 36 of Act 131 of 1998 as amended by section 13 of Act 55 of 2001

34. Section 36 of the Medical Schemes Act, 1998 is hereby amended –

(a) by the substitution in subsection (3) for paragraph (e) of the following paragraph:

“(e) a person who **[is disqualified from acting as an auditor in terms of section 275 of the Companies Act, 1973 (Act 61 of 1973)] does not comply with the requirements for appointment as an auditor as stipulated in section 90 of the Companies Act, 2008 (Act 71 of 2008).**”;

(b) by the substitution for subsection (4) of the following subsection:

“(4) The approval of an auditor of a medical scheme by the Registrar shall not lapse if an auditor of a medical scheme is a firm as contemplated in the **[Public Accountants' and Auditors' Act, 1991, (Act 80 of 1991)] Auditing Professions Act, 2005 (Act 26 of 2005)**, whose membership of the firm has changed, if not fewer than half of the members after the change, were members when the appointment of the firm was last approved by the Registrar.”;

(c) by the substitution in subsection (5) for paragraph (a) of the following paragraph:

“(a) whenever he or she furnishes a report or other document of particulars as contemplated in section **[20 (5) (b) of the Public Accountants' and Auditors' Act, 1991] 45 of the Auditing Professions Act, 2005 (Act 26 of 2005)**, also furnish a copy thereof to the Registrar.”;

- (d) by the substitution in subsection (5) for subparagraph (ii) of paragraph (c) of the following subparagraph:
- “(ii) if he or she would, but for that termination, have had reason to submit to the medical scheme a report as contemplated in section **[20 (5) (a) of the Public Accountants' and Auditors' Act, 1991]** 45 of the Auditing Professions Act, 2005 (Act 26 of 2005), submit such a report to the Registrar; and”; and
- (e) by the substitution in subsection (8) for paragraph (a) of the following paragraph:
- “(a) in respect of a return or statement which he or she is required to examine in terms of this Chapter, certify whether that return or statement complies with the requirements of this Act and whether the return or statement, including any annexure thereto, presents fairly the matters dealt with therein as if such return or statement were a financial statement contemplated in section **[20 of the Public Accountants' and Auditors' Act, 1991]** 44 of the Auditing Professions Act, 2005 (Act 26 of 2005); and”.

Amendment of section 37 of Act 131 of 1998 as amended by section 14 of Act 55 of 2001

35. Section 37 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) The annual financial statements of a medical scheme shall, subject to the provisions of the **[Public Accountants' and Auditors' Act, 1991]** Auditing Professions Act, 2005, be audited by an accountant and auditor registered in terms of that Act except where such accounts are to be audited by the Auditor-General in terms of any law.”.

Amendment of section 44 of Act 131 of 1998 as amended by section 17 of Act 55 of 2001

36. Section 44 of the Medical Schemes Act, 1998 is hereby amended –

- (a) by the substitution for subsection (2) of the following subsection:
- “(2) The Registrar, or such other person authorised by him or her, shall in addition to the powers and duties conferred or imposed upon him or her by this Act, have all the powers and duties conferred or imposed upon an

inspector appointed under section 2 of the **[Inspection of Financial Institutions Act, 1984 (Act 38 of 1984)]** Inspection of Financial Institutions Act, 1998 (Act 80 of 1998), as if he or she has been appointed an inspector under that Act.” and

(b) by the substitution for subsection (3) of the following subsection:

“(3) Any reference in this Act to an inspection made under this section shall also be construed as a reference to an inspection made under the **[Inspection of Financial Institutions Act, 1984]** Inspection of Financial Institutions Act, 1998.”.

Substitution of section 52 of Act 131 of 1998 as amended by section 20 of Act 55 of 2001

37. Section 52 of the Medical Schemes Act, 1998 is hereby substituted for the following section:

“Business rescue

52. (1) Chapter 6 of the Companies Act, 2008 (Act 71 of 2008), shall, subject to the provisions of this section and with the necessary changes, apply in relation to the business rescue of a medical scheme, and in such application the Registrar shall be deemed to be an affected person as contemplated by section 131 of the Companies Act, 2008.

(2) The Registrar may, with the concurrence of the Council, make an application under section 131 of the Companies Act, 2008 for an order placing a medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme if he or she is satisfied that it is in the interests of the members of that medical scheme to do so.

(3) In the application of Chapter 6 of the Companies Act, 2008, as provided for by subsection (1) –

- (a) a reference which relates to the inability of a medical scheme to pay its debts or to meet its obligations shall be construed as relating also to its inability to comply with the requirements prescribed by section 35 (1) of this Act;
- (b) in addition to any question which relates to the nature of a medical scheme as a successful concern, there shall be considered also the question whether any course of action is in the interest of its members;
- (c) a reference to an affected person in Chapter 6 of the Companies Act, 2008 shall be construed as a reference also to a member of a medical scheme;

- (d) a reference in sections 131, 132 and 155 to the Companies and Intellectual Property Commission shall be construed as a reference also to the Registrar;
- (e) a reference in section 140(1A) to a relevant regulatory authority shall be construed as a reference also to the Registrar;
- (f) a reference to a contravention of any provision of that Act shall be construed as a reference also to a contravention of any provision of this Act; and
- (g) a reference to a director shall be construed as referring also to a member of the board of trustees.

(4) If an application is made to a court for an order placing a medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme by a person other than the Registrar –

- (a) it shall not be heard unless copies of the notice of motion and of all accompanying affidavits and other documents filed in support of the application are lodged with Registrar at least 15 days, or such shorter period as the court may allow on good cause shown, before the application is set down for hearing; and
- (b) the Registrar may, if he or she is satisfied that the application is contrary to the interests of the beneficiaries of the medical scheme concerned make application to the court to join the application as a party and file affidavits and other documents in opposition to the application.

(5) As from the date on which an order placing a medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme is granted –

- (a) any reference in this Act to a medical scheme shall, unless clearly inappropriate, be construed as a reference to the business rescue practitioner appointed for the medical scheme; and
- (b) the business rescue practitioner appointed for a medical scheme shall not admit members unless he or she has been granted permission to do so by the court in the order placing the medical scheme under supervision and commencing business rescue proceedings in respect of the medical scheme, or any variation of the order.”

Amendment of section 53 of Act 131 of 1998 as amended by section 21 of Act 55 of 2001

38. Section 53 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) Item 9 of Schedule 5 of the Companies Act, 2008 (Act 71 of 2008) and Chapter XIV of the Companies Act, 1973 (Act 61 of 1973), shall, subject to the provisions of this section and with the necessary changes, apply in relation to the winding-up of a medical scheme and in such application the Registrar shall be deemed to be a person authorised by section 346 of the Companies Act, 1973, to make an application to the High Court for the winding-up of the medical scheme.”.

Amendment of section 54 of Act 131 of 1998

39. Section 54 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsection (1) of the following subsection:

“(1) Where any compromise or arrangement is proposed between a medical scheme and its creditors or any class of them, or between a medical scheme and its members or any group of them, the High Court may, on the application of the medical scheme or any creditor or member thereof or, in the case of a medical scheme being wound up, of the liquidator, or **[if the medical scheme is subject to a judicial management order, of the judicial manager,]** during business rescue proceedings of a medical scheme placed under supervision, of the business rescue practitioner, or if the medical scheme is subject to a curatorship order, of the curator, order a meeting of the creditors or class of creditors, or of the members of the medical scheme or a group of members, as the case may be, to be summoned in such manner as the High Court may direct.”.

Amendment of section 56 of Act 131 of 1998 as amended by section 22 of Act 55 of 2001

40. Section 56 of the Medical Schemes Act, 1998 is hereby amended by the substitution for subsections (2) and (3) of the following subsections, respectively:

“(2) The provisions of the **[Financial Institutions (Investment of Funds) Act, 1984 (Act 39 of 1984)]** Financial Institutions (Protection of Funds) Act, 2001 (Act 28 of 2001), insofar as those provisions relate to the appointment of a curator in terms of the said Act, and insofar as they are not inconsistent with the provisions of this Act, shall apply with the necessary changes to the appointment of a curator of a medical scheme in terms of this section.

(3) In the application of the **[Financial Institutions (Investment of Funds) Act, 1984]** Financial Institutions (Protection of Funds) Act, 2001 as provided for by subsection (1) –

- (a) a reference to a company and the registrar in section 1 of the **[Financial Institutions (Investment of Funds) Act, 1984]** Financial Institutions (Protection of Funds) Act, 2001, shall be construed as a reference also to a board of trustees and the Registrar, respectively;
- (b) a reference in that Act to a director, official, employee or agent shall be construed as a reference also to a member of the board of trustees or the principal officer, as the case may be; and
- (c) a reference in that Act to a financial institution shall be construed as a reference also to a medical scheme.”.

Amendment of section 10 of Act 37 of 2000

41. Section 10 of the National Health Laboratory Service Act 37 of 2000 is hereby amended by the substitution in subsection (2) for paragraph (c) of the following paragraph:

- “(c) he or she is declared by the High Court to be of unsound mind or mentally disordered or **[is detained]** becomes an involuntary mental health care user under the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002).”.

Amendment of section 16 of Act 37 of 2000

42. Section 16 of the National Health Laboratory Service Act 37 of 2000 is hereby amended by the substitution in subsection (1) for paragraph (d) of the following paragraph:

- “(d) import any human tissue or any blood, blood product or gamete in terms of **[section 25 of the Human Tissue Act, 1983 (Act 65 of 1983)]** the National Health Act, 2003 (Act 61 of 2003), for the purposes contemplated in paragraph (a), (b) or (c); and”.

Amendment of section 4 of Act 33 of 2005

43. Section 4 of the Nursing Act, of 2005 is hereby amended by the substitution in subsection (1) for paragraph (o) of the following paragraph:

- “(o) be regarded as an education and training quality assurer in terms of section **[5 of the South African Qualifications Authority Act, 1995 (Act 58 of**

1995)] 13 of the National Qualifications Framework Act, 2008 (Act 67 of 2008), for all nursing qualifications;”.

Amendment of section 1 of Act 22 of 2007

44. Section 1 of the Traditional Health Practitioners Act, 2007 is hereby amended –

(a) by the substitution in section 1 for the definition of “accredited institution” of the following definition:

“ ‘accredited institution’ 'accredited institution' means an institution, approved by the Council, which certifies that a person or body has the required capacity to perform the functions within the sphere of the **[National Quality Framework contemplated in the South African Qualifications Authority Act, 1995 (Act 58 of 1995)]** National Qualifications Framework contemplated in the National Qualifications Framework Act, 2008 (Act 67 of 2008);

(b) by the substitution in the definition of “traditional health practice” for the words following paragraph (d) of the following words:

“but excludes the professional activities of a person practising any of the professions contemplated in the Pharmacy Act, 1974 (Act 53 of 1974), the Health Professions Act, 1974 (Act 56 of 1974), **[the Nursing Act, 1974 (Act 50 of 1974),]** the Allied Health Professions Act, 1982 (Act 63 of 1982), **[or]** the Dental Technicians Act, 1979 (Act 19 of 1979), or the Nursing Act, 2005 (Act 33 of 2005), and any other activity not based on traditional philosophy;”.

Repeal of laws

45. Each of the laws referred to in the first two columns of the Schedule is hereby repealed to the extent specified opposite that law in the third column of that Schedule

Schedule

| No. and year of Act | Short title | Extent of repeal |
|----------------------------|-----------------------------------|-------------------------|
| Act 36 of 1919 | Public Health Act, 1919 | The whole |
| Act 57 of 1935 | Public Health Amendment Act, 1935 | The whole |

| | | |
|-----------------|---|-------------------------------------|
| Act 51 of 1946 | Public Health Amendment Act, 1946 | The whole |
| Act 44 of 1952 | Public Health Amendment Act, 1952 | The whole |
| Act 48 of 1976 | Mental Health Amendment Act, 1976 | The whole |
| Act 36 of 1977 | Health Laws Amendment Act, 1977 | Sections 1 to 3, 9, 10, 13 to 18 |
| Act 10 of 1978 | Mental Health Amendment Act, 1978 | The whole |
| Act 38 of 1981 | Mental Health Amendment Act, 1981 | The whole |
| Act 3 of 1984 | Mental Health Amendment Act, 1984 | The whole |
| Act 16 of 1985 | Mental Health Amendment Act, 1985 | The whole |
| Act 55 of 1987 | Mental Health Amendment Act, 1987 | The whole |
| Act 52 of 1988 | Mental Health Amendment Act, 1988 | The whole |
| Act 19 of 1992 | Mental Health Amendment Act, 1992 | The whole |
| Act 108 of 1990 | Mentally Ill Persons' Legal Interests Amendment Act, 1990 | The whole |
| Act 118 of 1993 | Health and Welfare Matters Amendment Act, 1993 | Sections 14 and 15 |
| Act 45 of 1997 | Extension of Terms of Office of Members of Certain Councils Act, 1997 | The whole |
| Act 91 of 1997 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act, 1997 | The whole |
| Act 6 of 2000 | Chiropractors, Homeopaths and Allied Health Service Professions Amendment Act, 2000 | The whole |
| Act 35 of 2004 | Traditional Health Practitioners Act, 2004 | The whole |
| Act 38 of 2004 | Choice on Termination of Pregnancy Amendment Act, 2004 | The whole |

Annexure C

National Health Amendment Bill

[] Words in bold type in square brackets indicate omissions from existing enactments.

_____ Words underlined with a solid line indicate insertions in existing enactments.

ACT

To amend the National Health Act 61 of 2003 in order to insert or substitute certain definitions; to correct references to other legislation; to amend provisions that are discriminatory on the basis of gender; to further provide for consent for research or experimentation conducted on a minor child; to further provide for procedures for entry and inspection or entry and search; and to provide for matters connected therewith.

Be it enacted by the Parliament of the Republic of South Africa, as follows:-

Amendment of section 1 of Act 61 of 2003, as amended by section 1 of Act 12 of 2013

1. Section 1 of the National Health Act, 2003 (hereinafter referred to as the principal Act), is hereby amended –

- (a) by the insertion after the definition of “Board” of the following definition:
- “ ‘ brain death’ means irreversible brain damage and loss of all functions of the entire brain, including the brain stem, as evidenced by cessation or absence of respiratory and other vital reflexes, fixed and dilated pupils, lack of eye movement, unresponsiveness to stimuli, absence of muscle activity and a demonstration of a total lack of electrical activity in the brain, drug intoxication or hypothermia having been ruled out;”;
- (b) by the substitution in the definition of “health care provider” for paragraph (c) of the following paragraph:
- “(c) Nursing Act, **[1978 (Act 50 of 1978)]** 2005 (Act 33 of 2005),”;

- (c) by the substitution for the definition of “health technology” of the following definition:
- “ ‘health technology’ means machinery or equipment that is used in the provision of health services, but does not include medicine as defined in section 1 of the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965);”;
- (d) by the insertion after the definition of “non-communicable disease” of the following definition:
- “ ‘non-therapeutic’ means aimed at obtaining knowledge which may contribute towards the future development of new forms of treatment or procedures;”;
- (e) by the substitution in the definition of “statutory health professional council” for paragraph (b) of the following paragraph:
- “(b) the South African Nursing Council established by section 2 of the Nursing Act, **[1978 (Act 50 of 1978)] 2005 (Act 33 of 2005)**;”;
- (f) by the insertion after the definition of “statutory health professional council” of the following definition:
- “ ‘therapeutic’ means dealing with the treatment and cure of disease and ill-health;”;
- and
- (g) by the substitution in the definition of “user” for paragraphs (a) and (b) of the following paragraphs:
- “(a) below the age contemplated in section **[39 (4) of the Child Care Act, 1983 (Act 74 of 1983)] 129 of the Children’s Act, 2005 (Act 38 of 2005)**, ‘user’ includes the person’s parent or guardian or another person authorised by law to act on the first mentioned person’s behalf;
- or
- (b) incapable of taking decisions, ‘user’ includes the person’s spouse or partner or, in the absence of such spouse or partner, the person’s parent, grandparent, **[adult] major** child or **[brother or sister] major sibling**, or another person authorised by law to act on the **[firstmentioned] first mentioned** person’s behalf;”.

Amendment of section 7 of Act 61 of 2003

2. Section 7 of the principal Act is hereby amended by the substitution for paragraph (b) of subsection (1) of the following paragraph:

“(b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, **[an adult]** a major child or a **[brother or a sister]** major sibling of the user, in the specific order as listed;”.

Amendment of section 13 of Act 61 of 2003

3. The following section is hereby substituted for section 13 of the principal Act:

“Subject to the National Archives and Record Service of South Africa Act, 1996 (Act 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act 2 of 2000), the person in charge of a health establishment must ensure that a health record containing such information as may be prescribed is created and maintained at that health establishment for every user of health services.”.

Amendment of section 45 of Act 61 of 2003

4. Section 45 of the principal Act is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) An agreement contemplated in subsection (2) must comply with the Public Finance Management Act, 1999 (Act 1 of 1999), or **[any municipal finance management legislation,]** the Local Authorities: Municipal Finance Management Act, 2003 (Act 56 of 2003) as the case may be.”.

Amendment of section 59 of Act 61 of 2003

5. Section 59 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

“(2) Subject to the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965), only a registered medical practitioner or dentist, or a person acting under the supervision or on the instructions of a medical practitioner or dentist, may for the purposes of this Chapter administer blood or a blood product to, or prescribe blood or a blood product for, a living person.”.

Amendment of section 62 of Act 61 of 2003

6. Section 62 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

“(2) In the absence of a donation under subsection (1) (a) or of a contrary direction given by a person whilst alive, the spouse, partner, major child, parent, guardian, or major **[brother or major sister]** sibling of that person, in the specific order mentioned, may, after that person's death, donate the body or any specific tissue of that person to an institution or a person contemplated in section 63.”.

Amendment of section 66 of Act 61 of 2003

7. Section 66 of the principal Act is hereby amended by the substitution for paragraph (b) of subsection (1) of the following paragraph:

“(b) the spouse, partner, major child, parent, guardian, or major **[brother or major sister]** sibling of the deceased, in the specific order mentioned, gave consent thereto; or”.

Amendment of section 71 of Act 61 of 2003

8. Section 71 of the principal Act 1991 is hereby amended –

(a) by the substitution for subsections (2) and (3) of the following subsections, respectively:

“(2) Where research or experimentation is to be conducted on a minor child for a therapeutic purpose, the research or experimentation may only be conducted –

- (a) **[if it is in the best interests of the minor]** with the consent of the relevant health research ethics committee;
- (b) in such manner and on such conditions as may be prescribed;
- (c) with the consent of the parent or guardian of the minor child; and
- (d) if the minor child is capable of understanding, with the consent of the minor child.

(3) (a) Where research or experimentation is to be conducted on a minor child for a non-therapeutic purpose, the research or experimentation may only be conducted –

- (i) in such manner and on such conditions as may be prescribed;
- (ii) with the consent of the **[Minister]** relevant health research ethics committee;
- (iii) with the consent of the parent or guardian of the minor child, unless there are good reasons for doing away with the consent of the parent or guardian; and

- (iv) if the minor child is capable of understanding, the consent of the minor child.

(b) The **[Minister]** health research ethics committee may not give consent in circumstances where –

- (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult;
- (ii) the research or experimentation is not likely to significantly improve scientific understanding of the **[minor's]** minor child's condition, disease or disorder to such an extent that it will result in significant benefit to the minor child or other **[minors]** minor children;
- (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor child are contrary to public policy;
- (iv) the research or experimentation poses a significant risk to the health of the minor child; or
- (v) there is some risk to the health or wellbeing of the minor child and the potential benefit of the research or experimentation does not significantly outweigh that risk.”; and

(b) by the addition after subsection (3) of the following subsection:

“(4) Where research or experimentation is to be conducted on a minor child as contemplated in subsection (2) or (3), the research or experimentation may only be conducted if it is in the best interests of the minor child.”.

Amendment of section 79E of Act 61 of 2003, as inserted by section 5 of Act 12 of 2013

9. Section 79E of the principal Act is hereby amended by the substitution for paragraph (c) of subsection (2) of the following paragraph:

“(c) he or she is declared by the High Court to be of unsound mind or mentally disordered or **[is detained]** becomes a mental health care user under the **[Mental Health Act, 1973 (Act 18 of 1973)]** Mental Health Care Act, 2002 (Act 17 of 2002);”.

Amendment of section 82 of Act 61 of 2003, as substituted by section 5 of Act 12 of 2013

10. Section 82 of the principal Act is hereby amended by the insertion after substitution (1) of the following subsection:

“(1A) The health officer or inspector must, upon entering the premises or health establishment, show proof of identity and his or her certificate of appointment as health officer or inspector to the person in charge of such premises or health establishment.”

Substitution of section 86 of Act 61 of 2003, as substituted by section 5 of Act 12 of 2013

11. The following section is hereby substituted for section 86 of the principal Act:

“(1) A health officer or an inspector may, subject to section 86A, without a warrant exercise any power referred to in section 84 (1) if –
(a) the person who is competent to do so consents to such exercise; or
(b) there are reasonable grounds to believe that a warrant would be issued in terms of section 84 (5) and that the delay in obtaining the warrant would defeat the object of the warrant.

“(2) The health officer or inspector must, upon entering the premises or health establishment, show proof of identity and his or her certificate of appointment as health officer or inspector to the person in charge of that premises or health establishment.”

Amendment of section 90 of Act 61 of 2003, as amended by section 6 of Act 12 of 2013

12. Section 90 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

“(2) The Minister, subject to the Medicines and Related Substances **[Control]** Act, 1965 (Act 101 of 1965), and after consultation with the National Health Research Ethics Council, may make regulations regarding research on human subjects.”

Short title and commencement

13. This Act is called the National Health Amendment Act, 2017, and takes effect on a date fixed by the President by proclamation in the *Gazette*.

Annexure D

National Health Act: Commencement of sections

| Section | Act | Commencement | Proclamation |
|---------------------------|---|--|--|
| Preamble | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Section 1 | Act 61 of 2003 Amended by Act 12 of 2013 | 2 May 2005 Amendment: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Amendment: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| authorised institution | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| blood product | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Board | Inserted by s1(a) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| central hospital | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| certificate of need | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chief Executive Officer | Inserted by s1(b) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| communicable disease | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Constitution | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| death | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Director-General | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| district health council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| essential health services | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |

| Section | Act | Commencement | Proclamation |
|---|--|---------------------|---|
| embryo | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Forum of Statutory Health Professional Councils | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| gamete | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| gonad | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health agency | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health care personnel | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health care provider | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health district | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health establishment | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health nuisance | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health officer | Act 61 of 2003 Substituted by s1(c) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| health research | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health research ethics committee | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health services | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health technology | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| health worker | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| hospital | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |

| Section | Act | Commencement | Proclamation |
|---|---|---------------------|---|
| inspector | Inserted by s1(d) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| Inspectorate for Health Establishments | Deleted by s1(e) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| military health establishment | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Minister | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| municipal council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| municipal health services | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| municipality | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| national department | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| National Health Council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| national health policy | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| National Health Research Committee | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| National Health Research Ethics Council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| national health system | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| non-communicable disease | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| norm | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Office | Inserted by s1(f) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| Ombud | Inserted by s1(f) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |

| Section | Act | Commencement | Proclamation |
|--|--|---------------------|---|
| | Act 12 of 2013 | | |
| Office of Standards Compliance | Deleted by s1(g) of Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| oocyte | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| organ | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| organ of state | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| pollution | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| premises | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| prescribed | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| primary health care services | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| private health establishment | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| provincial department | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Provincial Health Council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| public health establishment | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| rehabilitation | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| relevant member of the Executive Council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| statutory health professional council | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| this Act | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| tissue | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |

| Section | Act | Commencement | Proclamation |
|------------------|----------------|---------------------|--|
| use | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| user | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| zygote | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 1 | | | |
| 2 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 3 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 4 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 2 | | | |
| 5 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 6 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 7 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 8 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 9 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 10 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 11 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 12 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 13 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 14 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 15 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 16 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |

| Section | Act | Commencement | Proclamation |
|------------------|---|--|--|
| 17 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 18 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 19 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 20 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 3 | | | |
| 21 | Act 61 of 2003 Amended by section 2 of Amendment Act 12 of 2013 S21(2)(f) substituted | 2 May 2005 Amendment: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Amendment: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 22 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 23 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 24 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 4 | | | |
| 25 | Act 61 of 2003 Amended by section 3 of Amendment Act 12 of 2013 S25(2)(l) substituted | 2 May 2005 Amendment: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Amendment: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 26 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 27 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 28 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 5 | | | |
| 29 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |

| Section | Act | Commencement | Proclamation |
|------------------|----------------|---------------------|---|
| 30 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 31 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 32 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 33 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 34 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 6 | | | |
| 35 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 36 | Act 61 of 2003 | To be proclaimed | Proc 21 in GG 37501 of 31 March 2014 (which had declared the date of commencement of ss. 36 – 40 as 1 April 2014) declared invalid and set aside in <i>President of the Republic of South Africa and Others v South African Dental Association and Another</i> 2015 JDR 0103 (CC) |
| 37 | Act 61 of 2003 | To be proclaimed | Do |
| 38 | Act 61 of 2003 | To be proclaimed | Do |
| 39 | Act 61 of 2003 | To be proclaimed | Do |
| 40 | Act 61 of 2003 | To be proclaimed | Do |
| 41 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 42 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 43 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 44 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 45 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |

| Section | Act | Commencement | Proclamation |
|------------------|----------------|---------------------|--|
| 46 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 47 | Act 61 of 2003 | To be proclaimed | Commencement to be proclaimed. Amendment to s47 proclaimed by Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| Chapter 7 | | | |
| 48 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 49 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 50 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 51 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 52 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 8 | | | |
| 53 | Act 61 of 2003 | 30 June 2008 | Proc R22 of 2008 in GG 31187 of 27 June 2008 |
| 54 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 55 | Act 61 of 2003 | 17 May 2010 | Proc R20 of 2010 in GG 33187 of 14 May 2010 |
| 56 | Act 61 of 2003 | 17 May 2010 | Proc R20 of 2010 in GG 33187 of 14 May 2010 |
| 57 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 58 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 59 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 60 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 61 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 62 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |

| Section | Act | Commencement | Proclamation |
|-------------------|---|---------------------|--|
| 63 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 64 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 65 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 66 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 67 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 68 | Act 61 of 2003 | 17 May 2010 | Proc R20 of 2010 in GG 33187 of 14 May 2010 |
| Chapter 9 | | | |
| 69 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 70 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 71 | Act 61 of 2003 | 1 March 2012 | Proc 11 in GG 35081 of 27 February 2012 |
| 72 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 73 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 74 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 75 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 76 | Act 61 of 2003 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| Chapter 10 | | | |
| 77 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | To be proclaimed | Commencement to be proclaimed. Substitution proclaimed by Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 78 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | To be proclaimed | Commencement to be proclaimed. Substitution proclaimed by Proc 37 of 2013 in GG 36787 of 30 August 2013 |

| Section | Act | Commencement | Proclamation |
|----------------|--|---------------------|--|
| 79 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | To be proclaimed | Commencement to be proclaimed. Substitution proclaimed by Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79A | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79B | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79C | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79D | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79E | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79F | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79G | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79H | Inserted as part of substitution of Chapter 10 by Amendment Act | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |

| Section | Act | Commencement | Proclamation |
|----------------|--|--|---|
| | 12 of 2013 | | |
| 79I | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79J | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 79K | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 80 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 81 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Amendment: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Amendment: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 81A | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 81B | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 82 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 82A | Inserted as part of substitution of Chapter 10 by Amendment Act | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |

| Section | Act | Commencement | Proclamation |
|----------------|--|---|---|
| | 12 of 2013 | | |
| 83 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | To be proclaimed | Commencement to be proclaimed. Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 84 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 85 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 86 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 86A | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 87 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 88 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 88A | Inserted as part of substitution of Chapter 10 by Amendment Act 12 of 2013 | 2 September 2013 | Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| 89 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 Substitution: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Substitution: Proc 37 of 2013 in GG 36787 of 30 August 2013 |

| Section | Act | Commencement | Proclamation |
|-------------------|--|--|--|
| Chapter 11 | | | |
| 90 | Act 61 of 2003 Amended by Act 12 of 2013 <ul style="list-style-type: none"> •Intro to ss(1) substituted •Paragraphs (1)(b) and (1)(c) substituted •Paragraph (1)(cA) inserted •Paragraph (1)(n) substituted •Ss (1A) inserted | 2 May 2005 Amendment: 2 September 2013 | Proc 19 of 2005 in GG 27503 of 18 April 2005 Amendment: Proc 37 of 2013 in GG 36787 of 30 August 2013 |
| Chapter 12 | | | |
| 91 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 92 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 93 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |
| 94 | Act 61 of 2003 Substituted by Amendment Act 12 of 2013 | 2 May 2005 | Proc 19 of 2005 in GG 27503 of 18 April 2005 |

Annexure E

Pharmacy Bill

ACT

To provide for the establishment of the South African Pharmacy Council and for its objects and general powers; to extend the control of the council to the public sector; and to provide for pharmacy education and training, requirements for registration, the practice of pharmacy, the ownership of pharmacies and the investigative and disciplinary powers of the council; and to provide for matters connected therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:-

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Definitions

1. In this Act, unless the context otherwise indicates-

'body corporate' means any legal person registered in terms of any Act in operation in the Republic.

'council' means the council referred to in section 2;

'Director-General' means the Director-General: Health or his or her nominee;

'medicine' means medicine as defined in section 1 of the Medicines and Related Substances Act, 1965;

'member' means a member of the council;

'Minister' means the member of Cabinet responsible for Health;

'pharmaceutical technician' means a person registered as such under this Act;

'pharmacist' means a person registered as such under this Act;

'pharmacist intern' means a person registered as such in terms of this Act;

'pharmacist's assistant' means a person registered as such under this Act;

'pharmacy' means any place wherein or from which any service specially pertaining to the scope of practice of a pharmacist is provided;

'pharmacy practice' means acts specially pertaining to the scope of practice of a pharmacist as prescribed in terms of section 24 of this Act;

'pharmacy student' means a person registered as such in terms of this Act;

'pharmacy support personnel' means the various categories of support personnel as prescribed and registered as such in terms of this Act;

'prescribe' or **'prescribed'** means prescribe or prescribed by regulation;

'president' or **'vice-president'** means the president or vice-president of the council and includes a person lawfully acting as president or vice-president of the council, as the case may be, and for the purpose of section 31 (1), a member acting as chairman at an inquiry referred to in section 30;

'register', when used as a noun, means a register kept in accordance with the provisions of this Act, and when used in relation to any class or a member of any class of persons in respect of which a register is kept, means the register kept for that class and when used as a verb, means to enter in such register; the words **'registered'**, **'registrable'**, **'registration'** and all other words formed with or derived from the word **'register'** having a corresponding meaning;

'registrar' means the registrar of the council appointed in terms of section 4 of this Act or a person lawfully acting in that capacity;

'regulation' means any regulation made under this Act;

'responsible pharmacist' means a natural person who is a pharmacist and who shall be responsible to the council for complying with all the provisions of this Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision;

'scheduled substance' means a scheduled substance as referred to in the Medicines and Related Substances Act, 1965 (Act 101 of 1965);

'this Act' includes any proclamation, regulation, rule or order made under this Act;

'unprofessional conduct' means improper, disgraceful or dishonour- able or unworthy conduct or conduct which, when regard is had to the profession of a person

who is registered in terms of this Act, is improper or disgraceful or dishonourable or unworthy.

CHAPTER 1

ESTABLISHMENT OF THE SOUTH AFRICAN PHARMACY COUNCIL, ITS OBJECTS, GENERAL POWERS AND FUNCTIONS

Establishment of South African Pharmacy Council

2. (1) The South African Pharmacy Council established under section 2 of the Pharmacy Act 53 of 1974 continues to exist despite the repeal of that Act.

(2) The head office of the council shall be situated in Pretoria.

Objects of council

3. The objects of the council shall be –

- (a) to assist in the promotion of the health of the population of the Republic;
- (b) to advise the Minister or any other person on any matter relating to pharmacy;
- (c) to promote the provision of pharmaceutical care which complies with universal norms and values, in both the public and the private sector, with the goal of achieving definite therapeutic outcomes for the health and quality of life of a patient;
- (d) to uphold and safeguard the rights of the general public to universally acceptable standards of pharmacy practice in both the public and the private sector;
- (e) to establish, develop, maintain and control universally acceptable standards –
 - (i) in pharmaceutical education and training;
 - (ii) for the registration of a person who provides one or more or all of the services which form part of the scope of practice of the category in which such person is registered;
 - (iii) of the practice of the various categories of persons required to be registered in terms of this Act;
 - (iv) of professional conduct required of persons to be registered in terms of this Act; and
 - (v) of control over persons registered in terms of this Act by investigating in accordance with this Act, complaints or accusations relating to the conduct of registered persons;
- (f) to be transparent to the profession and the general public in achieving its objects and in performing its functions and executing its powers; and

- (g) to maintain and enhance the dignity of the pharmacy profession and the integrity of persons practising that profession.

General powers of council

4. The functions of the council shall be to endeavour to achieve the objects for which it was established, and for the purpose of achieving those objects the council shall, subject to the provisions of this Act, have power in addition to any other powers vested in it by this Act –

- (a) to cause copies of the registers or of supplementary lists showing amendments of the registers, to be printed and published;
- (b) to issue extracts from the registers and to charge such fees in respect thereof as may be prescribed;
- (c) to require any registered person to pay to the council the prescribed annual fee;
- (d) in such circumstances as may be prescribed, or where otherwise authorized by this Act, to remove any name from the registers or, upon payment of the prescribed fee, to restore it thereto;
- (e) to appoint examiners and moderators, conduct examinations and grant certificates, and to charge such fees in respect of such examinations or certificates as may be prescribed;
- (f) to approve, on such conditions as it may deem fit, the training of pharmacists;
- (g) subject to the provisions of this Act, to register a person as a pharmacist, to inspect the records and accounts of or investigate the activities at a pharmacy carried on by a person so registered, or to require any person so registered to submit to the council such information as the council may deem necessary;
- (h) in such circumstances as may be prescribed, to suspend or cancel any registration entitling a person to carry on the profession of a pharmacist;
- (i) to consider any matter affecting the pharmacy profession, and to make representations or take such action in connection therewith as the council deems advisable;
- (j) on the application of any person, to recognize any qualifications held by him (whether such qualifications have been obtained in the Republic or elsewhere) as being equal, either wholly or in part, to any prescribed qualifications, whereupon such person shall, to the extent to which the qualifications have so been recognized, be deemed to hold such prescribed qualifications;
- (k) to perform such other functions as may be prescribed;

- (l) to designate the office-bearers of the council and to determine the procedure for the election of office-bearers;
- (m) to appoint any committee it may deem necessary and to delegate any of its powers to any such committee and to prescribe the conditions of such delegation, including the power to subdelegate any delegated power to any member of its staff or officer duly appointed in terms of this Act;
- (n) to co-opt a representative of a professional board established in terms of this Act on to the council: Provided that such a representative shall not have the right to vote;
- (o) to co-opt any person on to any of its committees that it may deem necessary;
- (p) to determine the number of meetings to be held by the council and its committees, the procedure applicable to such meetings, the manner in which special meetings shall be convened and the procedures applicable to such special meetings;
- (q) to determine the quorum requirements for a meeting of the council and any of its committees;
- (r) to determine the manner in which decisions shall be taken at a meeting of the council or any of its committees;
- (s) to appoint or dismiss a registrar or such other staff members as it may deem necessary and to determine their conditions of service: Provided that the appointment or dismissal of the registrar shall be subject to the approval of the Minister;
- (t) to appoint any officer or inspector to perform any duty or act on behalf of the council in terms of this Act and to prescribe and determine their powers and duties;
- (u) to delegate any of its powers to any officer or inspector and in general to regulate the duties of any officer or inspector;
- (v) to delegate to any organisation such powers as it may deem necessary from time to time;
- (w) to determine the manner in which the business of the council shall be conducted and the manner in which the accounts of the council shall be kept;
- (x) to purchase or in any other manner acquire property, which shall include but not be limited to the acceptance of donations, or to sell, let, mortgage or in any other manner dispose of any property of the council;
- (y) to administer the assets of the council or any assets to be held in trust for the benefit of the council;
- (z) to settle the liabilities of the council;
- (zA) to establish and administer a pension or a provident fund for the employees of the council;
- (zB) to institute, defend and proceed with any legal action in its own name;

- (zC) to borrow money on such terms and conditions as the council may determine and to encumber any of the assets of the council as security therefor;
 - (zD) to pay to any members of the council, office-bearers, committee members, officers appointed in terms of this Act, or any other person or any witness *subpoenaed*, including persons employed by the State, such allowances as it may determine from time to time;
 - (zE) to determine the fees payable to the council for services performed by the council in terms of this Act or for any other reason the council may decide on;
 - (zF) to require any person or institution registered in terms of this Act, or involved in pharmacy practice or offering pharmaceutical education or training, to furnish the council with the information the council requires;
 - (zG) to establish professional boards for pharmacy support personnel registered in terms of this Act, when the council, in consultation with the Minister, deems it necessary; and
 - (zH) to prescribe the scope of practice of the various categories of persons registered in terms of this Act, and
- generally, to do all such things as the council deems necessary or expedient to achieve the objects of this Act.

Constitution of council

5. (1) The council shall consist of 25 persons elected or appointed as follows:
- (a) nine pharmacists registered with the council, resident in the Republic of South Africa and elected by pharmacists;
 - (b) nine pharmacists nominated by the Members of the Executive Council responsible for health matters in the provinces of the Republic and appointed by the Minister;
 - (c) an officer of the Department appointed by the Minister;
 - (d) two pharmacists who are members of the staff of a university at which provision is made for the education and training of pharmacists, nominated by such a university and appointed by the Minister: Provided that such pharmacists shall not be from the same university;
 - (e) four other persons appointed by the Minister, one of whom shall be a person appointed on account of his or her legal knowledge.
- (2) The council shall have a president and vice-president, and all members of the council shall be entitled to vote during the election of the president and the vice-president and other office-bearers of the council.

(3) Whenever the persons entitled in terms of subsection (1) (a) to elect any member of the council, fail, before the expiry of the prescribed period, to elect any person to fill any vacancy in respect of the office of such a member, the Minister may, after consultation with the executive committee of the council, appoint a pharmacist who shall thereafter be deemed to have been duly elected.

(4) Subject to the provisions of section 7, the members of the council shall hold office for a period of five years, but shall be eligible for reappointment or re-election, as the case may be, for one term only.

(5) The procedure to be followed at the election of the nine members referred to in subsection (1) (a) shall be prescribed.

(6) If anything required to be done in terms of this Act in connection with the appointment or election or nomination of any member is omitted or not done within the time or in the manner required by this Act, the Minister may order all such steps to be taken as may be necessary to rectify the omission or error, or may validate anything done in any irregular manner, in order to give effect to the objects of this Act.

(7) The registrar shall give notice in the *Gazette* of the appointment or election of any member of the council, the date of such appointment or election and the period for which such member has been appointed or elected.

(8) Any person who makes or causes to be made a false declaration in connection with the election contemplated in subsection (1) (a), shall be guilty of an offence and liable on conviction to a fine not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.

(9) The Minister may, in the public interest, and after consultation with a person or body responsible for the appointment or election of a member, terminate the membership of any member of the council after giving written notice to the member and affording the member an opportunity to furnish reasons to the Minister why his or her membership should not be terminated.

(10) The Minister shall notify the registrar in writing of the names of the members appointed in terms of subsection (1) of this Act.

Vacation of office and the filling of vacancies

- 6.** (1) A member of the council shall vacate his office if –
- (a) his estate is sequestrated;
 - (b) he is or becomes disqualified under this Act from practising his profession;
 - (c) he becomes a mental health care user as defined in section 1 of the Mental Health Care Act, 2002 (Act 17 of 2002);

- (d) he is convicted of an offence in respect whereof he is sentenced to imprisonment without the option of a fine;
- (e) he ceases to be a South African citizen;
- (f) he has been absent from more than two consecutive ordinary meetings of the council without the council's leave;
- (g) he or she ceases to hold any qualification necessary for his or her appointment or tenders his or her resignation in writing to the Minister and the Minister accepts his or her resignation; or
- (h) the Minister, in the public interest, terminates his membership.

(2) Every vacancy on the council arising from a circumstance referred to in subsection (1) and every vacancy caused by the death of a member shall be filled by appointment by the Minister of a person nominated by the council, and every member so appointed shall hold office for the unexpired portion of the period for which the vacating member was appointed.

Fees of council

7. (1) All fees payable in terms of this Act shall be paid to the council and shall be utilised as its funds for defraying expenses incurred in connection with the performance of its functions.

CHAPTER 2

REGISTRATION OF PHARMACISTS AND BODIES CORPORATE CARRYING ON BUSINESS AS A PHARMACIST AND MAINTENANCE OF REGISTERS

Registration

8. (1) No person shall be entitled to provide the services which form part of the services specially pertaining to the scope of practice of a pharmacist or assist therewith, unless he or she is duly registered in one of the categories prescribed in terms of this Act.

(2) No person shall practise as a specialist pharmacist or shall conduct himself or herself as such a specialist, or shall in any other manner profess to be a person in respect of whom any such speciality has been registered, unless the speciality in question has been registered in terms of this Act in respect of such person.

(3) Every person who has been suspended from practising in terms of this Act or whose name has been removed from a register, shall be disqualified from providing any of the services or performing any act specially pertaining to the scope of practice of

pharmacy as determined in the practice rules made by the council, and his or her registration certificate shall be deemed to be withdrawn until the period of suspension has expired or until his or her name has been restored to the register by the council.

(4) Any person who has been suspended from practising in terms of this Act or whose name has been removed from a register in terms of subsection 36 (1) (c) and whose name has not been restored to such register shall not be entitled to remain, or be registered as the owner of a pharmacy, or hold any beneficial interest in a pharmacy.

Registration of persons and recording of licensed premises

9. With regard to the registration of persons and the recording of licensed pharmacy premises in terms of this Act:

- (a) the various categories of persons who may be registered and pharmacies which may be recorded in terms of this Act shall be prescribed;
- (b) the requirements and conditions for registration, removal, restoration or reinstatement of the various categories of persons shall be prescribed;
- (c) the council shall require any person who is entitled and intends to provide one or more or all of the services which are deemed to be services specially pertaining to the scope of practice of a pharmacist, and pharmacy support personnel, or any person who assists in the provision thereof, to register with the council;
- (d) the council shall keep, amend, correct and maintain such registers in the format as the council deems necessary and cause copies of such registers to be printed at the discretion of the council;
- (e) the council may remove, in the prescribed manner, the name of any person from the relevant register;
- (f) the council may restore, in the prescribed manner, the name of any person to the relevant register on such conditions as the council may deem fit;
- (g) the council may issue, in the prescribed manner, any certificate the council may deem necessary, on such conditions as it may deem fit, and may cancel any certificate in the prescribed manner;
- (h) the council may refuse, in the prescribed manner, to record any person who or a pharmacy which does not comply with the prescribed conditions; and
- (i) the council may require, in the prescribed manner, all persons authorised in terms of section 12 to record the prescribed information with the council.

Community service

10. (1) Notwithstanding sections 8 and 9, any person registering for the first time as a pharmacist in terms of this Act shall –

- (a) perform remunerated pharmaceutical community service for a period of one year in terms of the regulations contemplated in subsection (2); and
- (b) be entitled to registration to practise as a pharmacist on the completion of such service.

(2) The Minister may, after consultation with the council, make regulations regarding the performance of the pharmaceutical community service, including but not limited to –

- (i) the place at which it is to be performed;
- (ii) the conditions of employment.

Licensing of pharmacies

11. (1) A person authorised in terms of section 12 to own a pharmacy shall in the prescribed manner, specifying the prescribed particulars, apply to the Director-General for a licence for the premises wherein or from which such business shall be carried on and the Director-General may be entitled to issue or refuse such licence on such conditions as he or she may deem fit.

(2) A person issued with a licence in terms of subsection (1) shall notify the council thereof in writing and on production of the said licence the council shall record the name, address, date of licence, licence number and any other particulars as prescribed.

(3) A licence issued in terms of subsection (1) may be subject to conditions as determined by the Director-General.

(4) A pharmacy shall, subject to such conditions as may be prescribed, be conducted under the continuous personal supervision of a pharmacist, in accordance with good pharmacy practice as determined in the rules made by the council.

(5) The pharmacist referred to in subsection (4) shall be responsible to the council for any act performed by or on behalf of the body corporate in question, including any omission to perform an act required to be performed by or on behalf of the body corporate, which may involve disciplinary action by the council, unless he or she satisfies the council that the responsibility for such act rests upon a pharmacist other than himself or herself employed by the body corporate.

(6) The council shall have the right to inspect premises in which the business of a pharmacy is carried on in terms of this Act, and the registrar shall provide the Director-General and the person who made the application in terms of subsection (1) with a

written report of the findings of its inspection if it has been found that the inspected premises are not suitable for the business of a pharmacy.

(7) The Director-General may cancel or suspend any licence contemplated in subsection (1) which does not comply with the licensing conditions as determined in terms of subsection (3), after giving notice in writing to the owner of the pharmacy or the responsible pharmacist, and affording the owner or the responsible pharmacist an opportunity to furnish reasons why the licence should not be cancelled or suspended.

(8) If a licence is suspended or cancelled, the premises shall from the date of the suspension or the cancellation be considered to be unsuitable for the carrying on of the business of a pharmacy.

(9) A person registered to carry on the business of a pharmacy at the commencement of this Act shall be deemed to be licensed in terms of subsection (1).

(10) The Director-General in consultation with the council may close a pharmacy which is being conducted in contravention of this Act and the Medicines and Related Substances Act, 1965, or which does not comply with the licensing conditions, after giving notice to the owner or the responsible pharmacist, and affording the owner or the responsible pharmacist an opportunity to furnish reasons to the Director-General why the pharmacy should not be closed.

(11) Any person aggrieved by a decision of the Director-General or the council, as the case may be, may within the prescribed period, in the prescribed manner appeal against such decision to an appeal committee appointed by the Minister: Provided that the chairperson of such appeal committee shall be a person appointed on account of his or her knowledge of the law.

Ownership of pharmacies

12. The Minister may prescribe who may own a pharmacy, the conditions under which such person may own such pharmacy, and the conditions upon which such authority may be withdrawn.

Removal from and restoration to register of name

13. (1) The council may direct the registrar to remove from the register the name of any person –

- (a) who has been absent from the Republic during the three years preceding such removal;

- (b) who has failed to notify the registrar, within a period of three months as from the date of an enquiry sent by the registrar by registered letter to the address appearing in the register in respect of such person, of his present address;
- (c) who has requested that his name be removed from the register, in which case such person may be required to lodge with the registrar an affidavit to the effect that no disciplinary or criminal proceedings are being or are likely to be taken against him;
- (d) who has failed to pay to the council, within three months as from the date on which it became due for payment, any prescribed annual fee;
- (e) who has failed to furnish the registrar, within a period to be determined by the council, with such information as the registrar may require in terms of regulations made under this Act; or
- (f) whose name has been removed from the register, record or roll of any university, college, society or other body from which that person received the qualification by virtue of the holding whereof he was registered.

(2) Notice of the removal, in terms of subsection (1), of his name from the register, or of the removal, in terms of section 9 (4), of an entry from the register, shall be given by the registrar to the person concerned by way of a registered letter addressed to such person at the address appearing in respect of him in the register and such person shall, as from the date on which notice has so been given, cease to practise as a pharmacist or to perform any act which he, in his capacity as a registered person, was entitled to perform, and any registration certificate issued to him shall be deemed to be cancelled, until such time as his name or the entry removed from the register in terms of section 9 (4), as the case may be, is restored to the register.

(3) The name of a person whose name has in terms of this section been removed from the register, or an entry removed from the register in terms of section 9 (4), shall be restored to the register by the registrar upon the person concerned-

- (a) applying on the prescribed form for such restoration;
- (b) paying the fee prescribed in respect of such restoration (if any); and
- (c) complying with such other requirements as the council may determine.

Appeal against refusal to register or against removal of name

14. (1) Any person aggrieved by the council's decision –

- (a) to refuse to register him or to enter in the appropriate register any degree, diploma, certificate or additional qualification which he desires, and maintains to be entitled, to have so entered in terms of the provisions of this Act; or

(b) to remove from the register his name or any degree, diploma, certificate or additional qualification which he maintains to be entitled to have entered in the register in terms of the provisions of this Act,

may, after notice to the council and within a period of two months after the date of such decision, appeal against such decision to the provincial or local division of the Supreme Court of South Africa having jurisdiction in the area in which the appellant normally resides.

(2) The court may dismiss such appeal or, if it is of the opinion that the council has not acted in accordance with the provisions of this Act, may make an order reversing or modifying the council's decision or it may remit the matter to the council for further consideration or make such other order, including an order as to costs, as it may deem appropriate.

Publication of registers

15. The registrar shall, at intervals to be determined by the council and according to the instructions and under the authority of the council, cause copies of the registers, or of supplementary lists showing all alterations, additions, revisions and deletions made since the last publication of the complete registers, to be printed and published.

Register as proof

16. A copy of the last published issue of a register or any supplementary list purporting to be printed and published under the authority of the council shall be *prima facie* proof, in all legal proceedings, of the facts therein recorded, and the absence of the name of any person from such copy shall be proof, until the contrary is proved, that such person is not registered according to the provisions of this Act: Provided that in the case of any person whose name –

- (a) does not appear in such copy, or whose name has been added to the register after the date of the last published issue thereof, a certified copy under the hand of the registrar of the entry of the name of such person in the register, shall be proof that such person is registered under the provisions of this Act;
- (b) has been removed from the register since the date of the last published issue thereof and has not been restored thereto, a certificate under the hand of the registrar that the name of such person has been removed from the register shall be proof that such person is not registered according to the provisions of this Act.

Duplicate registration certificate, extract from register or certificate

17. (1) If the registrar is satisfied –

- (a) on proof submitted by the registered person concerned, that a registration certificate has been destroyed; or
- (b) by virtue of an affidavit submitted by the registered person concerned, that a registration certificate has been lost,

he may issue a duplicate registration certificate to that person upon payment of the prescribed fee.

(2) The registrar may issue a certified extract from the register or a certificate under his hand as provided in section 16 to any person upon payment of the prescribed fee.

Registration of additional qualifications and of specialities

18. (1) (a) The council may from time to time by notice in the *Gazette* make rules providing for the recognition by the council of the degrees, diplomas or certificates which may be registered as additional qualifications, and only qualifications so recognized shall be registrable under this section.

(b) The Minister may from time to time, on the recommendation of the council, prescribe the specialities which may be registered as specialities, and only specialities so prescribed shall be registrable under this section.

(2) Any person who desires to have a degree, diploma or certificate other than the degree, diploma or certificate by virtue of which he has in the first instance been registered, or who desires to have a prescribed speciality contemplated in subsection (1), registered, shall apply to the registrar, submitting such documentary proof that he holds the additional qualification in question as the board may require, or, in the case of an application for registration of a speciality, submitting proof that he complies with the prescribed requirements, and if the registrar is satisfied that such additional qualification is a degree, diploma or certificate recognized in terms of subsection (1), or, in respect of a speciality, that such speciality has been prescribed and that the prescribed requirements have been complied with, he shall, upon payment of the prescribed fee, cause such degree, diploma or certificate, or speciality, as the case may be, to be entered in the register.

(3) Any person whose application for registration of a speciality has been refused by the registrar on the ground of non-compliance with any prescribed requirement, may apply to the registrar to be permitted by the council to sit for an examination referred to in subsection (4) in respect of the speciality for which he desires registration, before

examiners appointed by the council and on a date and at a place determined by the council.

(4) The Minister may from time to time on the recommendation of the council make regulations relating to examinations which shall be required for the purposes of subsection (3) in respect of the prescribed specialities contemplated in subsection (1), and relating to fees which shall be paid by candidates for such examinations.

(5) If any person referred to in subsection (3) has passed, in accordance with the relevant regulations, any examination referred to in subsection (4) in respect of the speciality for which he desires registration, the registrar shall on payment of the prescribed fee cause the speciality concerned to be entered in the register in respect of the person concerned.

(6) (a) The registrar shall, on the instructions of the council, remove from the register any degree, diploma or certificate registered as an additional qualification in terms of this section, if in respect of such qualification the name of the holder thereof has been removed from the roll, register or record of the university, college, society or other body from which that person received such qualification.

(b) The registrar shall, on the instructions of the council, remove from the register any speciality registered in terms of this section, if in the opinion of the council, in the case of a person referred to in subsection (2), such person has ceased to comply with any prescribed requirement for the registration of the speciality in question, or if, in the case of any person in respect of whom a speciality is registered, such person has lodged with the registrar a written application for the removal of the speciality in question from the register.

(c) A degree, diploma or certificate removed in terms of paragraph (a), or a speciality removed in terms of paragraph (b), shall on the instruction of the council be restored by the registrar to the register upon the person concerned –

- (i) applying on the prescribed form for such restoration;
- (ii) paying the fee prescribed in respect of such restoration (if any); and
- (iii) complying in the opinion of the council with such other requirements (if any) as the council may determine.

(7) No registered person shall take, use or publish in any way whatsoever any name, title, description or symbol indicating or calculated to lead persons to infer that he possesses any professional qualification which is not shown in the register against his name.

(8) No registered person shall practise as a pharmacist who professes to be a specialist in respect of a prescribed speciality contemplated in subsection (1), or shall hold himself out as such a specialist, or shall in any other manner profess to be a person

in respect of whom any such speciality has been registered, unless the speciality in question has been registered in terms of this section in respect of such person.

Penalties for practising as unregistered pharmacist

19. (1) Subject to the provisions of subsection (3), any person who, not being registered as a pharmacist –

- (a) for gain practises as a pharmacist, or carries on business as a pharmacist or for gain performs any act specially pertaining to the profession of a pharmacist; or
- (b) pretends, or by any means whatsoever holds himself out, to be a pharmacist (whether or not he purports to be registered), or uses the name of pharmacist or any name, title, description or symbol indicating or calculated to lead persons to infer that he possesses a degree or diploma or other pharmaceutical qualification or that he is registered under this Act, or in describing his business activities or premises uses the term 'pharmacy' or 'chemist's shop' or 'drug store' or any other term of like meaning,

shall be guilty of an offence and on conviction liable to a fine not exceeding the amount determined by the Minister in consultation with the Minister of Justice from time to time by notice in the *Gazette*.

(2) The acts prescribed in terms of section 25 (a) (i) shall for purposes of subsection (1) be deemed to be acts specially pertaining to the profession of a pharmacist.

(3) The provisions of subsections (1) and (2) shall not prohibit –

- (a) the keeping of medicines or the supply of medicines to his or her own patients or clients by any medical practitioner, dentist, practitioner, veterinarian or nurse in accordance with the provisions of the Medicines and Related Substances Act, 1965.
- (b) the employment under the supervision of a pharmacist –
 - (i) of a pharmacist intern in the pharmacy in which he is undergoing his practical training;
 - (ii) of a pharmacist's assistant, pharmaceutical technician or other pharmaceutical support personnel;
- (c) the manufacture or packing of any medicine or medicinal or chemical substance by a person referred to in subsection (4), by virtue of a permit granted in terms of that subsection;
- (d) the handling of medicines or the supply of medicines to members of the armed forces, under the supervision of a medical practitioner or pharmacist, by members

of the medical service of the armed forces provided such members of the said medical service have undergone training therein;

- (e) the keeping of medicines and its supply to patients in hospitals or other institutions for the treatment of sick persons, under the direction of a medical practitioner and in accordance with the provisions of the Medicines and Related Substances Act, 1965, by any person registered or enrolled under the Nursing Act, 2005 (Act 33 of 2005);
- (f) the keeping of medicine and its supply by any person or organization performing a health service and authorized in writing by the Director-General acting after consultation with the council, to acquire medicines for the performance of such service.

(4) The Minister may in consultation with the council grant any person not registered in term of this Act authority to perform a service specially pertaining to the scope of practice of a pharmacist, or in writing exempt any person from the provision of this Act, on such conditions as he or she may determine.

(5) If he or she is of the opinion that it is in the public interest to do so, the Director-General may, pending the Ministers' decision in respect of an application for a authorisation referred to in subsection (4), grant a provisional authorisation to the applicant concerned, authorising him or her to manufacture, pack or sell any medicine or medicinal or chemical substance specified in such provisional authorisation, subject to such conditions to be determined by the said Director-General and set out in the provisional authorisation.

Penalty for false representation inducing registration, false entry in register and impersonation

20. Any person who –

- (a) procures or attempts to procure for himself or any other person registration under this Act or any certificate, licence, permit, order or prescription referred to in this Act by means of a false representation, whether verbally or in writing, or aids or abets any person in so doing; or
- (b) makes or causes to be made any unauthorized entry or alteration in or removal from a register or a certified copy thereof or extract therefrom or on any certificate issued under this Act; or
- (c) wilfully destroys or damages or renders illegible or causes to be destroyed, damaged or rendered illegible any entry in a register or, without the permission of the holder thereof, any certificate issued under this Act; or

- (d) forges or, knowing it to be forged, utters any document purporting to be a certificate issued under this Act; or
 - (e) impersonates any person registered under this Act,
- shall be guilty of an offence and on conviction liable to a fine not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.

Limitations in respect of unregistered persons and issue of licences (32)

21. (1) No remuneration shall be recoverable in respect of any act specially pertaining to the profession of a pharmacist, when performed by a person who is not authorized under this Act to perform such act for gain.

(2) Subject to the provisions of section 19 (3), no person other than a registered person holding the necessary qualifications shall be eligible for or entitled to hold any appointment to any establishment, institution, body, organization or association, whether public or private, if such appointment involves the performance of any act which an unregistered person may not perform for gain.

(3) No licence required to be obtained by a pharmacist shall be issued by the authority empowered by law to issue such licence unless the person applying for such licence submits a registration certificate or certified extract from the register, referred to in section 17 (2), as proof that he is registered as a pharmacist.

CHAPTER 3

CONTROL OF PHARMACEUTICAL EDUCATION

Pharmacy education and training

22. The Minister may in consultation with the council make regulations to –
- (a) develop, establish, maintain and control standards of pharmacy education and training;
 - (b) require any institution or person intending to provide education and training to apply for the approval of such institution or person;
 - (c) evaluate and authorise any institution or person to offer education and training to qualify a person for registration in terms of this Act, lay down the conditions upon which such education and training may be provided and amend such conditions from time to time, or cancel or withdraw such authority;
 - (d) make rules regarding the evaluation of a person applying for registration in terms of this Act to ensure competence;

- (e) prescribe the unit standards for pharmaceutical education and training required from a person entitled to be registered in terms of this Act;
- (f) conduct a pre-registration examination or evaluation to ensure competence of a person applying for registration in terms of this Act;
- (g) conduct, recognise and control supplementary training of a person registered in terms of this Act;
- (h) recognise qualifications, competencies and skills for purposes of registration in terms of this Act;
- (i) determine the number of pharmacy support personnel or pharmacist interns who may be trained under the supervision of a pharmacist;
- (j) investigate or cause to be investigated any institution or premises recognised by the council for purposes of education and training in terms of this Act, or request such information as may be deemed necessary from such institution to enable the council to establish compliance with the requirements prescribed by the council relating to such education and training;
- (k) conduct examinations or evaluations for purposes of registration or continued registration in terms of this Act;
- (l) appoint or accredit examiners or moderators needed for purposes of conducting any examination or evaluation prescribed by the council;
- (m) award, cancel or withdraw certificates or documents issued in respect of any examination or training provided or recognised by the council;
- (n) upon notice to the institution and pharmacy students who may be affected thereby, and after furnishing reasons, withdraw further recognition of any qualification for purposes of registration in terms of this Act on such conditions as the council may deem fit;
- (o) require any person registered in terms of this Act to remain competent in the manner prescribed;
- (p) make rules as to the additional qualifications, specialities or titles that may be registered in terms of this Act.

Pharmacy education and training institutions

23. (1) No person shall be entitled to offer education and training for purposes of registration in terms of this Act, unless such institution or person and the education and training concerned have been approved by the council.

(2) Any person intending to offer education and training referred to in subsection (1) shall, before offering such education and training, apply to the council in the prescribed manner for the approval of such education and training, and of such institution or person.

(3) Any person who prevents a person authorised in terms of this Act to perform a function for or to act on behalf of the council from entering, at a reasonable time, an institution or premises offering education and training or who hinders such person in making therein or therefrom any investigation required to be done by the council, shall be guilty of an offence: Provided that the person carrying out the investigation shall produce proof of his or her identity and such authority, on request.

CHAPTER 4

CONDUCT OF PHARMACEUTICAL PRACTICE

Authorisation for provision and levies for services

24. (1) Except with the prior approval of the council, or authorised in terms of this Act, no person shall provide a service which pertains specially to the scope of practice of the various categories of persons, as laid down in terms of this Act.

(2) No person registered in terms of this Act, shall pay any person directly or indirectly or in any other manner reward him or her or it in connection with a prescription, issued by an authorised prescriber, in terms of the Medicines and Related Substances Act, 1965.

Pharmacy practice

25. With regard to the control of pharmacy practice –

- (a) the following shall be prescribed:
- (i) the scope of practice of persons registered in terms of this Act, or the services or acts which shall for purposes of this Act be deemed to be services or acts specially pertaining to pharmacists or pharmacy support personnel, and the conditions under which those services may be provided or the acts which may be performed;
 - (ii) the services which may be provided in the various categories of pharmacies, and the conditions under which these services shall be provided;
- (b) the council shall be entitled to make rules as to:
- (i) a code of conduct for pharmacists and other persons registered in terms of this Act;
 - (ii) what constitutes good pharmacy practice;

- (iii) the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees;
- (c) the council may approve the title or name under which a pharmacy may be conducted;
- (d) the council shall be entitled to investigate and inspect the practice and the conduct of the business of a pharmacy.

Restriction in respect of business names

26. (1) Subject to the provisions of subsections (2) and (3), no person shall carry on business as a pharmacist, either alone or in partnership with another person, under any name, title or description which is or includes in any form the surname of a natural person, living or dead, if the use of such name, title or description is calculated or likely to lead persons to infer that a person of that surname is or has been associated with the pharmacy business in question.

(2) The provisions of subsection (1) shall not prohibit –

- (a) the inclusion in the name, title or description of any pharmacy business of the surname of an owner thereof
- (b) the use in respect of any pharmacy business of any name, title or description under which that business has lawfully been carried on immediately prior to the commencement of this Act.

(3) The provisions of subsection (1) shall not apply in respect of any pharmacist whose business activities consists solely of the manufacture of medicines and the sale thereof to pharmacists or dealers and who does not carry on business as a retail pharmacist.

(4) Any person who contravenes any of the provisions of this section shall be guilty of an offence and on conviction liable to a fine not exceeding the amount 1 determined by the Minister from time to time by notice in the *Gazette*.

Continuation of pharmacy business by certain persons

27. Notwithstanding anything to the contrary in this Act contained –

- (a) the person responsible for reporting the estate of a person who owns a pharmacy and registered in terms of this Act to the Master, or the executor of the deceased estate of such person who owns a pharmacy may, subject to the laws relating to the administration of estates, for a period not exceeding 12 months after the death of such person who owns a pharmacy, and for an additional period not exceeding 12 months, continue the pharmacy business of the deceased, and such pharmacy

- business shall be conducted under the continuous personal supervision of a pharmacist;
- (b) the executor shall, within 30 days of his or her appointment, inform the council by registered mail of his or her appointment and of the name and registration number of the pharmacist who shall be responsible to the council in respect of the pharmacy business referred to in paragraph (a);
 - (c) the trustee in the insolvent estate of a pharmacist registered in terms of this Act or the liquidator of a body corporate entitled to carry on business as a pharmacist may, subject to applicable laws, for a period not exceeding 12 months after such a final sequestration order or final liquidation order, and for such additional period as the council may allow, continue the business of such a pharmacist or body corporate, and such business shall be conducted under the continuous personal supervision of a pharmacist;
 - (d) the trustee or liquidator shall, within 30 days of his or her appointment, deliver, by hand or registered mail, to the council the sequestration or liquidation order, as the case may be, referred to in paragraph (c), and the trustee or the liquidator shall inform the council, in writing, of the name and registration number of the pharmacist who shall be responsible to the council in respect of the business referred to in paragraph (c);
 - (e) the curator of the estate of a person who is carrying on business as a pharmacist but who has been declared incapable of managing his or her affairs by an order of court, may, subject to applicable laws, for a period not exceeding 12 months after the order has been given and for such additional period as the council may allow, continue such pharmacy business, and such pharmacy business shall be conducted under the continuous personal supervision of a pharmacist;
 - (f) the curator referred to in paragraph (e) shall, within 30 days from the date on which the order was made, deliver, by hand or registered mail, such order to the council, and the curator shall inform the council, in writing, of the name and registration number of the pharmacist who shall be responsible to the council in respect of the business referred to in paragraph (e);
 - (g) the judicial manager or a judgment creditor of a body corporate carrying on business as a pharmacist may, subject to applicable laws, for a period not exceeding the period of judicial management or six months from the date on which the attachment order was made in the case of a judgment creditor, subject to conditions determined by the council, continue such pharmacy business, and such pharmacy business shall be conducted under the continuous personal supervision of a pharmacist;

- (h) the judicial manager or judgment creditor referred to in paragraph (g) shall, within 30 days of the granting or discharge of the order, deliver, by hand or registered mail, such order to the council, and such judicial manager or judgment creditor shall inform the council, in writing, of the name and registration number of the pharmacist who shall be responsible to the council in respect of the pharmacy business referred to in paragraph (e).

Restriction in, or suspension from, practice of registered person

- 28.** (1) Whenever it appears to the council that any person registered under this Act –
- (a) has become mentally or physically disabled to such an extent that it would be detrimental to the public interest to allow him to continue to practise;
 - (b) has become unfit to purchase, acquire, keep, use, order, supply or possess any scheduled substance;
 - (c) has been using a scheduled substance regularly for other than medicinal purposes as defined in section 1 of the Medicines and Related Substances Act, 1965; or
 - (d) has become addicted to the use of any scheduled substance, the council shall cause the matter to be investigated and the council may, if it deems it necessary, hold an inquiry *mutatis mutandis* in accordance with the provisions of section 31 and the regulations made under section 42 (1) (o), in respect of such person.
- (2) If the council, after holding an inquiry in terms of subsection (1), finds that any of the circumstances contemplated in paragraph (a), (b), (c) or (d) of that subsection exists in respect of the person concerned, it may, by order –
- (a) in the case of a person in respect of whom the circumstances contemplated in paragraph (a) of subsection (1) exist –
 - (i) suspend such person for a specified period from practising his profession or performing any act specially pertaining to his profession; or
 - (ii) impose such conditions as it may deem fit subject to which such person shall be entitled to continue practising his profession; or
 - (b) in the case of a person in respect of whom any of the circumstances contemplated in paragraph (b), (c) or (d) of subsection (1) exists –
 - (i) impose upon such person any of the penalties referred to in section 36 (1);
 - (ii) prohibit such person for a specified period from purchasing, acquiring, keeping, using, dispensing, ordering, supplying or possessing any scheduled substance; or

(iii) impose for a specified period such conditions as it may deem fit subject to which such person shall be entitled to purchase, acquire, keep, use, dispense, order, supply or possess any scheduled substance.

(3) The council may extend for any period determined by it the period of operation of, withdraw, or in any other manner amend, any order made by it under subsection (2).

(4) The provisions of section 40 shall apply in respect of any person who has been suspended by virtue of any provision of subsection (2).

(5) Any person registered under this Act who contravenes or fails to comply with any order made under subsection (2) shall be guilty of an offence.

CHAPTER 5

DISCIPLINARY POWERS OF THE COUNCIL

Powers of officers and other persons

29. (1) Any officer appointed in terms of this Act who is required or authorized to perform any duty on behalf of the council and any person appointed by virtue of the provisions of section 42 (1) (l) (v) to make any inspection, may enter any pharmacy at any time reasonable for the proper performance of such duty or the making of such inspection.

(2) Any person who fails to give or refuses access to any officer or person referred to in subsection (1), if he requests entrance to any pharmacy, or obstructs or hinders him in the execution of his duties under this Act, or who fails or refuses to give information that he may lawfully be required to give to such officer or person, or who gives to such officer or person false or misleading information knowing it to be false or misleading, shall be guilty of an offence.

(3) Every officer or person referred to in subsection (1) shall be issued with a document signed by the registrar and containing the name of the officer or person concerned as well as a statement to the effect that such officer or person is empowered to perform any duty or make any inspection in terms of this section.

(4) Whenever any officer or person performs any duty or makes any inspection as contemplated in this section, he shall exhibit to any person affected thereby the document issued to him in terms of subsection (3).

Inquiry by the council into charges of misconduct

30. (1) The council shall have power to inquire into any matter which is brought to the attention of the council or any complaint, charge or allegation of improper or disgraceful conduct against any person registered in terms of this Act and, on finding such person guilty of such conduct, to impose any of the penalties prescribed in section 36 (1).

(2) If the council is in doubt as to whether any inquiry should be held, it may, in connection with the complaint, charge or allegation in question, consult with or seek information from any person, including the person against whom the complaint, charge or allegation has been lodged.

(3) In the case of a complaint, charge or allegation which forms or is likely to form the subject of a criminal case in a court of law the council may postpone the holding of an inquiry until such case has been concluded.

(4) The council may appoint a person with adequate experience in the administration of justice to be present as an assessor at any inquiry held by the council under this Chapter and to advise it on matters of law, procedure or evidence.

Procedure for the conduct of an inquiry

31. (1) (a) For the purpose of any inquiry held in terms of section 30, the council may take evidence and may, under the hand of the president or the registrar, summon witnesses and require the production of any book, record, document or thing and may, through the president, administer an oath to any witness or accept an affirmation from him, and may examine any book, record, document or thing which any witness had been required to produce.

(b) A summons to appear before the council as a witness or to produce to it any book, record, document or thing shall be, as nearly as practicable, in the prescribed form, shall be signed by the president or the registrar and shall be served either by registered letter sent through the post or in the same manner as it would be served if it were a subpoena issued by a magistrate's court.

(c) Every person summoned in terms of this subsection shall be bound to obey the summons and any person who, having been duly summoned –

- (i) refuses, or without sufficient cause fails, to attend and give evidence relevant to the inquiry at the time and place specified in the summons;
- (ii) refuses to take the oath or to make an affirmation when required by the president to do so;

- (iii) refuses to produce any book, record, document or thing which he has in terms of the summons been required to produce; or
- (iv) attends before the council and refuses to answer, or to answer fully and satisfactorily to the best of his knowledge and belief, any question lawfully put to him,

shall be guilty of an offence and on conviction liable to a fine not exceeding the amount to be determined by the Minister from time to time by notice in the *Gazette*: Provided that every person so summoned shall be entitled to all the privileges to which a witness subpoenaed to give evidence before a provincial division of the Supreme Court is entitled.

(2) Every person whose conduct is the subject of an inquiry under section 30, shall be afforded an opportunity, by himself or through his legal representative, of answering the charge and of being heard in his defence.

(3) The council shall be entitled to make an order as regards the costs incurred in an inquiry or investigation relating to the conduct of a registered person, of an amount not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.

Council to make rules relating to offences under this Chapter

32. (1) The council shall from time to time make rules specifying the acts or omissions in respect of which the council may take disciplinary steps under this Chapter: Provided that the powers of the council to inquire into and deal with any complaint, charge or allegation under this Chapter shall not be limited to the acts or omissions so specified.

(2) No rule made in terms of subsection (1) or any amendment or withdrawal thereof shall be of force and effect until approved by the Minister and published in the *Gazette*.

Charges by pharmacists

33. (1) No pharmacist shall make or attempt to make or to recover, or enter into any agreement or associate himself in any way with any other person for the purpose of making or fixing, excessive charges for any article supplied or to be supplied by him in his capacity as a pharmacist.

(2) Any pharmacist who contravenes any provision of subsection (1) shall be guilty of improper conduct as contemplated in section 30 and the council shall take cognizance of and deal with such conduct in terms of the provisions of this Chapter.

Commission on prescription

34. (1) No pharmacist shall pay to any person any commission or in any other manner reward him in connection with a prescription issued by a medical practitioner or veterinarian.

(2) Any pharmacist who contravenes the provisions of subsection (1) shall be guilty of an offence and, in addition, may be dealt with by the council in terms of the provisions of this Chapter.

Improper or disgraceful conduct by registered persons

35. (1) Every registered person who, either before or after registration, has been convicted of any offence by a court of law may be dealt with by the council in terms of the provisions of this Chapter if the council is of the opinion that such offence constitutes improper or disgraceful conduct, or conduct which when regard is had to such person's profession is improper or disgraceful, and shall be liable on proof of the conviction to one or other of the penalties referred to in section 36: Provided that, before imposition of any penalty, such person shall be afforded an opportunity of tendering an explanation to the council in extenuation of the conduct in question.

(2) When in the course of any proceedings before any court of law it appears to the court that there is *prima facie* proof of improper or disgraceful conduct on the part of a registered person, or of conduct which when regard is had to such person's profession is improper or disgraceful, the court shall direct that a copy of the record of such proceedings, or such portion thereof as is material to the issue, or in the case of the payment by such person of an admission of guilt fine referred to in section 57 of the Criminal Procedure Act, 1977 (Act 51 of 1977), a copy of the summons or written notice in question, shall be transmitted to the council.

(3) The council shall appoint a person, excluding the registrar or a member to institute and conduct before the council proceedings under this Chapter: Provided that if a person so appointed is absent or for any other reason unable to perform his duties, the council may, subject to the provisions of this subsection, appoint any other person to perform, during such absence or incapacity, the duties of such first-mentioned person.

(4) When it appears –

(a) from any disciplinary proceedings held by an employer into the conduct of a person registered in terms of this Act or any institution at which education and training in pharmacy is offered, that there is *prima facie* evidence of unprofessional conduct on the part of such employee or a student being trained as a pharmacist;

(b) that the registration of a pharmacy student with an education and training institution has been suspended or cancelled,

then the employer or the institution shall furnish the council with a copy of the record of such proceedings, or such portion thereof that is material to the issue, or notify in writing the council of such suspension or cancellation.

Penalties the council may impose

36. (1) Any person registered under this Act who, after an inquiry held by the council in accordance with the provisions of this Chapter, has been found guilty of improper or disgraceful conduct, or conduct which when regard is had to such person's profession is improper or disgraceful, shall be liable to one or other of the following penalties:

- (a) a reprimand or a caution or a reprimand and a caution; or
- (b) suspension for a specified period from practising or performing any acts forming part of his or her scope of practice as prescribed in terms of this Act;
- (c) removal of his name from the register.
- (d) a fine not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.

(2) When the council has imposed one or other of the penalties referred to in subsection (1) the registrar shall cause to be published in the *Gazette* the name of the person concerned, the nature of the conviction and the penalty imposed.

(3) Any person aggrieved by a finding of or penalty imposed by the council in terms of this section, may, after notice to the council and within a period of two months after the date of such finding or the imposition of the penalty, appeal to the provincial or local division of the Supreme Court of South Africa having jurisdiction in the area wherein the appellant normally practises in the capacity in which he is registered, against such finding or penalty, and the provisions of section 14 shall apply *mutatis mutandis* to such an appeal: Provided that no finding of or penalty imposed by the council shall be set aside by reason only of an irregularity which did not embarrass or prejudice the appellant in answering the charge or in the conduct of his defence.

(4) The council may, if it deems fit, and subject to such conditions (if any) as it may determine –

- (a) terminate any suspension under subsection (1) before the expiry of the specified period; or
- (b) on payment of the prescribed fee restore to the register any name removed therefrom in terms of subsection (1).

Postponement of imposition, and suspension of operation, of penalty

37. (1) Where the council finds a person referred to in section 36 (1) guilty of conduct referred to therein, it may –

- (a) postpone, for such period and on such conditions as it may determine, the imposition of a penalty; or
- (b) impose any penalty mentioned in section 36 (1) (b) or (c), but order the execution of such penalty to be suspended for such period and on such conditions as it may determine.

(2) (a) If at the end of the period for which the imposition of a penalty has been postponed in terms of subsection (1) (a), the council is satisfied that the person concerned has observed all the relevant conditions, the council shall inform him that no penalty will be imposed upon him.

(b) If the execution of a penalty has been suspended in terms of subsection (1) (b), and the council is satisfied that the person concerned has observed all relevant conditions throughout the period of suspension, the council shall inform him that such penalty will not be executed.

(c) If the execution of a penalty has been suspended in terms of subsection (1) (b) and the person concerned fails to observe any of the conditions of suspension, the council shall put such penalty into operation unless such person satisfies the council that the non-observance of the condition in question was due to circumstances beyond his control.

Recovery of fines and cost orders

38. (1) Any fine imposed in terms of this Act shall, unless an appeal has been noted against such penalty, be paid to the council within 14 days after the imposition thereof, or within such extended period and in such instalments as the council may in its discretion determine.

(2) Any cost order made in terms of this Act shall –

- (a) in the event of such order being made against the *pro forma* complainant or against the council be paid by the council within 14 days after the amount thereof has been fixed;
- (b) in the event of such order being made against any other person be paid to the council within 14 days after the amount thereof has been fixed, or within such extended period and in such instalments as the council may in its discretion determine.

(3) The imposition of a fine or the making of a cost order in terms of this Act shall have the effect of a judgment in civil proceedings in the magistrate's court of the district in which the person liable to pay such fine resides or has his or her registered address or main place of business.

Penalty for false evidence

39. Any person who gives false evidence on oath at an inquiry held under this chapter, knowing such evidence to be false, shall be guilty of an offence and liable on conviction to the penalties prescribed by law for the crime of perjury.

Effect of suspension or removal from register

40. Every person who has been suspended or whose name has been removed from the register under this Chapter shall, if his profession is one which, under this Act, cannot be lawfully carried on by an unregistered person, be disqualified from carrying on his profession and his registration certificate shall be deemed to be cancelled until the period of suspension has expired or until his name has been restored to the register by the council.

Limitation of liability

41. Subject to the provisions of this Act the council or any member or officer of the council shall not be liable in respect of any act done in good faith or duty performed in accordance with this Act.

CHAPTER 6

GENERAL AND SUPPLEMENTARY PROVISIONS

Regulations

42. (1) The Minister may, in consultation with the council, make regulations relating to –

(a) the practice of pharmacy, the conduct of the business of a pharmacist, the tariff of fees payable to a pharmacist in respect of professional services rendered by him and the trading activities of a pharmacist, including the goods or class of goods in which the pharmacist may not deal on the premises where the business of a pharmacist is conducted;

- (b) the manner in which the business of the council shall be conducted, the procedure to be followed at meetings of the council or committees of the council, and the manner in which the minutes of such meetings shall be kept;
- (c) the manner in which the accounts of the council shall be kept and money accruing to the council shall be disposed of;
- (d) any fees payable under this Act;
- (e) the conditions of service of officers appointed by the council;
- (f) the forms of the registers, certificates, forms and documents to be kept, issued, completed or compiled in terms of this Act;
- (g) the information to be furnished to the registrar by pharmacists, including pharmacists who are owners or managers of pharmacies or directors of bodies corporate or members or managers of corporations carrying on business in the Republic as pharmacists;
- (h) the registration by the council of pharmacy students studying at any university or at any pharmacy school or other institution approved by the council;
- (i) the standards of general education required of such students as a condition precedent to registration as a pharmacy student;
- (j) the minimum requirements of the curriculum and the duration of the course of study for a degree or diploma in pharmacy;
- (k)
 - (i) the syllabuses for the various subjects included in the curriculum for the diploma in pharmacy;
 - (ii) the manner in which examinations for the diploma in pharmacy referred to in subparagraph (i) shall be conducted;
- (l)
 - (i) the registration by the council of pharmacist interns;
 - (ii) the practical training to be undergone by such pharmacist intern;
 - (iii) the accommodation facilities, material, equipment and other requisites to be provided in a pharmacy where a pharmacist intern is being trained;
 - (iv) the appointment of persons to inspect pharmacies where it is proposed to train pharmacist interns or where pharmacist interns are being trained;
 - (v) the duties of persons appointed in terms of subparagraph (iv) and the fees payable to them by the council in respect of inspections done by them;
- (m)
 - (i) the registration by the council of pharmaceutical technicians and other pharmaceutical auxiliary personnel;
 - (ii) the persons required to be registered as pharmaceutical technicians or other pharmaceutical auxiliary personnel and the circumstances under which such persons shall be required to be so registered;

- (iii) the training and the educational or other qualifications required for registration as pharmaceutical technicians or other pharmaceutical auxiliary personnel;
- (n) supplementary training or refresher courses to be undergone or taken by persons registered under this Act and the provision of and control over such training or courses;
- (o)
 - (i) the specialities in respect of which registered persons may apply for registration under section 18;
 - (ii) the requirements with which an applicant for registration of a speciality shall comply;
 - (iii) the exemption of an applicant for registration of a speciality, or any category of such applicants, from such requirements;
 - (iv) the conditions subject to which any registered person may carry on the profession of pharmacist in respect of any registered speciality, including conditions restricting the practice of any such person to the speciality registered in respect of such person;
- (p)
 - (i) the election of members of the council required to be elected in terms of section 5 (1);
 - (ii) the requirements for a valid nomination of a candidate for election as a member of the council;
- (q) the conduct of an inquiry held in terms of section 30, including –
 - (i) the manner in which complaints or charges brought against a registered person shall be lodged;
 - (ii) the method of summoning an accused person and the penalties for failure or refusal on the part of any such person to attend as summoned or for obstructing or interrupting the proceedings;
 - (iii) any other matter relating to the conduct of such an inquiry;
- (r) any matter which, in terms of any provision of this Act, is required to be or may be prescribed by regulation;
- (s) generally, all matters which he considers it necessary or expedient to prescribe in order that the purposes of this Act may be achieved.

(2) The Minister may, after consultation with the executive committee of the council, if he deems it to be in the public interest –

- (a) without the recommendation of the council make regulations relating to any of the matters referred to in subsection (1) or amend or repeal any regulation made in terms of that subsection;
- (b) amend or repeal any rule made in terms of the provisions of this Act.

(3) Any proclamation or notice issued or regulation, rule or order made under this Act may from time to time be amended or repealed by the authority which issued or made it.

(4) The council shall, not less than two months before any rule is made in terms of this Act, cause the text of such rule to be published in the *Gazette* together with a notice declaring the council's intention to make such a rule and inviting interested persons to furnish the council with comments thereon or any representations they may wish to make in regard thereto.

(5) The Minister shall, not less than three months before any regulation is made in terms of this Act, cause the text of such draft regulation to be published in the *Gazette* together with a notice declaring the Minister's intention to make such a regulation and inviting interested persons to furnish the Minister with comments thereon or any representations they may wish to make in regard thereto: Provided that if the Minister thereafter decides to alter the draft regulations as a result of any objections or representations so submitted, it shall not be necessary to publish such alterations before making the regulations.

Delegation of powers

43. (1) The Minister may delegate or authorise in writing the Director-General or any officer of the Department or the council to exercise any of the powers conferred upon him or her by this Act, other than the powers referred to in section 42.

(2) The Director-General may delegate or authorise in writing any officer of the Department or the council to exercise any of the powers conferred upon him or her by this Act.

Penalty where not expressly provided

44. Any person who contravenes any provision of this Act in respect of the contravention of which no penalty is expressly provided shall on conviction be liable to a fine not exceeding the amount determined by the Minister from time to time by notice in the *Gazette*.

Savings

45. (1) Any proclamation, notice, regulation, authorisation or order issued, made or granted or any registration, removal from a register, appointment or any other thing done in terms of a provision of any law repealed, shall, except in so far as may be otherwise

required by this Act, be deemed to have been issued, made, granted or done under the provisions of this Act.

(2) The members of the council as constituted immediately prior to the commencement of this Act shall continue to be members, and the council shall be deemed to be validly constituted in terms of this Act, until a date determined by the Minister and published in the *Gazette*.

(3) If any of the members referred to in subsection (2) vacates his or her office, the council shall, until the date referred to in that subsection, consist of the remaining members.

Act binding on State

46. This Act is binding on the State.

Short title and commencement

47. This Act shall be called the Pharmacy Act, 2017, and shall come into operation on a date to be fixed by the State President by proclamation in the *Gazette*.

SCHEDULE

LEGISLATION REPEALED

| No and year | Title | Extent of repeal |
|--------------------|--|-------------------------|
| 53 of 1974 | Pharmacy Act, 1974 | The whole |
| 36 of 1977 | Health Laws Amendment Act, 1977 | Sections 9 to 11 |
| 20 of 1979 | Pharmacy Amendment Act, 1979 | The whole |
| 39 of 1982 | Pharmacy Amendment Act, 1982 | The whole |
| 20 of 1983 | Pharmacy Amendment Act, 1983 | The whole |
| 69 of 1985 | Pharmacy Amendment Act, 1985 | The whole |
| 6 of 1995 | Pharmacy Amendment Act, 1995 | The whole |
| 88 of 1997 | Pharmacy Amendment Act, 1997 | The whole |
| 1 of 2000 | Pharmacy Amendment Act, 2000 | The whole |
| 10 of 2002 | Veterinary and Para-Veterinary Professions Amendment Act, 2002 | Section 18 |

Annexure F

Health Professions Bill

ACT

To establish the Health Professions Council of South Africa and professional boards; to provide for control over the education, training and registration for and practising of health professions registered under this Act; and to provide for matters incidental thereto.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows: –

ARRANGEMENT OF SECTIONS

CHAPTER 1 DEFINITIONS

1. Definitions

CHAPTER 2 HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA AND PROFESSIONAL BOARDS

2. Establishment of Health Professions Council of South Africa
3. Objects and functions of council
4. General powers of council
5. Constitution of council
6. Vacation of office and filling of vacancies
7. President and vice-president
8. Meetings of council
9. Quorum and procedure at meetings
10. Committees
11. Appointment of registrar and staff
12. Corporate finance and governance
13. Minister may rectify defects

14. Establishment of professional boards
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CHAPTER 3 EDUCATION, TRAINING AND REGISTRATION

17. Control over education and training
18. Registration prerequisite for practising
19. Keeping of registers
20. Removal of name from, and restoration to, register
21. Suspension and revocation of suspension
22. Right to appeal
23. Custody and publication of registers
24. Register as proof
25. Duplicate registration certificate, certificate of status or certified extract
26. Qualifications for registration
27. Community service
28. Registration of person who hold other qualifications
29. Continuing professional development to retain registration
30. Registration of non-residents for education and training
31. Registration of non-residents for post-graduate studies
32. Universities and other educational institutions to furnish particulars
33. Scope of registrable health professions and registration of certain persons
34. Registration of additional qualifications, specialists, subspecialists, professional categories and additional professional categories

CHAPTER 4 OFFENCES BY UNREGISTERED PERSONS

35. Prohibition of performance of certain acts by unregistered persons
36. Penalty for professing to be registered or holder of certain qualifications

CHAPTER 5 DISCIPLINARY POWERS OF PROFESSIONAL BOARDS

37. Inquiries into unprofessional conduct

38. Manner in which investigations may be instituted
39. Matters for and procedure at inquiry
40. Postponement or suspension of penalty
41. Effect of suspension or removal from register
42. Cognizance of conduct of registered persons
43. Penalty for false evidence
44. Limitation of liability
45. Rules relating to offences
46. Regulations relating to investigations in respect of certain persons

CHAPTER 6 GENERAL AND SUPPLEMENTARY PROVISIONS

47. Dispensing of medicines
48. Fees charged by registered persons
49. Exemption from provisions of Act
50. Penalty for false representations, false entries and impersonation
51. Death of person undergoing certain procedures
52. Commission on prescriptions
53. Limitations in respect of unregistered persons
54. Investigation of matters relating to education or training
55. Regulations
56. Rules
57. Levying of annual fee on certain registered persons
58. Repeal of laws and savings
59. Transitional provisions
60. Short title and commencement

CHAPTER 1 DEFINITIONS

Definitions

1. In this Act, unless the context otherwise indicates –

'accredit' means recognition or certification by the council or the relevant professional board in terms of this Act or any other Act as meeting the prescribed education and training requirements;

'community representative' means a person appointed by the Minister as a community representative and who is not registered in terms of this Act;

'council' means the council referred to in section 2;

'dentist' means a person registered as such under this Act;

'Director-General' means the Director-General: Health or his or her nominee;

'fruitless and wasteful expenditure' has the same meaning as assigned to it in section 1 of the Public Finance Management Act, 1999 (Act 1 of 1999);

'health practitioner' means any person, including a student, registered with the council in a profession registrable in terms of this Act;

'health profession' means any profession for which a professional board has been established in terms of section 14 and includes any category or group of persons provided for by such a board;

'impairment' refers to a condition which renders a practitioner incapable of practising a profession with reasonable skill and safety;

'intern' means a person registered as such under this Act in a profession which provides for internship training;

'intern-psychologist' means a person registered as such under this Act;

'irregular expenditure' means expenditure other than unauthorised expenditure-

- (a) incurred in contravention of or that is not in accordance with a requirement of any applicable legislation; or
- (b) that falls outside of the scope of the functions of the council or a professional board contemplated in this Act;

'medical practitioner' means a person registered as such under this Act;

'medicine' means medicine as defined in section 1 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965);

'medicinal purposes' in relation to a scheduled substance, means the purpose of treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or a craving for the substance used or for any other scheduled substance except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial administration, or approved for that purpose by the Minister;

'member' means a member of the council or of a professional board;

'Minister' means the member of Cabinet responsible for health;

'prescribe' means prescribe by regulation and **'prescribed'** shall have a corresponding meaning;

'president' means the president of the Council;

'professional board' means a professional board established in terms of any of the provisions of section 14;

'professional category' means the division or subdivision of a field in which any registered health profession may be practised;

'public representative' means a person appointed by the Council to serve in the committees or subcommittees of the Council or professional boards for a particular purpose, and who is not registered in any of the professions falling under this Act;

'psychologist' means a person registered as such under this Act;

'qualification' means any degree, diploma or certificate awarded after examination of a person's proficiency in a particular subject;

'register', when used as a verb, means to enter in a register, the words **'registered'**, **'registrable'**, **'registration'** and all other words formed with or derived from the word 'register' having a corresponding meaning;

'register', when used as a noun, means a register kept in accordance with the provisions of this Act, and when used in relation to any registration category or a member of any such category of persons in respect of which a register is kept, means the register kept for that category;

'registrar' means the registrar appointed under section 11 or a person lawfully acting in that capacity;

'regulation' means any regulation made under this Act;

'rule' means any rule made under this Act;

'scheduled substance' means a scheduled substance as defined in section 1 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965);

'speciality', in relation to a person registered in respect of any profession under this Act, means any particular discipline, division or subdivision of a profession which is recognised under this Act as a speciality in which such person specialises or intends to specialise;

'student intern' means a person registered as such under this Act;

'this Act' includes the regulations, rules and any proclamation or order issued or made under this Act;

'unprofessional conduct' means improper or disgraceful or dishonourable or unworthy conduct or conduct which, when regard is had to the profession of a person who is registered in terms of this Act, is improper or disgraceful or dishonourable or unworthy;

'vice-president' means the vice-president of the council.

CHAPTER 2
HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA AND PROFESSIONAL
BOARDS

Establishment of Health Professions Council of South Africa

2. (1) The Health Professions Council of South Africa established under section 2 of the Medical Professions Act 56 of 1974 continues to exist despite the repeal of that Act.

(2) The head office of the council shall be situated in Pretoria.

(3) The first meeting of the council shall be convened by the registrar.

Objects and functions of council

3. The objects and functions of the council are –

- (a) to co-ordinate the activities of the professional boards established in terms of this Act and to act as an advisory and communicatory body for such professional boards;
- (b) to promote and to regulate interprofessional liaison between health professions in the interest of the public;
- (c) to determine strategic policy in accordance with national health policy as determined by the Minister, and to make decisions in terms thereof, with regard to the professional boards and the health professions, for matters such as finance, education, training, registration, ethics and professional conduct, disciplinary procedure, scope of the professions, interprofessional matters and maintenance of professional competence;
- (d) to consult and liaise with relevant authorities on matters affecting the professional boards in general;
- (e) to assist in the promotion of the health of the population of the Republic;
- (f) subject to legislation regulating health care providers and consistency with national policy determined by the Minister, to control and to exercise authority in respect of all matters affecting the education and training of persons in, and the manner of the exercise of the practices pursued in connection with, the diagnosis, treatment or prevention of physical or mental defects, illnesses or deficiencies in human kind;
- (g) to promote liaison in the field of education and training referred to in paragraph (f), both in the Republic and elsewhere, and to promote the standards of such education and training in the Republic;

- (h) to advise the Minister on any matter falling within the scope of this Act in order to support the universal norms and values of health professions, with greater emphasis on professional practice, democracy, transparency, equity, accessibility and community involvement;
- (i) to communicate to the Minister information of public importance acquired by the council in the course of the performance of its functions under this Act;
- (j) to serve and protect the public in matters involving the rendering of health services by persons practising a health profession;
- (k) to exercise its powers and discharge its responsibilities in the best interest of the public and in accordance with national health policy determined by the Minister;
- (l) to be transparent and accountable to the public in achieving its objectives and when performing its functions and exercising its powers;
- (m) to uphold and maintain professional and ethical standards within the health professions;
- (n) to ensure the investigation of complaints concerning persons registered in terms of this Act and to ensure that appropriate disciplinary action is taken against such persons in accordance with this Act in order to protect the interest of the public;
- (o) to ensure that persons registered in terms of this Act behave towards users of health services in a manner that respects their constitutional rights to human dignity, bodily and psychological integrity and equality, and that disciplinary action is taken against persons who fail to act accordingly;
- (p) to submit to the Minister –
 - (i) a five-year strategic plan within six months of the council coming into office which includes details as to how the council plans to fulfil its objectives under this Act;
 - (ii) every six months a report on the status of health professions and on matters of public importance that have come to the attention of the council in the course of the performance of its functions under this Act; and
 - (iii) an annual report within six months of the end of the financial year; and
- (q) to ensure that an annual budget for the council and the professional boards is drawn up and that the council and the professional boards operate within the parameters of such budget.

General powers of council

4. The council may –

- (a) acquire, hire or dispose of property, borrow money on the security of the assets of the council and accept and administer any trust or donation;
- (b) render financial assistance to professional boards in order to enable such boards to perform their functions;
- (c) after consultation with the relevant professional board, consider any matter affecting the health professions registrable under this Act and, consistent with national health policy determined by the Minister, make representations or take such action in connection therewith as the council deems necessary;
- (d) consistent with national health policy determined by the Minister, make rules on all matters which the council considers necessary or expedient in order that the objects of this Act may be achieved;
- (e) delegate to any professional board or committee or any person such of its powers as it may determine, but shall not be divested of any power so delegated; and
- (f) perform such other functions as may be prescribed, and do all such things as the council deems necessary or expedient to achieve the objects of this Act within the framework of national health policy determined by the Minister.

Constitution of council

5. (1) The council shall be representative and shall consist of the following members, namely –

- (a) not more than 16 persons designated by the professional boards, on a basis proportional to the number of persons registered to practise the professions falling under each professional board: Provided that each professional board shall be entitled to designate at least one person registered in terms of this Act;
- (b) one person in the employment of the Department of Health, appointed by the Minister;
- (c) one person in the employment of the Department of Higher Education and Training, appointed by the member of Cabinet responsible for higher education;
- (d) nine community representatives not registered in terms of this Act, appointed by the Minister;
- (e) one person from the South African Military Health Service, appointed by the member of Cabinet responsible for defence;
- (f) three persons appointed by the South African University Vice-Chancellors' Association; and
- (g) one person versed in law, appointed by the Minister.

(2) Subject to the provisions of section 6, the members of the council shall hold office for a period of five years, but shall be eligible for re-designation or reappointment for one more term.

(3) Not less than three months prior to the date of expiry of the term of office of the members of the council, the persons and bodies referred to in subsection (1), except the Minister, shall inform the registrar in writing of the names of the persons to be designated or appointed by them in terms of that subsection.

(4) As soon as possible after the process referred to in subsection (3), the Minister shall inform the registrar of the names of the persons to be appointed by the Minister in terms of subsection (1).

(5) If any of the persons or bodies referred to in subsection (1), except the Minister, fails to make a designation or an appointment or to inform the registrar in terms of subsection (3) of the names of the persons to be designated or appointed by them, the Minister shall make the necessary designation or appointment, and any designation or appointment so made by the Minister shall be deemed to have been properly made in terms of the appropriate paragraph of subsection (1).

(6) The names of the members of the council and the date of commencement of their term of office shall be published by the registrar in the *Gazette* as soon as possible after the constitution of the council.

(7) A person may not be appointed as a member of the Council if he or she is, at the time of his or her appointment, or was, during the preceding 12 months –

- (a) a member of a municipal council, a provincial legislature or Parliament; or
- (b) a provincial or national office bearer or employee of any party, organisation or body of a political nature.

Vacation of office and filling of vacancies

6. (1) A member of the council shall vacate his or her office if –

- (a) his or her estate is sequestrated or he or she has entered into an agreement with the creditors of his or her estate;
- (b) he or she has been absent without leave of the president from more than two consecutive ordinary meetings of the council or of a committee referred to in section 10;
- (c) he or she has been found guilty of unprofessional conduct under this Act;
- (d) he or she ceases to hold any qualification necessary for his or her designation or appointment or tenders his or her resignation in writing to the person or body by

whom he or she was designated or appointed and that person or body accepts his or her resignation;

- (e) he or she ceases to be a South African citizen;
- (f) he or she becomes mentally ill to such a degree that it is necessary that he or she be detained, supervised or controlled;
- (g) he or she is convicted of an offence in respect whereof he or she is sentenced to imprisonment without the option of a fine;
- (h) the Minister, in the public interest and for just cause, and after consultation with the person or body by whom the member was designated or appointed, terminates his or her membership;
- (i) he or she deliberately acts in a manner that will prejudice the interests of the council, the health professions or the public or violates the Charter of the council;
- (j) the Minister dissolves the council in terms of this Act;
- (k) he or she is an office bearer of an organisation that has a conflict of interest with the council, unless such member elects to immediately vacate his or her office in that organisation; or
- (l) he or she becomes-
 - (i) a member of a municipal council, a provincial legislature or Parliament; or
 - (ii) a provincial or national office bearer or employee of any party, organisation or body of a political nature.

(2) Every vacancy on the council arising from a circumstance referred to in subsection (1) and every vacancy caused by the death of a member, shall be filled by designation or appointment by the person or body by whom and in the manner in which the vacating member was designated or appointed, and every member so designated or appointed shall hold office for the unexpired portion of the period for which the vacating member was designated or appointed.

(3) (a) The Minister may dissolve the council if the council fails to comply with any of the provisions of this Act.

(b) All the functions of the council are vested in the Minister until a new council is appointed.

(4) (a) The Minister may in writing request copies of the records, including minutes of meetings and financial statements, of the council in order to ascertain the extent of the council's compliance with the provisions of this Act and the Charter.

(b) The registrar must furnish copies of all such records within 15 days of receipt of the Minister's request.

(5) If the Minister reasonably believes that the council is failing to comply with the provisions of this Act or the Charter, he or she may appoint a person or persons to investigate the affairs of the council and to prepare a report upon such investigation.

(6) The Minister may terminate membership of a member of the council where the member –

- (a) fails to perform the duties of a member in terms of this Act or the Charter;
- (b) obstructs or impedes the council or other members in the fulfilment of their functions in terms of this Act or the Charter;
- (c) fails to declare a conflict of interest between his or her affairs and those of the council;
- (d) acts in a manner that is likely to bring the council or health profession into disrepute;
- (e) misuses or misappropriates council funds or resources; or
- (f) approves or engages in unauthorised or irregular expenditure or fruitless and wasteful expenditure;

President and vice-president

7. (1) At the first meeting of every newly constituted council the members of the council shall elect a president and a vice-president from among themselves.

(2) The president and vice-president shall hold office during the term of office of the members of the council unless the president or vice-president shall sooner resign or cease to be a member of the council.

(3) (a) The vice-president may, if the president is absent or for any reason unable to act as president, perform all the functions and exercise all the powers of the president.

(b) If both the president and vice-president are temporarily absent for any reason, the president or vice-president may appoint another member of the executive committee of the council to act in their place.

(4) If both the president and vice-president are absent from any meeting, the members present shall elect one of their number to preside at that meeting and the person so presiding may, during that meeting and until the president or the vice-president resumes duty, perform all the functions and exercise all the powers of the president.

(5) If both the president and vice-president are absent or unable to perform their functions in terms of this Act, the members of the council shall elect one of their number to act as president until the president or the vice-president resumes duty or vacates office.

(6) If the office of president or vice-president becomes vacant, the members of the council shall, at the first meeting after such vacancy occurs or as soon thereafter as may be convenient, elect from among themselves a new president or vice-president, as the case may be, and the member so elected shall hold office for the unexpired portion of the period for which his or her predecessor was elected.

(7) A president or a vice-president may vacate office as such without such vacation by itself terminating his or her membership of the council.

Meetings of council

8. (1) The council shall hold at least two meetings in each year at venues to be determined by the council, and may in addition hold such further meetings as the council may from time to time determine.

(2) (a) The president may at any time convene a special meeting of the council, to be held on such a date and at such place as he or she may determine and he or she shall, upon a written request by the Minister or a written request signed by at least one third of the total number of members, convene a special meeting to be held, within thirty days after the date of receipt of the request, on such a date and at such a place as he or she may determine.

(b) The request must clearly state the purpose of the meeting.

Quorum and procedure at meetings

9. (1) The majority of the members of the council shall constitute a quorum at any meeting of the council.

(2) A decision of the majority of the members of the council present at any meeting shall constitute a decision of the council: Provided that in the event of an equality of votes the member presiding shall have a casting vote in addition to a deliberative vote.

(3) No decision taken by the council or act performed under authority of the council shall be invalid by reason only of an interim vacancy on the council or of the fact that a person who is not entitled to sit as a member of the council sat as a member at the time when the decision was taken or the act was authorized, if the decision was taken or the act was authorized by the requisite majority of the members of the council who were present at the time and entitled to sit as members.

Committees

10. (1) (a) The council may establish such committees as it may deem necessary, each consisting of so many persons, appointed by the council, as the council may determine but including, except in the case of an appeal committee referred to in subsection (2), at least one member of the council, who shall be the chairperson of such committee.

(b) The council may, subject to the provisions of subsection (3), delegate to any committee so established or to any person some of its powers as it may from time to time determine, but shall not be divested of any power so delegated.

(2) The council shall establish *ad hoc* appeal committees, each consisting of, as chairperson, a person with knowledge of the law with at least 10 years' relevant experience, not more than two registered persons drawn from the profession of the registered person in respect of whose conduct a professional conduct committee of a professional board had held an inquiry, and a member of the council appointed to represent the community.

(3) An appeal committee referred to in subsection (2) shall have the power to vary, confirm or set aside a finding of a professional conduct committee established in terms of section 14 (5) (f) or to refer the matter back to the professional conduct committee with such instructions as it may deem fit.

(4) A decision of a professional conduct committee shall be of force and effect from the date determined by the professional conduct committee.

(5) Where a matter has been considered by an appeal committee, the decision of the appeal committee shall be of force and effect from the date determined by that appeal committee.

(6) The council may, after consultation with one or more professional boards, establish a joint standing committee of the council and the board or boards.

Appointment of registrar and staff

11. (1) The Minister must, after consultation with the council, appoint a registrar and the council may delegate to the registrar the power to appoint such other persons as the registrar may deem necessary for carrying out the functions specified under this Act, and the council may also delegate to the registrar the power to dismiss such other persons.

(2) The registrar is the accounting officer and secretary of the council and of each professional board and he or she shall perform the functions and carry out the duties assigned to or imposed upon him or her in terms of this Act as well as such functions and

duties as may from time to time be assigned to or imposed upon him or her by the council or a professional board or a committee established in terms of section 10.

(3) The registrar may in writing authorise any member of his or her staff to exercise or perform any power, duty or function conferred or imposed on him or her by or in terms of this Act.

(4) The appointment or dismissal of the registrar shall be subject to the approval of the Minister.

Corporate finance and governance

12. (1) All registration, examination, annual and other fees payable under this Act shall be paid to the council, unless otherwise provided, and shall constitute the funds of the council and the council shall utilise the funds for defraying expenses incurred in connection with the performance of its functions and the functions of professional boards.

(2) The council may invest any unexpended portion of its moneys and may establish such reserve funds and pay therein such amounts as it may deem necessary or expedient.

(3) The registrar must –

- (a) keep full and proper records of all money received and expenses incurred by, and of all assets, liabilities and financial transactions of, the council and the registrar;
- (b) as soon as is practicable, but not later than four months after the end of each financial year, prepare annual financial statements in respect of the financial year in question;
- (c) ensure that the council has and maintains –
 - (i) effective, efficient and transparent systems of financial and risk management and internal control;
 - (ii) an appropriate procurement and provisioning system which is fair, equitable, transparent, competitive and cost effective; and
 - (iii) a system for properly evaluating all projects involving expenditure of capital prior to a final decision on the project;
- (d) ensure the effective, efficient, economical and transparent use of the resources of the council;
- (e) take effective and appropriate steps to –
 - (i) collect all money due to the council;
 - (ii) prevent unauthorised, irregular and fruitless and wasteful expenditure and losses resulting from criminal conduct; and
 - (iii) manage available working capital efficiently and economically;

- (f) take into account all relevant financial considerations, including issues of propriety, regularity and value for money, when policy proposals affecting the registrar's responsibilities are considered and, when necessary, bring those considerations to the attention of the council;
- (g) be responsible for the management, including the safeguarding and maintenance, of the assets and for the management of the liabilities of the council;
- (h) settle all contractual obligations and pay all money owing by the council within 30 days of due date or within a period agreed by the relevant creditor and the council;
- (i) ensure that expenditure of the council is in accordance with the decisions of the council and that effective and appropriate steps are taken to prevent unauthorised expenditure;
- (j) keep full and proper records of the financial affairs of the council in accordance with any prescribed norms and standards;
- (k) prepare financial statements for each financial year in accordance with recognised accounting practice;
- (l) submit the financial statements within two months after the end of a financial year to an independent auditor for auditing; and
- (m) submit within six months after the end of a financial year to the council for approval, and thereafter to the Minister within one month of such approval –
 - (i) an annual report on the activities of the council during that financial year;
 - (ii) the financial statements for that financial year after those statements have been audited; and
 - (iii) an independent auditor's report on those statements.

(4) The council must ensure that the requirements of subsection (3) are met and properly fulfilled.

(5) If an accounting officer is unable to comply with any of the responsibilities determined in subsection (3), he or she must promptly report the inability, together with reasons, to the Minister and the council.

(6) Any person who obstructs the registrar or the council in fulfilling the requirements of subsections (3) and (4) is guilty of an offence and is liable on conviction to a fine or imprisonment for a period not exceeding two years or to both a fine and such imprisonment.

Minister may rectify defects

13. If anything required to be done under this Act in connection with the appointment of any member is omitted or not done within the time or in the manner required by this

Act, the Minister may order all such steps to be taken as may be necessary to rectify the omission or error or may validate anything done in an irregular manner or form, in order to give effect to the objects of this Act.

Establishment of professional boards

14. (1) The Minister shall, on the recommendation of the council, establish a professional board with regard to any health profession in respect of which a register is kept in terms of this Act, or with regard to two or more such health professions.

(2) The Minister may, on the recommendation of the council, reconstitute the professional boards with regard to the health professions for which the boards have been established, and establish other boards.

(3) Before making a recommendation as contemplated in subsection (2), the council shall consult with any persons who are or body which is in the opinion of the council representative of the majority of persons to be affected by such change or establishment.

(4) The Minister may, on the recommendation of the council, make regulations relating to the constitution, functions and functioning of a professional board.

(5) Regulations relating to the constitution, functions and functioning of a professional board shall at least provide for –

- (a) the appointment of the members of a professional board by the Minister on the basis of nominations made by the members of the health profession or professions involved;
- (b) persons representing the community to comprise not less than 20 per cent of the membership of a professional board, with a minimum of one such representative for every professional board and such representatives must not be persons registered with that board;
- (c) relevant educational institutions to be represented;
- (d) the health authorities to be represented;
- (e) one or more persons versed in law to be appointed, where appropriate;
- (f) the establishment by a professional board of such committees as it may deem necessary, each consisting of so many persons appointed by the board as the board may determine, but including at least one member of the board who shall be the chairperson of such committee, and the delegation to any person or any committee so established, such of its powers as it may from time to time determine, but shall not be divested of any power so delegated;
- (g) the establishment of professional conduct committees, each consisting of so many persons as may be prescribed, but including at least three board members or

- members of the relevant profession and at least two public representatives one of whom shall be the chairperson of such committee;
- (h) the procedure to be followed for the nomination and appointment, as the case may be, of the members of a professional board;
 - (i) the election of a chairperson and vice-chairperson by the members of a professional board and the powers and functions of such a chairperson and vice-chairperson;
 - (j) the term of office of the members of a professional board; and
 - (k) the vacation of office by a member of and the filling of vacancies in a professional board.

Objects of professional boards

- 15.** The objects of a professional board are –
- (a) to consult and liaise with other professional boards and relevant authorities on matters affecting the professional board;
 - (b) to assist in the promotion of the health of the population of the Republic on a national basis;
 - (c) subject to legislation regulating health care providers and consistency with national policy determined by the Minister, to control and to exercise authority in respect of all matters affecting the education and training of persons in, and the manner of the exercise of the practices pursued in connection with, any health profession falling within the ambit of the professional board;
 - (d) to promote liaison in the field of the education and training contemplated in paragraph (c), both in the Republic and elsewhere, and to promote the standards of such education and training in the Republic;
 - (e) to make recommendations to the council to advise the Minister on any matter falling within the scope of this Act as it relates to any health profession falling within the ambit of the professional board in order to support the universal norms and values of such profession or professions, with greater emphasis on professional practice, democracy, transparency, equity, accessibility and community involvement;
 - (f) to make recommendations to the council and the Minister on matters of public importance acquired by the professional board in the course of the performance of its functions under this Act;
 - (g) to maintain and enhance the dignity of the relevant health profession and the integrity of the persons practising such profession; and
 - (h) to guide the relevant health profession or professions and to protect the public.

General powers of professional boards

16. (1) A professional board may –

- (a) in such circumstances as may be prescribed, or where otherwise authorised by this Act, remove any name from a register or, upon payment of a fee, restore thereto, or suspend a registered person from practising his or her profession pending the institution of a formal inquiry in terms of section 37 or investigation in terms of section 46;
- (b) appoint examiners and moderators, conduct examinations or evaluations, grant certificates, and charge such fees in respect of the examinations, evaluations or certificates as may be prescribed;
- (c) subject to the prescribed accreditation process and prescribed conditions, including the submission of reports by accreditation teams or evaluators appointed by the professional board, accredit teaching institutions and training facilities;
- (d) consider any matter affecting any health profession falling within the ambit of the professional board and make representations or take such action in connection therewith as the professional board deems advisable;
- (e) upon application by any person, recognise any qualification held by him or her, whether such qualification was obtained in the Republic or elsewhere, as being equal, either wholly or in part, to any prescribed qualification, whereupon such person shall, to the extent to which the qualification has been so recognised, be deemed to hold such prescribed qualification and upon compliance with any other additional requirements as may be determined by the professional board, register such person;
- (f) after consultation with another professional board or boards, establish a joint standing committee or committees of the boards concerned; and
- (g) perform such other functions as may be prescribed, and generally, do all such things as the professional board deems necessary or expedient to achieve the objects of this Act in relation to the health professions falling within the ambit of the professional board.

(2) Any decision of a professional board relating to a matter falling entirely within its ambit shall not be subject to ratification by the council, and the council shall, for this purpose, determine whether a matter falls entirely within the ambit of a professional board.

CHAPTER 2

EDUCATION, TRAINING AND REGISTRATION

Control over education and training

17. (1) Notwithstanding anything to the contrary in any other law but subject to the provisions of the Nursing Act, 2005 (Act 33 of 2005), no person, educational institution or training facility, may offer or provide any education or training having as its object to qualify any person for the practising of any health profession to which the provisions of this Act apply or for the performance of any other activity directed to the mental or physical examining of any person or to the diagnosis, treatment or prevention of any mental or physical defect, illness or deficiency in humankind, unless such education and training has been accredited by the professional board concerned as being appropriate education and training for such purposes.

(2) Any person, educational institution or training facility wishing to offer education or training as referred to in subsection (1) shall, before offering such education or training, apply to the professional board concerned in writing for the accreditation of the education or training, shall furnish such particulars regarding the education or training as the professional board concerned may require and pay the prescribed accreditation and annual fees to remain accredited.

(3) The professional board concerned may grant or refuse any application made in terms of subsection (2) and, having granted such application, may impose such conditions and requirements as it may deem fit subject to which the education or training in question may be provided.

(4) Any person who contravenes or fails to comply with any provision of this section shall be guilty of an offence and on conviction be liable to a fine or to imprisonment for a period not exceeding 12 months or both a fine and such imprisonment.

(5) The council is the education and training quality assurer for the health professionals registered under this Act, in terms of the National Qualifications Framework Act, 2008 (Act 67 of 2008).

Registration prerequisite for practising

18. (1) No person shall be entitled to practise within the Republic –
(a) any health profession registrable in terms of this Act; or

- (b) except in so far as it is authorised by legislation regulating health care providers and sections 33 and 35 of this Act, any health profession the practice of which mainly consists of –
- (i) the physical or mental examination of persons;
 - (ii) the diagnosis, treatment or prevention of physical or mental defects, illnesses or deficiencies in humankind;
 - (iii) the giving of advice in regard to such defects, illnesses or deficiencies; or
 - (iv) the prescribing or providing of medicine in connection with such defects, illnesses or deficiencies,

unless he or she is registered in terms of this Act.

(2) The provisions of subsection (1) (b) must not be construed as permitting the performance by a person registered under any of the laws contemplated in that subsection of any act which is not performed in the ordinary course of the practising of his or her profession.

(3) Every person desiring to be registered in terms of this Act shall apply to the registrar and shall submit the qualification which, in his or her submission, may entitle him or her to registration, together with such proof of identity and good character and of the authenticity and validity of the qualifications submitted as may be required by the professional board concerned.

(4) If the registrar is satisfied that the qualifications and the other documents submitted in support of the application satisfy the requirements of this Act, he or she shall, upon payment by the applicant of the prescribed registration fee, issue a registration certificate authorising the applicant, subject to the provisions of this Act or of any other law, to practise the health profession in respect whereof he or she has applied for registration, within the Republic.

(5) If the registrar is not satisfied that the qualification or other documents submitted in support of the application satisfy the requirements of this Act, he or she shall refuse to issue a registration certificate to the applicant, but shall, if so required by the applicant, submit the application to the professional board concerned for decision.

(6) Any person who is not registered in terms of this Act and practises a health profession in contravention of this section or who pretends to hold such registration is guilty of an offence and on conviction is liable to a fine or to imprisonment for a period not exceeding 12 months or to both a fine and such imprisonment.

Keeping of registers

19. (1) The registrar shall keep registers in respect of persons registered in terms of this Act, and must enter in the appropriate register the name, relevant contact details, qualifications, date of initial registration and such other particulars (including the registration category in which they hold registration and the name of their speciality, subspeciality, professional category or categories, if any) as the relevant professional board may determine, of every person whose application for registration in terms of section 18 (2) has been granted.

(2) The registrar shall keep the registers correctly and in accordance with the provisions of this Act and shall remove therefrom the names of all registered persons who have died or whose names have to be removed in terms of this Act and shall from time to time make the necessary alterations to the entries contemplated in subsection (1) in respect of registered persons.

(3) Every registered person who changes his or her contact details shall in writing notify the registrar thereof within thirty days after such change.

(4) No qualification shall be entered in the register unless the registrar is satisfied that the person claiming to possess such qualification is entitled thereto, or if the professional board is not so satisfied, and any entry which is proven to the satisfaction of the professional board to have been in error or through misrepresentation or in circumstances not authorised by this Act, may be removed from the register and a record of the reason for every such removal shall be made in the register, and the person in respect of whose entry such removal has been made, shall be notified thereof in the manner contemplated in section 20 (2) and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

Removal of name from, and restoration to, register

20. (1) The professional board or a committee to whom the function has been delegated may direct the registrar to, or the registrar acting on the established policies of the professional board may, remove from the register the name of any person –

- (a) who has failed to notify the registrar, within a period of three months as from the date of an enquiry sent by the registrar by certified mail to the address appearing in the register in respect of such person, of his or her present address;
- (b) who has requested that his or her name be removed from the register, in which case such person may be required to lodge with the registrar an affidavit to the

effect that no unprofessional conduct proceedings are pending against him or her, or criminal proceedings are being or are likely to be taken against him or her;

- (c) who has failed to pay to the professional board, within three months as from the date on which it became due for payment, any annual fee prescribed by the professional board in terms of section 57;
- (d) whose name has been removed from the register, record or roll of any university, hospital, college, society or other body from which that person received the qualification by virtue of the holding whereof he or she was registered;
- (e) who has been registered in error or through fraud; or
- (f) who has been found guilty of unprofessional conduct and on whom a penalty specified in section 39 (1) (c) is imposed.

(2) Notice of the removal, in terms of subsection (1), of his or her name from the register, or of the removal, in terms of section 19 (5), of an entry from the register, shall be given by the registrar to the person concerned by way of certified mail addressed to such person at the address appearing in respect of him or her in the register.

(3) As from the date on which notice has been given in terms of subsection (2) –

- (a) any registration certificate issued in terms of this Act to the person concerned shall be deemed to be cancelled; and
- (b) such person shall cease to practise the health profession in respect of which he or she was registered or to perform any act which he or she, in his or her capacity as a registered person, was entitled to perform,

until such time as his or her name or the entry removed from the register in terms of section 18 (5), as the case may be, is restored to the register.

(4) If it appears to the judge concerned from the documents submitted to him or her in terms of the Mental Health Care Act, 2002 (Act 17 of 2002), or it is brought to his or her notice in any other manner, that the person to whom the documents relate is a person registered under this Act, he or she shall, if the said person is declared a mentally ill person as contemplated by the said Mental Health Care Act, direct that a copy of the order declaring such a person a mentally ill person be transmitted to the registrar and the registrar shall, on receipt of the said copy, remove the name of the person concerned from the register.

(5) The name of a person whose name has in terms of this section been removed from the register or an entry removed from the register in terms of section 19 (5), shall be restored to the register by the registrar upon the person concerned –

- (a) applying on the prescribed form for such restoration;
- (b) paying the fee prescribed in respect of such restoration (if any);

- (c) in the case where his or her name has been removed from the register in terms of subsection (4), submitting proof to the satisfaction of the relevant professional board of his or her discharge in terms of the provisions of the Mental Health Care Act, from the institution at which he or she had been detained, but subject to any conditions of registration or practice which may be imposed on him or her in terms of section 51; and
- (d) complying with such other requirements as the relevant professional board may determine.

Suspension and revocation of suspension

21. (1) A relevant professional board or a committee of a professional board to whom the function has been delegated may authorise the registrar to suspend the registration of any person –

- (a) who has failed to notify the registrar of his or her present address, within a period of three months from the date of an inquiry sent by the registrar by certified mail, which is returned unclaimed, to the address appearing in the register in respect of such person;
- (b) who has failed to pay his or her prescribed annual fee on a date when it became due in terms of section 56;
- (c) who has been found guilty of unprofessional conduct and on whom a penalty referred to in section 39 (1) (b) of the Act is imposed;
- (d) who has failed to comply with the requirements in respect of continuing professional development as prescribed under section 29; or
- (e) who on the basis of a complaint lodged with the council or information available at the disposal of council is posing an imminent threat or danger to the public in terms of his or her professional practice.

(2) The registrar must issue the notice of suspension and forward it to the person contemplated in subsection (1) by way of certified mail, fax or electronic transmission to the address appearing in respect of him or her in the register.

(3) As from the date of issue of the notice referred to in subsection (2) and its receipt by the person concerned-

- (a) any registration certificate issued in terms of this Act to the person concerned must be deemed to be suspended; and
- (b) such person must immediately cease to practise the health profession in respect of which he or she is registered or to perform any act which he or she in his or her

capacity as a registered person is entitled to perform, until such time as the suspension of his or her registration is lifted.

(4) The suspension of any person in terms of subsection (1) must be revoked by the registrar upon-

- (a) the payment of any annual fee which was not paid and payment of a restoration fee and other penalties as may be prescribed;
- (b) the expiry of the suspension period;
- (c) such person complying with requirements in respect of continuing professional development as prescribed under section 29; and
- (d) such person complying with such other requirements as the relevant professional board may determine.

Right to appeal

22. (1) Any person who is aggrieved by any decision of the council, a professional board or a disciplinary appeal committee, may appeal to the appropriate High Court against such decision.

(2) Notice of appeal must be given within one month from the date on which such decision was given.

Custody and publication of registers

23. The registers shall be kept at the office of the council and the registrar shall, at intervals to be determined by the council and according to the instructions and on the authority of the council, cause copies of the registers, or of supplementary lists showing all alterations, additions, revisions and deletions made since the last publication of the complete registers, to be printed and published or to be made available in electronic or any other appropriate format approved by the council.

Register as proof

24. (1) A copy of the last published issue of a register or any supplementary list purporting to be printed and published on the authority of the council shall be *prima facie* proof, in all legal proceedings, of the fact therein recorded, and the absence of the name of any person from such copy shall be proof, until the contrary is proven, that such person is not registered according to the provisions of this Act: Provided that in the case of any person whose name –

- (a) does not appear in such copy, or whose name has been added to the register after the date of the last published issue thereof, a certified copy under the hand of the registrar of the entry of the name of such person in the register, shall be proof that such person is registered under the provisions of this Act;
- (b) has been removed from the register since the date of the last published issue thereof and has not been restored thereto, a certificate under the hand of the registrar that the name of such person has been removed from the register shall be proof that such person is not registered according to the provisions of this Act.

(2) A certificate of registration shall be evidence of registration for a period of one year only and thereafter an annual practising certificate, which shall be issued upon payment of the required annual fee and the submission of such information as may be required by the council to enable it to keep accurate statistics on human resources in the health field, shall be regarded as proof of registration.

Duplicate registration certificate, certificate of status or certified extract

25. (1) If the registrar is satisfied –

- (a) on proof submitted by the registered person concerned, that a registration certificate has been damaged or destroyed; or
- (b) by virtue of an affidavit submitted by the registered person concerned, that a registration certificate has been lost,

he or she may issue a duplicate registration certificate to that person upon payment of the prescribed fee.

(2) The registrar may, upon payment of a fee, issue to any registered person, after submission of an affidavit that no criminal or unprofessional conduct proceedings are pending against him or her, a certificate of status containing particulars relating to –

- (a) such person's registration under this Act;
- (b) whether or not the person is disqualified in part or totally from practising his or her profession;
- (c) whether or not any steps pertaining to unprofessional conduct are pending against the person concerned at the time of the issuing of the certificate;
- (d) whether or not the person concerned was, in the past, found guilty of any unprofessional conduct, and if so –
 - (i) the date of such finding;
 - (ii) the nature of such unprofessional conduct; and
 - (iii) the penalty imposed; and
- (e) whether or not the person concerned has been found to be impaired and, if so –

- (i) the date of such finding; and
- (ii) the nature of the conditions of registration and practice that may be in place at the time of the issuing of the certificate.

(3) The registrar may issue a certified extract from the register or a certificate under his or her hand as provided in section 24 to any person upon payment of the prescribed fee.

(4) A certificate may be issued subject to certain conditions imposed by the professional board concerned and such conditions shall be indicated on the certificate.

Qualifications for registration

26. The Minister may, on the recommendation of the council, prescribe the qualifications obtained by virtue of examinations conducted by an accredited university, or other educational institution or examining authority in the Republic, which, when held singly or conjointly with any other qualification, shall entitle any holder thereof to registration in a registration category in terms of this Act if he or she has, before or in connection with or after the acquisition of the qualification in question, complied with such conditions or requirements as may be prescribed.

Community service

27. (1) Notwithstanding section 26, any person registering for the first time in a category of registration listed in the regulations made in terms of this Act shall perform remunerated community service in health care for a period of one year in terms of the regulations contemplated in subsection (2) and shall, on the completion of such service, be entitled to practise the profession.

(2) The Minister may, after consultation with the council, make regulations concerning the performance of the service contemplated in subsection (1), including but not limited to –

- (a) the place or places at which it is to be performed;
- (b) the conditions of employment pertaining to persons who perform such service; and
- (c) the registration categories excluded from such service.

Registration of person who hold other qualifications

28. (1) The Minister may, after consultation with the council by regulation provide that any person who holds a qualification which the council may accept by virtue of the fact

that such qualification, in the opinion of the council, indicates a satisfactory standard of professional education and training, may be registered in terms of this section in the applicable prescribed registration category, and thereupon the relevant professional board may in its discretion, but subject to any regulations and national health policy and international protocols which the Minister may make or be subject to, register such person.

(2) A professional board may require a person who holds a qualification referred to in subsection (1) and who applies for registration in terms of this section, to pass to the satisfaction of the professional board, on a date and at a place determined by the professional board, an evaluation contemplated in subsection (3) before persons appointed by the professional board, for the purpose of determining whether such person possesses adequate professional knowledge, skill and competence and whether he or she is proficient in any of the official languages of the Republic.

(3) The council may from time to time determine –

- (a) the nature of the evaluation which shall be conducted the purpose of subsection (2), the requirements for admission and any other matter relating to such evaluation, including the number of attempts; and
- (b) the fees which shall be paid by persons who present themselves for such evaluation by persons who present themselves for such evaluation.

(4) (a) Despite section 27, no person with a foreign qualification may be registered in the category independent practice unless he or she is a South African citizen or has attained permanent residence status in terms of the Immigration Act 2002, (Act 13 of 2002).

(b) The Council may exempt any person who has applied for exemption and is in the Republic for a temporary and particular purpose.

(5) The Minister may, in consultation with the council and the relevant professional board, make regulations concerning the imposition of restrictions on any person registered in terms of subsection (1), subject to which he or she shall be entitled to practise the profession in question, and the lifting of such restrictions.

Continuing professional development to retain registration

29. The council may, after consultation with a professional board, make rules which –

- (a) determine conditions relating to continuing professional development to be undertaken by persons registered in terms of this Act in order to retain such registration;

- (b) determine the nature and extent of continuing professional development to be undertaken by persons registered in terms of this Act;
- (c) relate to the criteria for recognition by the professional board of continuing professional development activities and of providers offering such activities; and
- (d) relate to offences in respect of, and penalties for, non-compliance with this section.

Registration of non-residents for education and training

30. (1) For the purpose of promoting education or training for the practising of a health profession in respect of which registration in terms of this Act is a requirement, the relevant professional board may, notwithstanding the provisions of this Act, register any person not permanently resident within the Republic to teach and train in and practise such profession for such period as the professional board may determine.

(2) Any person registered in terms of subsection (1) may provide education and training at institutions approved for that purpose by the professional board in respect of such health profession as part of such education and training.

Registration of non-residents for post-graduate studies

31. (1) Any person not permanently resident within the Republic and having such education, training and experience as the relevant professional board may, for the purposes of this section, deem satisfactory, may, notwithstanding the provisions of this Act, be registered by the professional board for the purposes of subsection (2) for such period, not exceeding two years, as the professional board may determine.

(2) Any person registered in terms of subsection (1) shall only be entitled to engage in post-graduate or post-diploma studies at such university or other educational institution in the Republic as the professional board may determine.

Universities and other educational institutions to furnish particulars

32. (1) Every university or other educational institution at which a qualification can be obtained which entitles any holder thereof to registration under this Act, shall furnish a professional board on its request with full particulars as to –

- (a) the minimum age and evidence of compliance with set standards of education and training required of students;

- (b) evidence of compliance with the set course of study, training and examinations or assessment methodologies required of a student before such qualification is granted;
- (c) the results of any examinations conducted by it,
- and any other particulars relating to the education and training offered by such institution as the professional board may from time to time require for the accreditation of the qualification or qualifications offered by that institution for the purpose of registration under this Act.

(2) If any university or other educational institution referred to in subsection (1) fails or refuses to furnish any particulars requested by a professional board under that subsection, or if it appears to the professional board that any provision of this Act is not being properly complied with by any such university or other educational institution and that such improper compliance is having or may have an adverse effect on the standards of education and training maintained at that university or other educational institution, the professional board concerned may suspend accreditation of the university or other educational institution referred to in subsection (1) until such time as the university or other educational institution concerned has complied with the conditions and terms determined by the board.

(3) The professional board may, when it has been made to appear to it upon representations made by the affected institution that satisfactory provision has been made for complying with the requirements of this Act by the said institution, reinstate, by notice in the *Gazette*, the accreditation of that institution.

(4) A qualification specified in a notice issued under subsection (2) which has been granted by the university or educational institution to which such notice relates between the date specified in that notice and the date of the repeal of that notice, shall not entitle the holder thereof to registration under this Act.

(5) The relevant professional board may appoint a person to be present whenever tests or examinations are being conducted by any university or other educational institution in respect of the academic progress made by students at such university or other educational institution and to report to the relevant professional board thereon.

Scope of registrable health professions and registration of certain persons

33. (1) The Minister may, on the recommendation of the council and the relevant professional board, by regulation define the scope of any health profession registrable in terms of this Act by specifying the acts which shall for the purposes of the application of this Act be deemed to be acts pertaining to that profession: Provided that such

regulations shall not be made unless any professional board established in terms of section 15 in respect of any profession which may in the opinion of the Minister be affected by such regulation, has been given an opportunity of submitting, through the council, representations as to the definition of the scope of the profession in question: Provided further that if there is a difference of opinion between the council and such professional board as to the definition of the scope of the profession concerned, the council shall mention this fact in its recommendation.

(2) When a professional board has been established under section 14 in respect of any health profession, the professional board shall, subject to such restrictions in respect of his or her professional activities as it may determine, register in respect of such profession, the name of any person who –

- (a) (i) was engaged in the practice of such profession in the Republic or in a territory which formerly formed part of the Republic for a continuous period of not less than five years immediately prior to the date referred to in paragraph (b);
 - (ii) is dependent, wholly or mainly, for his or her livelihood on the practice of such profession; and
 - (iii) submits a certificate to the professional board stating that he or she is of good character; and
- (b) submits to the professional board an application in the prescribed form containing proof to the satisfaction of the professional board of the facts referred to in subparagraphs (i) and (ii) of paragraph (a), within six months (or such longer period as the professional board may allow) after the date on which the scope of such profession was defined by the Minister in regulations contemplated in subsection (1).

(3) The professional board may conduct an oral or practical examination for a person referred to in subsection (2) in order to determine the restrictions referred to in that subsection in respect of his or her professional activities.

(4) Any person registered under subsection (2) in respect of any other health profession shall only be entitled to practise that profession subject to –

- (a) such restrictions in respect of his or her professional activities; and
- (b) the use of such name, title and description in respect of his or her profession, as the professional board may determine.

(5) The professional board may allow a person referred to in subsection (2) to sit for an examination and if such person passes such examination to the satisfaction of the professional board, it shall exempt him or her from all restrictions imposed in respect of him or her under subsection (2).

(6) Subject to the provisions of subsection (2)(c) and section 35, no person shall practise within the Republic any health profession the scope of which has been defined by the Minister in terms of subsection (1), unless he or she is registered in terms of this Act in respect of such profession.

(2) Any person who contravenes the provisions of subsection (1) shall be guilty of an offence and on conviction liable to the penalties mentioned in section 35.

Registration of additional qualifications, specialists, subspecialists, professional categories and additional professional categories

34. (1) A person who desires to have a qualification registered, other than the qualification by virtue of which he or she has in the first instance been registered, or to be registered as a specialist or in a subspeciality, professional category or additional professional category recognised by a professional board shall, upon payment of a prescribed fee and subject to the provisions of subsection (2), be entitled to be registered as a specialist or in a professional category or additional professional category or to have such additional qualification entered in the register.

(2) Where a person fails in respect of any provision of a regulation made under section 55 (1) (f) and applies to be registered as a specialist or in a professional category or an additional professional category in terms of this section, the relevant professional board may require him or her to pass to the satisfaction of the professional board, on a date and at a place determined by the professional board, an examination prescribed under subsection (3) before examiners appointed by the professional board, for the purpose of determining whether his or her professional knowledge, skills and competence in the discipline of his or her speciality or field of his or her professional category is sufficiently adequate to enable him or her to practise as a specialist or to be registered in that professional category or additional professional category.

(3) The Minister may on the recommendation of the council, and in consultation with the relevant professional board, from time to time make regulations which prescribe the examination which shall be conducted for the purposes of subsection (2), and the fees which shall be paid by persons who sit for such examination.

(4) Only such additional and specialist qualifications, specialities and subspecialities, professional categories or additional professional categories as may be prescribed, shall be registrable under this section.

(5) No registered person shall take, use or publish in any way whatsoever any name, title, description or symbol indicating or calculated to lead persons to infer that he or she holds any professional qualification which is not shown in the register as registered

against his or her name, nor shall any registered person practise as a specialist or hold himself or herself out to be a specialist unless his or her speciality has been registered as prescribed.

(6) (a) The relevant professional board may remove from the register any qualification registered in terms of subsection (1), if in respect of such qualification the name of the holder thereof has been removed from the roll, register or record of the university, hospital, college, society or other body from which that person received such qualification.

(b) The relevant professional board may remove from the register any speciality if it is satisfied that the person on whose application such speciality has been registered has not complied with the requirements prescribed in regard to the registration of specialities, and shall so remove any speciality on the written application of the person concerned.

(c) A qualification removed in terms of paragraph (a) or a speciality removed in terms of paragraph (b), shall be restored to the register by the registrar upon the person concerned—

- (i) applying on the prescribed form for such restoration;
- (ii) paying the fee prescribed in respect of such restoration; and
- (iii) complying with such other requirements, if any, as the relevant professional board may determine.

CHAPTER 3

OFFENCES BY UNREGISTERED PERSONS

Prohibition of performance of certain acts by unregistered persons

35. (1) No person shall perform any act deemed to be an act pertaining to any health profession as may be prescribed under this Act unless he or she –

- (a) is registered in terms of this Act in respect of such profession;
- (b) (i) is registered in terms of this Act in respect of any other profession referred to in section 33 to which such act is also deemed to pertain; or
- (ii) practises a health profession in respect of which the registrar in terms of this Act keeps a register and such act is deemed to be an act which also pertains to such profession; or
- (c) is registered or enrolled as a nurse under the Nursing Act, 2005 (Act 33 of 2005), and such act is an act which also pertains to the profession of a nurse.

(2) A person who contravenes subsection (1) shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding 12 months, or to both a fine and such imprisonment.

Penalty for professing to be registered or holder of certain qualifications

36. Any person who is not registered in respect of any health profession, but –

- (a) pretends to be so registered in respect of such profession; or
- (b) uses any name, title, description or symbol indicating, or calculated to lead persons to infer that he or she is the holder of any qualification which by rule under this Act is recognized by the relevant professional board as acceptable for registration in respect of such profession, but of which qualification he or she is not the holder; or
- (c) uses any name declared by regulation to be a name which may not be used,

shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding five years, or to both a fine and such imprisonment.

CHAPTER 4

DISCIPLINARY POWERS OF PROFESSIONAL BOARDS

Inquiries into unprofessional conduct

37. (1) A professional board shall have power to institute an inquiry into any complaint, charge or allegation of unprofessional conduct against any person registered under this Act, and, on finding such person guilty of such conduct, to impose any of the penalties prescribed in section 39 (1).

(2) A professional board may, whenever it is in doubt as to whether an inquiry should be held, in connection with the complaint, charge or allegation in question consult with or seek information from any person, including the person against whom the complaint, charge or allegation has been lodged.

Manner in which investigations may be instituted

38. (1) The registrar may, where necessary in order to establish more facts, appoint an officer of the professional board as an investigating officer for the purposes of this section.

(2) If the registrar deems it necessary, he or she may appoint any person other than a member of the professional board, who is not in the full-time employment of the

professional board, as investigating officer for a particular investigation, or to assist the investigating officer contemplated in subsection (1) with a particular investigation.

(3) A person appointed in terms of subsection (2) shall, for the purpose of the investigation in question, have the same powers and duties as the investigating officer contemplated in subsection (1).

(4) The registrar shall issue to every person appointed under subsection (1) or (2) a certificate to the effect that he or she has so been appointed, and, in the case of a person appointed for, or to assist with, a particular investigation, that he or she has been appointed for such investigation, and in the exercise of his or her powers and the carrying out of his or her duties that person shall on demand produce such certificate.

(5) If the registrar deems it necessary for the achievement of the objects of this Act, he or she may institute or cause to be instituted an investigation –

- (a) into an alleged contravention of, or failure to comply with, any provision of this Act;
- (b) in order to determine if any provision of this Act applies to or has been contravened by a registered person; and
- (c) into a charge, complaint or allegation of unprofessional conduct by a registered person.

(6) (a) An investigating officer carrying out an investigation in terms of this section may request any person to –

- (i) produce to him or her any book, document, electronic data or thing which such investigating officer on reasonable grounds believes to relate to the matter which he or she is investigating, and which such investigating officer on reasonable ground believes to be –
 - (aa) on any premises which are owned by or in the possession of or controlled by such person; or
 - (bb) in the possession of or under the control of or upon such person; and
- (ii) furnish such explanations to him or her as he or she may reasonably require in relation to any such book, document, electronic data or thing.

(b) Subject to paragraph (h), an investigating officer carrying out an investigation in terms of this section must apply to a magistrate or a judge for a search warrant for –

- (i) any premises on which the investigating officer on reasonable ground believes one or more articles referred to in paragraph (a) may be found; or
- (ii) any person whom the investigating officer on reasonable grounds believes to have in his or her possession or upon his or her person or under his or her control one or more articles referred to in paragraph (a).

(c) The magistrate or judge to whom an application in terms of paragraph (b) is made may issue the search warrant if it appears to him or her from information on oath that there are reasonable grounds for believing that any such article is –

- (i) upon or at any such premises within his or her area of jurisdiction; or
- (ii) in the possession or under the control of or upon any such person within his or her area of jurisdiction.

(d) A search warrant issued under paragraph (c) must require the investigating officer and, if so requested by the investigating officer, any named police official or police officials who have agreed to assist in executing the search warrant, to seize the article or articles in question, and must to that end authorise such investigating officer and police official or police officials to search any person identified in the warrant or to enter and search any premises identified in the warrant and to search any person found on or at such premises.

(e) A search warrant issued under paragraph (c) must be executed by day, unless the magistrate or judge issuing the warrant in the warrant authorises the execution thereof by night.

(f) A search warrant may be issued under paragraph (c) on any day and must be of force until it is executed or cancelled by the magistrate or judge who issued it or, if such person is not available, by a person with like authority.

(g) An investigating officer executing a warrant under this section must after such execution, upon demand of any person searched or who owns or is in possession of or controls any premise searched or whose rights in respect of any search or article seized under the warrant may have been affected, hand to such person a copy of the warrant so executed.

(h) An investigating officer carrying out an investigation in terms of this section may without a search warrant issued under paragraph (c) search any person or premises for the purpose of seizing any article referred to in paragraph (a) if –

- (i) the person concerned consent to such search for and the seizure of the article in question;
- (ii) the person who may consent to the search of the premises consents to such search for and the seizure of the article in question; or
- (iii) the investigating officer on reasonable grounds believes that a search warrant will be issued to him or her under paragraph (c) if he or she applies for such warrant and that the delay in obtaining such warrant would defeat the object of the search.

(8) (a) The registrar or an investigating officer who carries out an investigation under this section, shall compile a report of the investigation, and a report compiled by an investigating officer shall be submitted to the registrar.

(b)(i) If such a report reveals *prima facie* evidence of unprofessional conduct contemplated in this Act and no complaint or charge has been lodged or laid or allegation regarding the conduct in question has been made for the purpose of an inquiry in terms of section 41, such report shall be deemed to be a complaint made for that purpose, and the registrar shall serve a copy thereof on the registered person concerned.

(ii) If such a report reveals *prima facie* evidence which makes it desirable that an investigation in terms of section 51 be instituted, the registrar shall serve a copy thereof on the health committee to further investigate and deal with the matter in terms of this Act.

(iii) If such a report does not reveal *prima facie* evidence of unprofessional conduct contemplated in this Act, the registrar shall serve a copy thereof on the registered person concerned.

(c) To the extent that such a report contains statements of witnesses which would have been admissible as oral evidence at an inquiry in terms of section 41 or an investigation in terms of section 51, the provisions of section 213 of the Criminal Procedure Act, 1977 (Act 51 of 1977), shall apply *mutatis mutandis* in respect of those statements at such an inquiry.

(9) (a) A person who carries out or assists with the carrying out of an investigation in terms of this section, shall keep or assist in preserving confidentiality in respect of all facts which come to his or her notice in the performance of his or her functions, and shall not disclose any such fact to any person except the registrar, the president, chairperson of a relevant professional board or the public prosecutor concerned in the case of an offence in terms of this Act, or by order of a court.

(b) Notwithstanding the provisions of paragraph (a), no personal particulars regarding a patient shall be disclosed to any person except by order of a court or with the consent of the presiding officer at an inquiry contemplated in section 41 or an investigation contemplated in section 51.

(10) Such an order shall be executed as if it were a judgment in a civil case in a magistrate's court.

(11) Any person who –

- (a) refuses or neglects to produce any book, document, electronic data or thing to any person who is in terms of this section authorized to ask for it;
- (b) hinders or obstructs the registrar or an investigating officer in the exercise of his or her powers or the carrying out of his or her duties;

- (c) pretends that he or she is the registrar or an investigating officer;
- (d) contravenes a provision of subsection (9),

shall be guilty of an offence and liable on conviction –

- (i) in the case of a contravention contemplated in paragraph (a), (b) or (c), to a fine or to imprisonment for a period not exceeding twelve months or to both a fine and such imprisonment;
- (ii) in the case of a contravention contemplated in paragraph (d), to a fine or to imprisonment for a period not exceeding two years or to both a fine and such imprisonment.

(12) The provisions of this section shall be without prejudice to the power of any authority to institute an investigation into any alleged contravention of, or failure to comply with, any provision of this Act.

Matters for and procedure at inquiry

39. (1) Any person registered under this Act who, after a determination made by a preliminary committee of inquiry on minor transgressions or an inquiry held by a professional conduct committee, is found guilty of improper or disgraceful conduct, or conduct which, when regard is had to such person's profession, is improper or disgraceful, shall be liable to one or more of the following penalties:

- (a) A caution or a reprimand or a reprimand and a caution;
- (b) suspension for a specified period from practising or performing acts specially pertaining to his or her profession;
- (c) removal of his or her name from the register;
- (d) a prescribed fine;
- (e) a compulsory period of professional service as may be determined by the professional board; or
- (f) the payment of the costs of the proceedings or a restitution or both.

(2) If an appeal is lodged against a penalty of erasure or suspension from practice, such penalty shall remain effective until the appeal is finalised.

(3) Every person whose conduct is the subject of an inquiry under section 37 shall be afforded an opportunity, by himself or herself or through his or her legal representative, of answering the charge and of being heard in his or her defence.

(4) (a) For the purposes of any inquiry held in terms of section 37, a professional board may take evidence and may, under the hand of the chairperson of the professional board or the registrar, summon witnesses and require the production of any book, record, document or thing, and may, through the chairperson of the professional board or the

person presiding at the inquiry, administer an oath to any witness or accept an affirmation from him or her, and may examine any book, record, document or thing which any witness had been required to produce.

(b) A summons to appear before a professional board as a witness or to produce to it any book, record, document or thing shall be, as nearly as practicable, in the prescribed form, shall be signed by the chairperson of the professional board or the registrar and shall be served either by registered letter sent through the post or in the same manner as it would have been served if it were a subpoena issued by a magistrate's court.

(c) Every person summoned in terms of this subsection shall be bound to obey the summons and any person who, having duly been summoned –

- (i) refuses, or without sufficient cause fails, to attend and give evidence relevant to the inquiry at the time and place specified in the summons;
- (ii) refuses to take the oath or to make an affirmation when required by the chairperson of a professional board or the person presiding at the inquiry to do so; or
- (iii) refuses to produce any book, record, document or thing which he or she has in terms of the summons been required to produce,

shall be guilty of an offence and on conviction liable to a fine determined by the Minister in consultation with the Minister of Justice by notice in the *Gazette*: Provided that every person so summoned shall be entitled to all the privileges to which a witness subpoenaed to give evidence before a provincial division of the High Court is entitled.

(5) The chairperson of a professional board, where the professional board itself holds an inquiry in terms of section 37, or the chairperson of a professional conduct committee of a professional board, where such a committee holds an inquiry under powers delegated to it by the professional board, may appoint a person with adequate experience in the administration of justice to be present as an assessor at such an inquiry and to advise the professional board or such committee, as the case may be, on matters of law, procedure or evidence.

(6) The professional board may, if it deems fit, and subject to such conditions as it may determine –

- (a) terminate any suspension under subsection (1) before the expiry of the specified period; or
- (b) on payment of the prescribed fee, restore to the register any name which has been removed therefrom.

(7) If a person registered in terms of this Act (in this section referred to as the respondent) is alleged to be guilty of unprofessional conduct and the professional board

on reasonable grounds is of the opinion that it shall impose a fine as determined by the Minister in consultation with the Minister of Justice by notice in the *Gazette* on conviction after an inquiry under section 37, the professional board may issue a summons as prescribed on which an endorsement is made by the professional board or the registrar that the respondent may admit that he or she is guilty of the said conduct and that he or she may pay the fine stipulated without appearing at the said inquiry.

(8) Where a summons in terms of subsection (7) is issued against a respondent, he or she may, without appearing at an inquiry in terms of section 37, admit his or her guilt in respect of the conduct referred to in subsection (1) by paying the stipulated fine (in this section referred to as the admission of guilt fine) to the relevant professional board before a date specified in the summons.

(9) (a) Any penalty imposed under this section, excluding an admission of guilt fine, shall be paid to the professional board within 14 days after such imposition.

(b) The imposition of a penalty shall have the effect of a civil judgment of the magistrate's court of the district in which the inquiry under section 41 took place.

(10) The Minister may on the recommendation of the professional board amend the amount mentioned in subsection (7) by notice in the *Gazette*.

Postponement or suspension of penalty

40. (1) Where a professional board finds a person referred to in section 39 (1) guilty of conduct referred to therein, it may –

- (a) postpone for such period and on such conditions as may be determined by it, the imposition of the penalty; or
- (b) impose any penalty mentioned in paragraph (b), (c) or (d) of section 39 (1), but order the execution of such penalty or any part of the penalty to be suspended for such period and on such conditions as may be determined by it.

(2) (a) If at the end of the period for which the imposition of a penalty has been postponed in terms of subsection (1) (a), the professional board is satisfied that the person concerned has observed all the relevant conditions, the professional board shall inform the person concerned that no penalty will be imposed upon him or her.

(b) If the execution of a penalty or any part of a penalty has been suspended in terms of subsection (1) (b), and the professional board is satisfied that the person concerned has observed all the relevant conditions, the professional board shall inform such person that such penalty or part thereof will not be executed.

(c) If the execution of a penalty or any part of a penalty has been suspended in terms of subsection (1) (b) and the person concerned fails to observe any of the

conditions of suspension, the professional board shall put such penalty or part thereof into operation, unless such person satisfies the professional board that the non-observance of the condition concerned was due to circumstances beyond his or her control.

Effect of suspension or removal from register

41. Every person who has been suspended or whose name has been removed from the register in terms of section 39 shall, if his or her profession is one which, under this Act, cannot be lawfully practised by an unregistered person, be disqualified from practising his or her profession and his or her registration certificate shall be deemed to be cancelled until the period of suspension has expired or until his or her name has been restored to the register by the professional board.

Cognizance of conduct of registered persons

42. (1) Every registered person who, either before or after registration, has been convicted of any offence by a court of law may be dealt with by the professional board in terms of the provisions of this Chapter if the professional board is of the opinion that such offence constitutes unprofessional conduct, and shall be liable on proof of the conviction to one or other of the penalties referred to in section 39: Provided that, before imposition of any penalty, such person shall be afforded an opportunity of tendering an explanation to the professional board in extenuation of the conduct in question.

(2) Whenever in the course of any proceedings before any court of law it appears to the court that there is *prima facie* proof of unprofessional conduct on the part of a registered person, or of conduct which, when regard is had to such person's profession, is unprofessional, the court shall direct that a copy of the record of such proceedings, or such portion thereof as is material to the issue, shall be transmitted to the relevant professional board.

Penalty for false evidence

43. Any person who gives false evidence on oath at any inquiry held under this Chapter, knowing such evidence to be false, shall be guilty of an offence and liable on conviction to the penalties prescribed by law for the crime of perjury.

Limitation of liability

44. Save as is provided in this Act, the council or a professional board or any member or officer thereof shall not be liable in respect of any act done in good faith or duty performed in accordance with this Chapter.

Rules relating to offences

45. (1) The council shall, in consultation with a professional board, from time to time make rules specifying the acts or omissions in respect of which the professional board may take disciplinary steps under this Chapter: Provided that the powers of a professional board to inquire into and deal with any complaint, charge or allegation relating to a health profession under this Chapter, shall not be limited to the acts or omissions so specified.

Regulations relating to investigations in respect of certain persons

46. The Minister may, after consultation with the council and the professional boards, make regulations relating to investigations in respect of students or persons registered in terms of this Act who appear to be impaired, on the assessment of their condition, the conditions to be imposed on their registration or practice, their suspension or removal from practising, revocation of conditions, suspension or removal and on acts of unprofessional conduct committed before or during assessment or investigation.

CHAPTER 5

GENERAL AND SUPPLEMENTARY PROVISIONS

Dispensing of medicines

47. (1) A medical practitioner, dentist or other person registered in terms of this Act –
- (a) may compound or dispense medicines only on the authority and subject to the conditions of a licence granted by the Director-General in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965);
 - (b) shall not be entitled to keep an open shop or pharmacy.
- (2) For the purposes of this section '**open shop**' means a situation where the supply of medicines and scheduled substances to the public is not done by prescription by a person authorized to prescribe medicine.

Fees charged by registered persons

48. (1) Every person registered under this Act (in this section referred to as the practitioner) shall, unless the circumstances render it impossible for him or her to do so, before rendering any professional services inform the person to whom the services are to be rendered or any person responsible for the maintenance of such person, of the fee which he or she intends to charge for such services –

(a) when so requested by the person concerned; or

(b) when such fee exceeds that usually charged for such services,

and shall in a case to which paragraph (b) relates, also inform the person concerned of the usual fee.

(2) Any practitioner who in respect of any professional services rendered by him or her claims payment from any person (in this section referred to as the patient) shall, subject to the provisions of section 32 of the Medical Schemes Act, 1998 (Act 131 of 1998), furnish the patient with a detailed account within a reasonable period.

(3) (a) The patient may, within three months after receipt of the account referred to in subsection (2), apply in writing to the professional board to determine the amount which in the opinion of the professional board should have been charged in respect of the services to which the account relates, and the professional board shall, as soon as possible after receipt of the application, determine the said amount and notify the practitioner and the patient in writing of the amount so determined: Provided that before the professional board determines the said amount, it shall afford the practitioner concerned an opportunity to submit to it in writing his or her case in support of the amount charged.

(b) The Minister may, after consultation with the council, make such regulations as he or she may deem necessary in relation to the procedure which a professional board shall follow in disposing of an application under this subsection.

(c) A professional board may from time to time determine and publish the fees used by the professional board as norm for the determination of amounts contemplated in paragraph (a).

(4) A claim which is the subject of an application referred to in subsection (3) of which notice has been given by the professional board or the patient to the practitioner, shall not be recoverable until a determination has been made in terms of that subsection, and when such a determination has been made no amount which exceeds the amount so determined, shall be payable: Provided that if the patient has paid to the practitioner an amount in settlement or part settlement of such claim and such amount exceeds the

amount so determined, the practitioner shall pay the amount by which that payment exceeds the amount so determined back to the patient.

(5) This section shall not be deemed to divest a professional board of any of its powers or functions under Chapter 4 with regard to acts or omissions in respect of which it may take disciplinary steps.

(6) For the purposes of this section 'professional services' shall include the supply of any artificial part for the human body and the fitting of such part to the human body.

Exemption from provisions of Act

49. (1) The Minister may in consultation with the council by notice in the *Gazette* exempt any juristic person or class of juristic persons specified in the notice, either generally or subject to such conditions as may be specified in the notice, from the operation of any of the provisions of this Act, so as to enable such juristic person to practise a profession, likewise specified, in respect of which registration in terms of this Act is a prerequisite for practising.

(2) Any reference in this Act or any other law to a person registered in terms of this Act to practise a profession referred to in subsection (1) or to a partner of or a partnership in relation to such registered person, shall be deemed to include a reference to a juristic person referred to in subsection (1) or to a member of such a juristic person, as the case may be, unless the context otherwise indicates.

(3) The Minister may in consultation with the council at any time by notice in the *Gazette* amend or repeal any notice issued under subsection (1).

Penalty for false representations, false entries and impersonation

50. Any person who –

- (a) procures or attempts to procure for himself or herself or any other person registration under this Act or any certificate, order or prescription referred to in this Act by means of a false representation, whether verbally or in writing, or aids or abets any person in so doing;
- (b) makes or causes to be made any unauthorized entry or alteration in or removal from a register or certified copy thereof or extract therefrom or on any certificate issued under this Act;
- (c) wilfully destroys or damages or renders illegible or causes to be destroyed, damaged, or rendered illegible any entry in the register or, without the permission of the holder thereof, any certificate issued under this Act;

- (d) forges or, knowing it to be forged, utters any document purporting to be a certificate issued under this Act;
- (e) impersonates any person registered in terms of this Act; or
- (f) supplies or offers to supply to any person not registered under this Act or the Nursing Act, 2005, any instrument or appliance which can be used, or is claimed to be effective, for the purpose of diagnosing, treating or preventing physical or mental defects, illnesses or deficiencies in humankind, knowing that such instrument or appliance will be used by such unregistered person for the purpose of performing an act which such unregistered person is in terms of the provisions of this Act or the said Nursing Act prohibited from performing,

shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding 12 months or to both a fine and such imprisonment.

Death of person undergoing certain procedures

51. The death of a person undergoing, or as a result of, a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquests Act, 1959 (Act 58 of 1959), or the Births and Deaths Registration Act, 1992 (Act 51 of 1992).

Commission on prescriptions

52. (1) No medical practitioner or dentist or any other person registered in terms of this Act shall accept or obtain from a pharmacy any commission or other reward in connection with any prescription given by such medical practitioner or dentist or person.

(2) Any medical practitioner or dentist or any other person registered in terms of this Act who contravenes the provisions of subsection (1) shall be guilty of an offence and on conviction liable to a fine as determined by the Minister in consultation with the Minister of Justice by notice in the *Gazette*, and in addition may be dealt with by the professional board in terms of the provisions of Chapter 4.

Limitations in respect of unregistered persons

53. (1) No remuneration shall be recoverable in respect of any act specially pertaining to the profession of a registered person when performed by a person who is not registered under this Act to perform such act.

(2) No person other than a registered person holding the necessary qualifications shall be eligible for or entitled to hold any appointment to any establishment, institution, body, organization or association, whether public or private, if such appointment involves the performance of any act which an unregistered person, in terms of the provisions of this Act, may not perform: Provided that nothing in this subsection shall be construed as prohibiting the education and training of health professionals under the supervision of a health professional, or the employment in any hospital or similar institution of any person undergoing education and training with a view to registration in terms of this Act in respect of any health profession, under the supervision of a health professional.

Investigation of matters relating to education or training

54. (1) Notwithstanding anything to the contrary contained in any law, any person who has been authorized by a professional board in writing to investigate any matter relating to the education or training of any person who is undergoing such education or training for the purpose of qualifying for the practising of any profession to which the provisions of this Act apply, may, for the purpose of making such investigation, enter any institution or premises utilized in the education or training of any such person.

(2) Any person who prevents any person authorized in terms of subsection (1) from entering any institution or premises referred to in that subsection, or who hinders him or her in the making therein or thereon of any investigation contemplated in that subsection, shall be guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding 12 months or to both a fine and such imprisonment.

Regulations

55. (1) The Minister may, after consultation with the council, make regulations relating to –

- (a) (i) the registration by the council of students in registrable professions studying at any accredited educational institution or training facility, the fees payable in respect of such registration and the removal by the council from the register in question of the names of such students so registered;
- (ii) the standards of general education required of such students as a condition precedent to such registration;
- (iii) the duration of the curricula to be followed by such students at such educational institution or training facility;

- (iv) the minimum requirements of the curricula and the standards of education, training and examinations to qualify for registration in terms of this Act, which must be maintained at every educational institution or training facility offering education and training in any such profession, in order to secure recognition under this Act of the qualifications in question at such educational institution or training facility;
- (b)
 - (i) the minimum age and the standard of general education required of a candidate for examination for a certificate entitling the holder thereof to registration in terms of this Act;
 - (ii) the persons who may be admitted to such examinations;
 - (iii) the courses of study and the training required for such examinations;
 - (iv) the institutions and facilities at which such education or training may be taken or undergone and any other requirements in connection with such education or training;
 - (v) the registration by the council of persons taking or undergoing such education or training provided for in section 56 (1) (l);
 - (vi) the appointment and remuneration of moderators and examiners, as well as any other person required to assist in such examinations;
 - (vii) the issue of certificates by the council and any other matter incidental to such examinations or the issue of such certificates;
 - (viii) the nature and duration of the training to be undergone by persons who have obtained such certificates but who have not yet been registered, before they may be so registered;
 - (ix) the nature and duration of the training to be undergone by any person who has obtained a qualification in a profession prescribed in terms of section 26 or 28, but who is not yet registered as such, before he or she may be registered as such;
- (c) the conditions under which any registered person may practise his or her profession;
- (d) the names which in terms of section 36 (c) may not be used;
- (e)
 - (i) the registration of interns, where applicable, to a registrable profession, including the recording of particulars of their training and proof of the performance thereof;
 - (ii) the hospitals or other facilities at which or the persons with whom such training may be undertaken and the accreditation of such facilities or persons;
 - (iii) any other matter incidental to the registration or training of interns;

- (f)
 - (i) the registration in terms of section 34 of the specialities or subspecialities or professional categories or additional professional categories of the health professions;
 - (ii) the requirements to be satisfied, including the education and training to be obtained, the nature and duration of the education and training to be undergone and the qualifications to be held by persons before any person may be registered as a specialist or in any subspeciality, professional category or additional professional category;
 - (iii) the circumstances under which any applicant for registration as a specialist shall be exempted from any of such requirements;
 - (iv) conditions in respect of the practising of a specialist or a person whose subspeciality, professional category or additional professional category has been registered, including conditions restricting the practice of such a specialist or any such person to the speciality, subspeciality or professional category or additional professional category in which he or she holds registration;
- (g) the requirements for a valid nomination of a candidate for appointment by the Minister as a member of a professional board;
- (h)
 - (i) the manner in which complaints, charges or allegations brought against a registered person shall be lodged;
 - (ii) the method of summoning a respondent and the penalties for failure or refusal on the part of any such respondent to respond to or attend or for obstructing or interrupting any part of the professional conduct inquiry;
 - (iii) the continuation of a professional conduct inquiry, after a plea has been lodged, by the committee conducting the inquiry, should one or more members of the committee be unable to continue to serve: Provided that not less than four of the original members of the committee are available to continue with the inquiry;
 - (iv) the procedure to be followed to lodge an appeal with an appeal committee and the time within which an appeal may be lodged;
 - (v) any other matter relating to the conduct of such an inquiry;
- (i) the accreditation by a professional board of pathology laboratories providing services which fall within the ambit of this Act, the laying down of conditions with which such laboratories must comply to obtain accreditation;
- (j) any matter which in terms of this Act is required to be prescribed by regulation; and

(k) generally, all matters which the Minister considers necessary or expedient to prescribe in order that the purposes of this Act may be achieved, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.

(2) The Minister may, after consultation with the council, if he or she deems it to be in the public interest, amend or repeal any regulation or rule made in terms of this Act.

(3) Any regulation made under this section may prescribe penalties for any contravention thereof or failure to comply therewith.

(4) Any proclamation or notice issued or regulation, rule or order made under this Act may from time to time be amended or repealed by the authority by which it was issued or made.

(5) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the *Gazette* together with a notice declaring his or her intention to make such regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

(6) The provisions of subsection (5) shall not apply in respect of-

- (a) any regulation which, after the provisions of subsection (5) have been complied with, has been amended by the Minister in consequence of representations received by him or her in pursuance of the notice issued thereunder; and
- (b) any regulation in respect of which the Minister is advised by the council that the public interest requires it to be made without delay.

Rules

56. (1) The council may make rules or adopt policies relating to –

- (a) the conduct of the business and the procedure at meetings of the council and committees of the council and the manner in which minutes of such meetings shall be kept;
- (b) the manner in which contracts shall be entered into on behalf of the council, the accounts of the council shall be kept and the manner in which money accruing to the council shall be disposed of;
- (c) the professional fees and allowances which may be paid to members of the council or to members of professional boards established in terms of section 14 or to members of committees or subcommittees of the council or professional boards and other persons who render services to the council or professional boards;
- (e) any fees payable in terms of this Act, which may include –
 - (i) registration fees;

- (ii) annual fees provided for in section 57;
- (iii) fees payable for restoration of –
 - (aa) a name to a register from which it had been removed and such fees may vary according to the reason for the removal thereof and the period for which it was so removed;
 - (bb) a person as a specialist or in a subspeciality or an additional qualification;
 - (cc) a professional category or an additional professional category;
- (iv) fees payable for the issuing of certificates;
- (v) fees payable for examinations conducted by or on behalf of professional boards; and
- (vi) fees payable for accreditation of educational institutions, training facilities, activities for continuing professional development, and pathology laboratories;
- (f) the forms of the registers to be kept in terms of this Act and of all certificates which may be issued under this Act and the manner in which alterations may be effected in such registers;
- (g) the forms to be completed and the documents to be submitted by applicants for registration or for restoration to the register;
- (h) the returns and information to be furnished by any person registered in terms of this Act;
- (i) the qualifications which may be registered as specialist and additional qualifications in terms of section 34; and
- (j) any matter which in terms of this Act is required to be or may be promulgated as rules.

(2) The council shall, after consultation with the professional boards, not less than three months before any rule is made in terms of this Act, cause the text of such rule to be published in the *Gazette* together with a notice declaring the council's intention to make such rule and inviting interested persons to furnish the council with any comments thereon or any representations they may wish to make in regard thereto.

Levying of annual fee on certain registered persons

57. (1) The Minister may, on the recommendation of the council, at any time by notice in the *Gazette* authorise the council to prescribe a fee to be paid annually to the council by the registered persons concerned: Provided that in prescribing such fee the council may differentiate between persons according to whether they have been registered before or after a date specified in the notice and may vary such fee according to whether

it is paid before or after a specific date, and the profession and registration category in which they hold registration.

(2) If any person liable to pay any annual fee prescribed in terms of subsection (1) fails or refuses to pay such fee within the period specified in the notice in question, the council may recover such fee by action in a competent court.

(3) If a person's name has been removed from the register in terms of section 20 (1) (d), it shall be a condition precedent for the restoration of his or her name to the register that he or she pays the outstanding annual fee or fees and such restoration fees as may be prescribed.

(4) A professional board may by resolution exempt for an indefinite or definite period any registered person specified in the resolution from payment of any annual fee prescribed in terms of subsection (1).

Repeal of laws and savings

58. (1) Subject to the provisions of subsection (2), the laws specified in the Schedule are hereby repealed to the extent set out in the third column of the said Schedule.

(2) Any proclamation, notice, regulation, rule, authorization or order issued, made or granted, or any registration, removal from a register, appointment or any other thing done in terms of a provision of any law repealed by subsection (1), shall, in so far as it could have been made under a corresponding provision of this Act, be deemed to have been issued, made, granted or done under the provisions of this Act.

Transitional provisions

59. (1) For the purposes of this section –

- (a) “Council” means the Health Professions Council of South Africa established by section 2 of the Health Professions Act 56 of 1974;
- (b) “commencement date” means the date on which this Act takes effect;
- (c) “Department” means the national Department of Health.

(2) The Council continues to perform the functions which it performed before the commencement date.

(3) Persons who are registered on the commencement date must be regarded as having been registered in terms of this Act and the registrar must retain them in the relevant register.

(5) (a) The registration of any person which was pending before the commencement date, must be dealt with by the Council as if this Act has not been passed.

(b) Any appeal in terms of the Health Professions Act 56 of 1974 that is pending on the commencement date must be dealt with as if this Act had not been passed.

(c) Rules, decisions, guidelines and procedures made and adopted by the Council that are in force on the commencement date and that deals with matters in respect of which the Council may make rules and guidelines in terms of this Act, remain in force until amended or repealed by the Council.

Short title and commencement

60. This Act shall be called the Health Professions Act, 2018, and shall come into operation on a date fixed by the State President by proclamation in the *Gazette*.

SCHEDULE

LEGISLATION REPEALED

| No and year | Title | Extent of repeal |
|-------------|--|------------------------|
| 56 of 1974 | Health Professions Act, 1974 | The whole |
| 57 of 1975 | General Law Amendment Act, 1975 | Sections 46, 47 and 48 |
| 33 of 1976 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1976 | The whole |
| 36 of 1977 | Health Laws Amendment Act, 1977* | Sections 12 to 18 |
| 52 of 1978 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1978 | The whole |
| 43 of 1980 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1980 | The whole |
| 66 of 1981 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1981 | The whole |
| 38 of 1982 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1982 | The whole |
| 58 of 1984 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1984 | The whole |
| 79 of 1990 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1990 | The whole |
| 58 of 1992 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1992 | The whole |

| | | |
|------------|--|-----------|
| 18 of 1995 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1995 | The whole |
| 89 of 1997 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1997 | The whole |
| 1 of 1998 | Medical, Dental and Supplementary Health Service Professions Amendment Act, 1998 | The whole |
| 29 of 2007 | Health Professions Amendment Act, 2007 | The whole |

Annexure G

Medicines and Related Substances Bill

ACT

To provide for the registration and control of medicines, medical devices, *in vitro* diagnostic devices and related substances intended for human and for animal use; to provide for the establishment of the South African Health Products Regulatory Authority; to provide that such Authority shall be a juristic person; to provide for a board through which the Authority acts; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to prohibit the sale of medicines, medical devices and IVDs which do not comply with prescribed requirements; to provide for measures for the supply of more affordable medicines, medical devices and IVDs; to provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and act as wholesalers or distributors; to provide for generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines; to provide for appeals against decisions of the Director-General or the Authority; to regulate the Minister's power to make regulations; and to provide for matters connected therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:-

ARRANGEMENT OF SECTIONS

CHAPTER 1 DEFINITIONS

1. Definitions

CHAPTER 2
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

2. Establishment of South African Health Products Regulatory Authority
3. Objects of Authority
4. Functions of Authority
5. Funds of Authority
6. Composition of Board
7. Appointment of members of Board
8. Appointment of chairperson and vice-chairperson of Board
9. Disqualification from membership of Board and vacation of office
10. Meetings of Board
11. Committees of Board
12. Dissolution of Board
13. Chief Executive Officer and other staff of Authority

CHAPTER 3
REGISTRATION OF MEDICINES, MEDICAL DEVICES AND IVDS

14. Registers
15. Prohibition on sale of certain medicines, medical devices and IVDs
16. Registration of medicines, medical devices and IVDs
17. Amendment of entries in register
18. Transfer of certificate of registration
19. Measures for more affordable medicines
20. Cancellation of registration
21. Notification of registration or cancellation

CHAPTER 4
CONTROL OF MEDICINES, SCHEDULED SUBSTANCES, MEDICAL DEVICES AND
IVDS

22. Labels and advertisements
23. Bonus and rebate systems and incentive schemes
24. Sampling of medicines, medical devices and IVDs
25. Marketing of medicines, medical devices and IVDs
26. Prohibition on sale of certain medicines, medical devices and IVDs

- 27. False advertisements concerning medicines, medical devices and IVDs
- 28. Sale of unregistered medicines, medical devices and IVDs for certain purposes
- 29. Furnishing of information
- 30. Control of medicines, scheduled substances, medical devices and IVDs
- 31. Publication of information

CHAPTER 5

LICENSING

- 32. Licence to manufacture, import, export, act as wholesaler or distribute
- 33. Period of validity and renewal of licence
- 34. Suspension and cancellation of licence
- 35. Generic substitution
- 36. Pricing committee
- 37. Purchase and sale by wholesalers
- 38. Disposal of undesirable medicines, medical devices and IVDs

CHAPTER 6

APPEALS, INSPECTORS, OFFENCES AND PENALTIES

- 39. Appeal against decision of Director-General
- 40. Appeal against decision of Authority
- 41. Privileges of Authority and committees
- 42. Inspectors
- 43. Analysts, pharmacologists, engineers, technicians and pathologists
- 44. Powers of inspectors

CHAPTER 7

ADMINISTRATION OF ACT

- 45. Offences
- 46. Penalties
- 47. Procedure and evidence
- 48. Act or omission by manager, agent or employee
- 49. Preservation of secrecy
- 50. Delegation of powers
- 51. Regulations

52. Exclusion of medicines, scheduled substances, medical devices and IVDs from Act

53. Prohibition of manufacture, sale or use of certain veterinary medicines

CHAPTER 8 MISCELLANEOUS MATTERS

54. Amendment of Schedules

55. Operation of Act in relation to other laws

56. Transitional provisions

57. State bound

58. Repeal of laws

59. Short title and commencement

CHAPTER 1 DEFINITIONS

Definitions

1. (1) In this Act, unless the context otherwise indicates –

'advertisement', in relation to any medicine, scheduled substance, medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference –

(a) appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that medicine, scheduled substance, medical device or IVD, and **'advertise'** has a corresponding meaning;

'analyst' means an analyst to whom authority has been granted under section 42;

'approved name', in relation to a medicine, means the international non-proprietary name (INN) of such medicine or, where no such name exists, such other name as the council may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1993 (Act 194 of 1993);

'Authority' means the South African Health Products Regulatory Authority established by section 2;

'Board' means the Board referred to in section 2;

'certificate of registration' means a certificate of registration issued under section 16(4), 17(4) or 18(4);

'dentist' means a person registered as such under the Health Professions Act, 1974;

'Director-General' means the Director-General: Health;

'export' includes deliver or supply within the Republic for dispatch to any destination outside the Republic;

'hospital' means any institution established as a hospital or a nursing home or registered as such in terms of any law;

'immediate container', in relation to a medicine or scheduled substance, means a container which is in direct contact with the medicine or substance;

'inspector' means a person authorized as such under section 42;

'interchangeable multi-source medicine' means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed;

'IVD' (*in vitro* diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

'label', when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article;

'magistrate' means a magistrate as defined in section 1 of the Magistrates Act, 1993 (Act 90 of 1993), and includes an additional magistrate and an assistant magistrate;

'medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act 15 of 1973) –

- (a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:
- (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
 - (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
 - (iv) supporting or sustaining life;
 - (v) control of conception;

- (vi) disinfection of medical devices; or
 - (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and
- (b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

'medical device or IVD establishment' means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;

'medical practitioner' means a person registered as such under the Health Professions Act, 1974, and includes an intern registered under that Act;

'medicine' –

- (a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in –
- (i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
 - (ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and
- (b) includes any veterinary medicine;

'Minister' means the member of Cabinet responsible for health;

'nurse' means a person registered as such under the Nursing Act, 2005 (33 of 2005);

'package' means anything in or by which any medicine or scheduled substance is enclosed, covered, contained or packed;

'pathologist' means a pathologist to whom authority has been granted under section 43;

'pharmacist' means a person registered as such under the Pharmacy Act, 1974;

'pharmacist intern' means a person registered as such under the Pharmacy Act, 1974;

'pharmacist's assistant' means a person registered as such under the Pharmacy Act, 1974;

'pharmacologist', except for the purposes of section 39(1)(c), means a pharmacologist to whom authority has been granted under section 43;

'practitioner' means a person registered as such under the Allied Health Professions Act, 1982 (Act 63 of 1982);

'prescribed' means prescribed by or under this Act;

'public' includes a section of the public concerned with manufacturing, dispensing, selling or administering, or the issue of prescriptions for, medicines or a scheduled substance;

'register', when used as a noun, means the register referred to in section 14, and when used as a verb, means to enter in such register;

'registered' means entered in the register;

'regulation' means a regulation made and in force under this Act;

'scheduled substance' means any medicine or other substance prescribed by the Minister under section 30;

'sell' means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and **'sale'** and **'sold'** have corresponding meanings;

'this Act' includes any regulation;

'veterinarian' means a person registered as such under the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982);

'veterinary medicine' means any substance or mixture of substances, other than a stock remedy or farm feed [to be] registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying any somatic or organic function, or for correcting or modifying behaviour; and

'vigilance', in relation to a medicine, medical device or IVD, means the continuous monitoring and evaluation of its safety, efficacy and performance profile and the management of any risk throughout its life-cycle.

CHAPTER 2

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Establishment of South African Health Products Regulatory Authority

2. (1) The South African Health Products Regulatory Authority is hereby established as an organ of state within the public administration but outside the public service.

(2) The Authority is –

- (a) a juristic person;
- (b) subject to the Public Finance Management Act, 1999 (Act 1 of 1999); and
- (c) accountable to and reports to the Minister.

(3) The Authority may exercise the powers and shall perform the functions conferred upon or assigned to it by this Act.

(4) In performing its functions, the Authority shall act without fear, favour or prejudice.

(5) The Authority acts through its Board.

Objects of Authority

3. The objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest.

Functions of Authority

4. (1) The Authority must, in order to achieve its objects –

- (a) ensure the efficient, effective and ethical evaluation or assessment and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety, efficacy and performance, where applicable;
- (b) ensure that the process of evaluating or assessing and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously;
- (c) ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVDs;
- (d) ensure that evidence of existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon;
- (e) ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and
- (f) ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.

(2) The Authority may –

- (a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange

information with and receive information from any such authority or institution in respect of –

- (i) matters of common interest; or
 - (ii) a specific investigation; and
- (b) enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

Funds of Authority

5. (1) The funds of the Authority shall consist of –

- (a) State funds received through the Department of Health;
- (b) fees raised and interest on overdue fees;
- (c) money accruing to the Authority from any other source.

(2) (a) The Authority may accept money or other goods donated or bequeathed to the Authority, provided no condition is attached to such donation or bequest.

(b) Details of any such donation or bequest shall be specified in the relevant annual report of the Authority.

(3) The Authority shall utilise its funds for the defrayal of expenses incurred by the Authority in the performance of its functions under this Act.

(4) The Authority shall open an account with a bank as defined in section 1 (1) of the Banks Act, 1990 (Act 94 of 1990), and shall deposit in that account all money

Composition of Board

6. (1) The Board of the Authority consists of not less than 10 but not more than 15 members appointed by the Minister.

(2) Subject to section 7, the Minister must appoint as members of the Board –

- (a) not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health or epidemiology;
- (b) one person on account of his or her knowledge of the law;
- (c) one person on account of his or her knowledge of good governance;
- (d) one person on account of his or her knowledge of financial matters and accounting;
- (e) one person on account of his or her knowledge of information technology; and
- (f) one person on account of his or her knowledge of human resource management.

(3) The Chief Executive Officer is by virtue of his or her office a member of the Board but with no voting rights.

Appointment of members of Board

7. (1) The Minister must, before appointing the members contemplated in section 6(2), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based.

(2) If the Minister receives no nominations or an insufficient number of nominations within the period specified in the notice referred to in subsection (1), the Minister may either readvertise or, in any other transparent manner, appoint the required number of qualified persons in terms of this Act.

(3) Subject to section 9, a member of the Board –

- (a) holds office for a minimum period of three years, but not exceeding five years, determined by the Minister at the time of the appointment of the member; and
- (b) is eligible for re-appointment for one additional term.

(4) A member of the Board, excluding a member who is in the full-time employment of the State, must be appointed on such conditions as the Minister may, with the concurrence of the Minister of Finance, determine.

Appointment of chairperson and vice-chairperson of Board

8. (1) The Minister must appoint a chairperson and vice-chairperson of the Board from among the members contemplated in section 6(2).

(2) Whenever the chairperson of the Board is absent or unable to perform his or her functions as chairperson, the vice-chairperson must act as chairperson and if the vice-chairperson is absent or unable to act as chairperson the Minister must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available.

(3) Any person acting as chairperson of the Board in terms of subsection (2) has all the powers and duties of the chairperson.

Disqualification from membership of Board and vacation of office

9. (1) A person may not be appointed as a member of the Board if that person –

- (a) is not a South African citizen and ordinarily resident in the Republic;
- (b) is an unrehabilitated insolvent;
- (c) has at any time been convicted of an offence involving dishonesty, whether in the Republic or elsewhere, and sentenced to imprisonment without the option of a fine; or
- (d) has been removed from an office of trust.

(2) A member of the Board must vacate office if –

- (a) he or she becomes disqualified in terms of subsection (1), from being appointed as a member of the Board;
- (b) he or she submits his or her resignation to the Minister in writing;
- (c) he or she is declared by the High Court to be of unsound mind or mentally disordered or is detained under the Mental Health Care Act, 2002 (Act 17 of 2002);
- (d) he or she has, without the leave of the Board, been absent from more than two consecutive meetings of the Board; or
- (e) the Minister, after consultation with the Board, withdraws the appointment of that member because the member is incompetent or unfit to fulfil his or her duties.

(3) If a member of the Board dies or vacates office in terms of subsection (2), the Minister may, subject to section 7, appoint a person to fill the vacancy for the unexpired portion of the period for which that member was appointed.

Meetings of Board

10. (1) The meetings of the Board and the conduct of business at meetings must be determined by the rules of the Board.

(2) A quorum for a meeting of the Board is the majority of its voting members.

(3) A decision of the majority of the members of the Board present at any meeting constitutes a decision of the Board and, in the event of an equality of votes, the member presiding at the meeting has a casting vote in addition to his or her deliberative vote.

(4) A decision taken by the Board or an act performed under the authority of the Board is not invalid by reason only of a vacancy on the Board, or that a person who is not entitled to sit as a member of the Board sat as a member at the time when the decision was taken or the act was authorised, if the decision was taken or the act was authorised

by the requisite majority of the members of the Board who were present at the time and entitled to sit as members.

(5) Minutes of the proceedings of every meeting of the Board must be prepared and stored by such means as may be determined by the Board.

(6) Minutes of the proceedings of each meeting must be submitted at the next meeting of the Board and, if passed as correct, must be confirmed by the signature of the chairperson or other member presiding thereat and may, when so confirmed, be evidence in a court of law of the proceedings of the first-mentioned meeting.

(7) In the absence of the chairperson or the person acting as the chairperson from a particular meeting of the Board, the members present at that meeting may elect one of their number to preside at that meeting.

Committees of Board

11. The Board may appoint one or more committees from among its members to assist it with the performance of its functions.

Dissolution of Board

12. (1) The Minister may dissolve the Board if the Minister, on good cause shown, loses confidence in the ability of the Board to perform its functions effectively and efficiently.

(2) The Minister may dissolve the Board only –

- (a) after having given the Board a reasonable opportunity to be heard; and
- (b) after having afforded the Board a hearing on any submissions received.

(3) If the Minister dissolves the Board, the Minister –

- (a) may appoint an administrator to take over the functions of the Board and to do anything which the Board might otherwise be empowered or required to do by or under this Act, subject to such conditions as the Minister may determine; and
- (b) must, as soon as it is feasible but not later than three months after the dissolution of the Board, replace the members of the Board in the same manner in which they were appointed.

(4) The costs associated with the appointment of an administrator shall be for the account of the Authority.

(5) The appointment of the administrator terminates when the Board members have been replaced in terms of section 6(2).

Chief Executive Officer and other staff of Authority

13. (1) The Board, after consultation with the Minister, must appoint a suitably qualified person as the Chief Executive Officer of the Authority.

(2) A person may not be appointed as the Chief Executive Officer if such person-

- (a) is an unrehabilitated insolvent;
- (b) is mentally unfit; or
- (c) has been convicted of an offence committed after the Constitution of the Republic of South Africa, 1993 (Act 200 of 1993) took effect and sentenced to imprisonment without the option of a fine.

(3) The Chief Executive Officer may be removed from office for –

- (a) serious misconduct;
- (b) permanent incapacity; or
- (c) engaging in any activity that is reasonably capable of undermining the integrity of the Authority.

(4) The Chief Executive Officer-

- (a) is appointed for a term of five years and may be reappointed for one additional term of five years;
- (b) is appointed subject to the conclusion of a performance agreement with the Board;
- (c) is accountable to and reports to the Board; and
- (d) is entitled to the benefits as may be determined by the Minister in consultation with the Minister for the Public Service and Administration;
- (e) is responsible for the general administration of the Authority and for the carrying out of any functions assigned to the Authority by this Act and the Minister;
- (f) must manage and direct the activities of the Authority;
- (g) must appoint and supervise staff of the Authority; and
- (h) must compile business and financial plans and reports in terms of the Public Finance Management Act, 1999 (Act 1 of 1999).

(5) The Chief Executive Officer shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions.

(6) (a) The Minister shall, after consultation with the Minister for Public Service and Administration, determine the structure and the human resources policy for the Authority.

(b) The human resources policy shall include a code of conduct and provisions on conflict of interests applicable to the Chief Executive Officer and the staff of the Authority.

(7) The Authority may utilise persons seconded or transferred from the public service, and such transfer must be in accordance with the Labour Relations Act, 1995 (Act 66 of 1995).

(8) The Chief Executive Officer and the staff of the Authority become members of the Government Employees' Pension Fund contemplated in section 2 of the Government Employees Pension Law, 1996 (Proclamation 21 of 1996).

(9) The Chief Executive Officer shall, in consultation with the Board, appoint committees, as he or she may deem necessary, to investigate and report to the Authority on any matter within its purview in terms of this Act.

CHAPTER 3

REGISTRATION OF MEDICINES, MEDICAL DEVICES AND IVDs

Registers

14. (1) The Chief Executive Officer shall keep separate registers for medicines, medical devices or IVDs, in which he or she shall record –

- (a) the registration of medicines, medical devices or IVDs by the Authority; and
- (b) such particulars in regard to the medicines, medical devices or IVDs and the holder of certificate of registration in respect of such medicines, medical devices or IVDs as are required by this Act.

(2) The Chief Executive Officer shall publish on the Authority's website the registers referred to in subsection (1) and update those registers when registration is obtained.

Prohibition on sale of certain medicines, medical devices and IVDs

15. (1) Save as provided in this section or sections 28 and 30, no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered.

(2) (a) The Authority may from time to time determine that a medicine, medical device or IVD, or class or category of medicine, medical device or IVD or part of any class or category of medicine, medical devices or IVDs mentioned in the declaration, shall be subject to registration in terms of this Act.

(b) Any such declaration may also relate only to medicines, medical devices or IVDs which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines, medical devices or IVDs which were not then so available.

(c) Any such declaration shall be published in the *Gazette* by the Chief Executive Officer and shall come into operation on the date on which it is so published.

(3) In the case of a medicine, medical device or IVD which was available for sale in the Republic immediately prior to the date of publication in the *Gazette* of the declaration by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation –

- (a) if no application for the registration of such medicine, medical device or IVD is made within the period of six months immediately succeeding that date, on the expiration of that period; or
- (b) if an application for the registration of such medicine, medical device or IVD is made within the said period, on the date one month after the date on which a notice in respect of such medicine, medical device or IVD is published in the *Gazette* in terms of section 16(9) or section 21(a).

(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine –

- (a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 32(1)(a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or
- (b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, and referred to in section 30, as the case may be,

if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected, and is not or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been registered under this Act.

Registration of medicines, medical devices and IVDs

16. (1) Every application for the registration of a medicine, medical device or IVD shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by –

- (a) the prescribed particulars;
- (b) samples of the relevant medicines;
- (c) where practicable, samples of medical devices or IVDs; and
- (d) the prescribed registration fee.

(2) As soon as possible after receipt by the Chief Executive Officer of an application contemplated in subsection (1), he or she shall inform the applicant in writing that the application is being considered.

(3) (a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the medicine, medical device or IVD in question –

- (i) is suitable for the purpose for which it is intended;
- (ii) complies with the prescribed requirements;
- (iii) is safe, efficacious and of good quality and, in the case of a medical device and IVD, performs as intended.

the Authority shall issue the applicant with a certificate of registration to that effect.

(b) If the Authority is not satisfied as contemplated in paragraph (a), it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may within a period of 30 days after the date of the notification furnish the Chief Executive Officer with his or her comments on the Authority's reasons for not being so satisfied.

(c) If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the Authority is still not satisfied as aforesaid, it shall reject the application.

(4) Every medicine, medical device or IVD shall be registered under such name as the Authority may approve.

(5) The Chief Executive Officer shall allocate to every medicine, medical device or IVD registered under this Act a registration number which shall be recorded in the register opposite the name of such medicine, medical device or IVD and which shall be stated in the certificate of registration issued in respect of such medicine, medical device or IVD.

(6) Any registration under this section –

(a) may be made subject to such conditions as may be determined by the Authority;
and

(b) shall in the case of medicines, be valid for a period of five years.

(7) No condition shall be imposed under subsection (6) whereby the sale of the medicine in question by any person other than a pharmacist is prohibited or until after the applicant has in writing been notified by the Chief Executive Officer that the imposition of such condition is contemplated and invited to submit written representations to the Authority in regard to the matter.

(8) If no such representations are lodged by the applicant concerned within a period of 30 days after the receipt by him or her of any notification referred to in subsection (7), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall register the medicine, medical device or IVD concerned subject to the said condition.

(9) Notice of the rejection of an application for registration under this section in respect of a medicine, medical device or IVD referred to in subsection (3) of section 15 shall be given in the *Gazette* by the Chief Executive Officer.

(10) The Chief Executive Officer shall as soon as possible after the date of expiry of the appropriate period referred to in section 15(3) publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him or her prior to such date.

(11) Subject to section 19, a medicine shall, notwithstanding the fact that its components are identical to those of any other medicine as to physical characteristics, quantity and quality, for the purpose of this Act not be regarded as being the same medicine as that other medicine if registration thereof is not applied for by the holder of the certificate of registration issued in respect of that other medicine.

Amendment of entries in register

17. (1) The entry made in the register in respect of any medicine, medical device or IVD may on application by the holder of a certificate of registration issued in respect of such medicine, medical device or IVD be amended by the Chief Executive Officer.

(2) An application for the amendment of an entry in the register shall be made to the Chief Executive Officer in the prescribed form and shall be accompanied by the prescribed application fee.

(3) The Chief Executive Officer may, if necessary, cancel the existing registration in respect of such medicine, medical device or IVD and issue a new certificate of registration.

Transfer of certificate of registration

18. (1) A certificate of registration may with the approval of the Chief Executive Officer be transferred by the holder thereof to any other person.

(2) An application for approval of the transfer of a certificate of registration shall be made to the Chief Executive Officer on the prescribed form and shall be accompanied by the certificate of registration in question and the prescribed application fee.

(3) If the Chief Executive Officer grants any application submitted to him or her in terms of subsection (2), the Chief Executive Officer shall make the necessary entries in the register relating to the person to whom the certificate of registration is transferred, cancel the existing certificate of registration and issue a new one in the prescribed form to such person.

Measures for more affordable medicines

19. The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may –

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the Authority in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

Cancellation of registration

20. (1) If the Authority –

- (a) is of the opinion that a holder of a certificate of registration has failed to comply with any condition subject to which any medicine, medical device or IVD was registered; or
- (b) is of the opinion that any medicine, medical device or IVD does not comply with any prescribed requirement,
- (c) is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be available to the public,

the Authority shall cause notice in writing to be given accordingly by the Chief Executive Officer to the holder of the certificate of registration issued in respect of that medicine, medical device or IVD.

(2) Any such notice shall specify the grounds on which the Authority's opinion is based, and shall indicate that the person to whom it is directed may within one month after receipt thereof submit to the Chief Executive Officer any comments he or she may wish to put forward in connection with the matter.

(3) If no such comments are so submitted, or if after consideration of any comments so submitted the Authority is of the opinion that the registration of the medicine, medical device or IVD in question should be cancelled, the Authority may cancel the registration thereof.

(4) In determining whether or not the registration or availability of a medicine is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of man or any animal, as the case may be.

(5) If the person who is the holder of the certificate of registration issued in respect of any medicine, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine, medical device or IVD before or on the prescribed date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that medicine, medical device or IVD.

Notification of registration or cancellation

21. The Chief Executive Officer shall give notice in the *Gazette* of the registration or cancellation of registration of any medicine, medical device or IVD in terms of this Act, and shall in such notice specify –

- (a) in the case of registration of any medicine, medical device or IVD, the name under which such medicine, medical device or IVD is registered, the active components of such medicine, if any, the name of the person who applied for registration of such medicine, medical device or IVD, the number allocated to it in terms of section 16 and the conditions (if any) subject to which it is registered;
- (b) in the case of a cancellation of the registration, the name under which such medicine, medical device or IVD was registered, the name of the holder of the certificate of registration issued in respect of such medicine, medical device or IVD and the number which was allocated to it in terms of section 16.

CHAPTER 4

CONTROL OF MEDICINES, SCHEDULED SUBSTANCES, MEDICAL DEVICES AND IVDS

Labels and advertisements

22. (1) No person shall sell any –

- (a) medicine or scheduled substance unless the immediate container or the package in which that medicine or scheduled substance is sold bears a label stating the prescribed particulars; and
- (b) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical, stating the prescribed particulars.

(2) No person shall advertise any medicine or scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.

(3) The label referred to in subsection (1) shall be approved by the Authority.

(4) The Authority may authorize a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labelling of medicines, medical devices or IVDs.

Bonus and rebate systems and incentive schemes

23. (1) No person shall supply any medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 36.

Sampling of medicines, medical devices and IVDs

24. (1) No person shall sample any product, medical devices or IVD.

(2) Use of products, medical devices or IVDs for exhibition or appraisal purposes shall be as prescribed.

(3) For the purposes of this section '**sample**' means the free supply of medicines, medical devices or IVDs by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act 56 of 1974), or any professional or person authorized to use the device.

Marketing of medicines, medical devices and IVDs

25. The Minister shall, after consultation with the relevant industries and other stakeholders, make regulations relating to the marketing of medicines, medical devices or IVDs and such regulations shall also provide for Codes of Practice for relevant industries.

Prohibition on sale of certain medicines, medical devices and IVDs

26. (1) No person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements.

(2) The Authority may by notice in writing require any person who manufactures or sells medicines, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine or medical device is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such medicine, medical device or IVD.

(3) The Authority may, if so requested by any person to whom a notice under subsection (2) is addressed, extend the period stipulated in such notice.

False advertisements concerning medicines, medical devices and IVDs

27. (1) No person shall –

- (a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine, medical device or IVD; or
- (b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine, medical device or IVD is other than that stated by the Authority in terms of section 29(1)(a)(ii) or state or suggest that any medicine, medical device or IVD should be used for a purpose or under circumstances or manner other than that stated by the Authority in terms of section 29(1)(a)(ii).

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of subsection (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine, medical device or IVD to which the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading.

Sale of unregistered medicines, medical devices and IVDs for certain purposes

28. (1) The Authority may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.

(2) Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

Furnishing of information

29. (1) The Chief Executive Officer shall cause, in such manner as he or she considers most suitable-

- (a) as soon as practicable after any medicine, medical device or IVD, other than a veterinary medicine, has been registered, medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine, medical device or IVD to be informed-
- (i) of the name and number under which such medicine, medical device or IVD is registered and the conditions, if any, subject to which such medicine, medical device or IVD is registered;
 - (ii) of the therapeutic efficacy and effect of such medicine;
 - (iii) of the purpose for which, the circumstances under which and the manner in which such medicine, medical device or IVD should be used; and
 - (iv) regarding any other matter concerning such medicine, medical device or IVD which, in the opinion of the Chief Executive Officer, may be of value to them;
- (b) as soon as practicable after the registration of any medicine, medical device or IVD, other than a veterinary medicine, has been cancelled in terms of section 20, medical practitioners, dentists, pharmacists, the public in general and the holder of the certificate of registration issued in respect of such medicine, medical device or IVD to be informed of the cancellation of such registration.

(2) The provisions of subsection (1) shall apply *mutatis mutandis* in respect of any veterinary medicine, and for the purposes of such application the reference in that subsection to medical practitioners and dentists shall be deemed to be a reference to veterinarians.

Control of medicines, scheduled substances, medical devices and IVDs (22A)

30. (1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine, scheduled substance, medical device or IVD, except in accordance with the prescribed conditions.

(2) The Minister may, on the recommendation of the Authority, prescribe the scheduled substances referred to in this section.

(3) Any Schedule 0 substance may be sold in an open shop.

(4) Any Schedule 1 substance shall not be sold –

(a) by any person other than –

- (i) a pharmacist, or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist;
- (ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;

- (iii) a medical practitioner or dentist, who may –
 - (aa) prescribe such substance;
 - (bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 32(1)(a);
 - (iv) a veterinarian who may prescribe, compound or dispense such substance;
 - (v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may –
 - (aa) prescribe only the scheduled substances identified in the Schedule for that purpose;
 - (bb) compound and dispense the scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 32(1)(a);
- (b) to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 32(1)(a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;
- (c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.
- (5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than –
- (a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;
 - (b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;
 - (c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
 - (d) a medical practitioner or dentist, who may –
 - (i) prescribe such substance;
 - (ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 32(1)(a);

- (e) a veterinarian who may prescribe, compound or dispense such substance;
 - (f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may –
 - (i) prescribe only the scheduled substances identified in the Schedule for that purpose;
 - (ii) compound and dispense the scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 32(1)(a).
- (6) Any sale under subsection (5) shall only take place on condition that –
- (a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;
 - (b) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription shall within seven days after giving such instructions furnish such pharmacist with a prescription confirming such instructions;
 - (c) in the case of verbal instructions the treatment period shall not exceed seven days;
 - (d) if a prescription is not presented for dispensing within 30 days of issue it shall not be dispensed;
 - (e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 32(1)(a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;
 - (f) in the case of a Schedule 2, Schedule 3 or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;
 - (g) in the case of a Schedule 5 substance, such sale shall not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;
 - (h) where a Schedule 5 substance is used for –
 - (i) its anxiolytic, antidepressant or tranquillising properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted a registered psychiatrist, or, in the case of a psychiatrist, another psychiatrist before issuing a new prescription;

- (ii) its analgesic properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted another medical practitioner, before issuing a new prescription;
- (i) in the case of a Schedule 6 substance, it shall not be repeated without a new prescription being issued;
- (j) in an emergency in which the health or life of a patient is at stake, a pharmacist engaged in wholesale practice may, on receipt of a telephonic or telefaxed or other electronic request, supply a Schedule 6 substance to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, without a written order: Provided that –
 - (i) it shall be the responsibility of such pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person to ensure that such pharmacist receives a written order within seven days.
 - (ii) the Schedule 6 substance shall be supplied in the smallest unit sales pack available;
 - (iii) a permanent record is made and kept of such supply.
- (k) in an emergency a pharmacist may sell any Schedule 5 or Schedule 6 substance in a quantity not greater than that required for continuous use for a period of 48 hours, on the verbal instructions of a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, who is known to such pharmacist, but the prescriber who has given such verbal instructions shall within 72 hours after giving such instructions furnish to such pharmacist a written prescription confirming the instructions;
- (l) in an emergency a pharmacist may sell a Schedule 2, Schedule 3 or Schedule 4 substance on a non-recurring basis for a period not exceeding 30 days in accordance with the original prescription in order to ensure that therapy is not disrupted if he or she is satisfied that an authorised prescriber initiated the therapy, with the intention that the therapy be continued, and that the particulars of such sale are recorded in a prescription book or other prescribed permanent record;
- (m) a pharmacist may sell a greater or a lesser quantity of a Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance than the quantity prescribed or ordered, according to the therapeutic pack in the original container of such substance as supplied to him or her, but the quantity so sold shall not exceed or be less than, 25 per cent of the quantity specified in the prescription or order in question;
- (n) any seller referred to in this subsection shall retain the prescription or order concerned for a period of not less than five years as from the date of such sale;

- (o) a Schedule 6 substance may only be sold if the course of treatment does not exceed 30 consecutive days;
- (p) the sale of a specified Schedule 5 or Schedule 6 substance by a manufacturer of or wholesale dealer in pharmaceutical products shall be recorded in a register which shall be kept in the prescribed manner, and shall be balanced so as to show clearly the quantity of every specified Schedule 5 or Schedule 6 substance remaining in stock as on the last day of March, June, September and December of each year, and such balancing shall be completed within the 14 days following each of the said dates;
- (q) a pharmacist shall endorse on the prescription the date of sale and the quantity of the substance sold, and when it is repeated, the date of sale and the quantity of the said substance sold, and the last seller shall retain the prescription for a period of not less than five years as from the date of the last sale;
- (r) any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practising a para-veterinary profession within the meaning of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian.

(7) (a) No person, other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General for such purpose.

(b) The Director-General may revoke any permit referred to in paragraph (a) if the conditions on which such permit was issued, are not complied with or if it is not in the public interest that the particular action be continued.

(8) Subject to subsection (9), a Schedule 8 substance shall not be acquired by any person other than the Director-General for the purpose of providing a medical practitioner therewith, on the prescribed conditions, for the treatment of a particular patient of that medical practitioner upon such conditions as the Director-General, on the recommendation of the council, may determine.

(9) (a) No person shall –

- (i) acquire, use, possess, manufacture or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture, or supply: Provided that the

Director-General may, subject to such conditions as he or she may determine, acquire or authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;

- (ii) manufacture, use or supply any Schedule 5 or Schedule 6 substance for other than medicinal purposes, unless he or she has been issued by the Director-General with a permit for such manufacture, use or supply upon the prescribed conditions.

(b) Notwithstanding paragraph (a), the Director-General may at any time revoke any permit issued in terms of that paragraph if any condition on which the permit was issued is not being complied with.

(c) A permit issued in terms of this subsection shall be valid for a period of 12 calendar months after the date of issue thereof.

(10) Notwithstanding anything to the contrary contained in this section, no person shall sell or administer any scheduled substance or medicine for other than medicinal purposes: Provided that the Minister may, subject to the conditions or requirements stated in such authority, authorise the administration outside any hospital of any scheduled substance or medicine for the satisfaction or relief of a habit or craving to the person referred to in such authority.

(11) (a) No person shall import or export any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General in the prescribed manner and subject to such conditions as may be determined by the Director-General;

(b) A permit referred to in paragraph (a) may be issued for any purpose other than the satisfaction or relief of a habit or craving in respect of such substance or medicine.

(c) The issue of a permit referred to in paragraph (a) may be refused if –

- (i) the Director-General is not convinced that the applicant is capable of keeping or storing the substance or medicine in a satisfactory manner in order to prevent the loss thereof;
- (ii) the use of such substance or medicine has not been authorised in terms of this Act;
- (iii) the Director-General is of the opinion that the annual importation quota for such substance has been exceeded or will be exceeded;

- (iv) the Director-General is of the opinion that such substance or medicine, of an acceptable quality, is already available in the Republic; or
- (v) the applicant did not comply with the conditions under which a previous permit was issued to him or her.

(d) If an application is refused, the applicant shall be furnished with the reasons for such refusal.

(e) A permit issued in terms of this subsection shall be valid for a period of six months from the date of issue thereof.

- (12) (a) The control on the importation of scheduled substances shall relate to –
- (i) any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance;
 - (ii) such substances irrespective of the scheduling status allocated thereto, as the Minister may prescribe;
 - (iii) any other substance which becomes subject to international control in terms of the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances entered into by the Republic.

(b) The obtaining of import or export permits as required in terms of subsection (11) shall not apply to any preparation which contains a substance as prescribed which is specifically exempted from all control measures for the obtaining of such import or export permits by the 1961 Single Convention on Narcotic Drugs referred to in paragraph (a).

(c) Notwithstanding paragraph (b), no such importation or exportation shall take place unless authorised by the Director-General.

(13) Any permit issued under subsection (11) shall be subject –

- (a) to the applicant's furnishing the Chief Executive Officer annually with the prescribed information;
- (b) to the requirement that there shall be no deviation from the particulars reflected on the permit: Provided that if the quantity of such substance or medicine to be imported is less than that provided for in the permit, the Director-General shall be informed in writing thereof within 10 days after the importation of such substance or medicine; and
- (c) to the conditions, as detailed on the permit, having been complied with, the triplicate copy of the permit having been certified by a customs officer or an employee of the S.A. Post Office Limited.

(14) Notwithstanding anything to the contrary contained in this section –

- (a) a pharmacist's assistant shall not handle any specified Schedule 5 or Schedule 6 substance except as contemplated in subsection (5) (a) and (b); and
- (b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or scheduled substance

unless he or she has been authorised to do so by his or her professional council concerned.

(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.

(16) Notwithstanding anything to the contrary contained in this section –

- (a) any person may possess a Schedule 0, Schedule 1 or Schedule 2 substance for medicinal purposes;
- (b) any person may possess a Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance if he or she is in possession of a prescription issued by an authorised prescriber;
- (c) any medicine or scheduled substance may be possessed by a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, or under the Veterinary and Para-Veterinary Professions Act, 1982, for the purposes of administering it in accordance with his or her scope of practice;
- (d) any medicine or scheduled substance may be possessed for sale by a pharmacist, a person licenced to own a pharmacy in terms of the Pharmacy Act, 1974, or a person who is the holder of a licence as contemplated in section 32 [22C].

(17) International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions.

(18) For the purposes of this section –

- (a) **'authorised prescriber'** means a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974; and
- (b) **'medicinal purpose'** means for the purposes of the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance, except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial government or approved for such purpose by the Minister.

Publication of information

31. (1) Notwithstanding the provisions of section 49 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, scheduled substance, medical device or IVD.

(2) The Director-General may publish the information referred to in subsection (1) or release it to the public in a manner which he or she thinks fit.

**CHAPTER 5
LICENSING****Licence to manufacture, import, export, act as wholesaler or distribute**

32. (1) Subject to the provisions of this section –

- (a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, veterinarian, nurse or other person registered under the Health Professions Act, 1974 (Act 56 of 1974), a licence to compound and dispense medicines, on the prescribed conditions;
- (b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, scheduled substance, medical device or IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

(2) A licence referred to in subsection (1) (a) shall not be issued unless the applicant has successfully completed a supplementary course determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa and the South African Nursing Council.

(3) The Director-General or the Authority, as the case may be, may require an applicant contemplated in subsection (1) to furnish such information, in addition to any information furnished by the applicant in terms of the said subsection, as the Director-General or the Authority may deem necessary.

(4) When the Director-General or the Authority, as the case may be, grants or refuses an application for a licence –

- (a) written notice shall be given of that fact to the applicant; and
- (b) in the event of the refusal of an application, the applicant shall be furnished with the reasons for such refusal.

(5) No person shall compound or dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1) (a).

(6) No medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any medicine, scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.

(7) Subsections (5) and (6) shall come into operation twelve months from the date of commencement of this section.

Period of validity and renewal of licence

33. A licence issued under section 32 shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the Authority, as the case may be, may allow and on payment of the prescribed fee.

Suspension and cancellation of licence

- 34.** (1) If the holder of a licence under section 32 –
- (a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the Authority, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;
 - (b) has contravened or failed to comply with a condition upon which the licence was issued;
 - (c) has contravened or failed to comply with a provision of this Act;
 - (d) has, in the case of a licence issued in terms of section 32(1)(a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines,

the Director-General or the Authority, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

(2) The Director-General or the Authority, as the case may be, may after considering the reasons furnished in terms of subsection (1) –

- (a) suspend the licence in question for such period the Director-General or the Authority may determine; or
- (b) revoke the license in question.

(3) No person shall be entitled to the repayment of any prescribed fee in respect of any application for the granting or renewal of a licence if such application has been refused or if the licence has been suspended or revoked.

Generic substitution

35. (1) Subject to subsections (2), (3) and (4), a pharmacist or a person licensed in terms of section 32(1)(a) shall –

- (a) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution;
- (b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

(2) If a pharmacist is forbidden as contemplated in subsection (1) (b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine-

- (a) if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;
- (b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

- (c) where the product has been declared not substitutable by the Authority.

Pricing committee

36. (1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

(2) The Minister may, on the recommendation of the pricing committee, make regulations-

- (a) on the introduction of a transparent pricing system for all medicines and scheduled substances sold in the Republic;
- (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 32(1)(a);
- (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

(3) (a) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and scheduled substances to any person other than the State.

(b) No pharmacist or person licensed in terms of 32(1)(a) or wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

(c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2) (b).

(4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

Purchase and sale by wholesalers

37. (1)(a) No wholesaler shall purchase medicines, scheduled substances, medical devices or IVDs from any source other than from the original manufacturer or from the primary importer of the finished product.

(b) A wholesaler shall –

- (i) sell medicines, medical devices or IVDs only into the retail sector; and

(ii) sell scheduled substances to any person who may lawfully possess such substance.

(2) Subsection (1) shall not be construed as preventing the return of medicines, medical devices or IVDs for credit purposes only, to the manufacturer or wholesaler from which those medicines, medical devices or IVDs were initially obtained.

(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1).

Disposal of undesirable medicines, medical devices and IVDs

38. (1) If the Authority is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be made available to the public, it may –

(a) by notice in writing transmitted by registered post to any person direct that person;

or

(b) by notice in the *Gazette* direct any person,

to return any quantity of such medicine, medical device or IVD which he or she has in his or her possession to the manufacturer thereof or (in the case of any imported medicine, medical device or IVD) to the importer concerned or to deliver or send it to any other person designated by the Authority.

(2) The Authority may by notice in writing direct any medical device or IVD establishment, manufacturer or importer of any such medicine, medical device or IVD who has in his or her possession any quantity thereof (including any quantity returned, delivered or sent to him or her in pursuance of a direction under subsection (1)), or any other person to whom any quantity of such medicine, medical device or IVD has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) No person shall sell any medicine, medical device or IVD which is the subject of a notice under subsection (1) which has not been set aside on appeal.

CHAPTER 6
APPEALS, INSPECTORS, OFFENCES AND PENALTIES

Appeal against decision of Director-General

39. (1) Any person aggrieved by the decision of the Director-General may within the prescribed period and in the prescribed manner make written representations with regard to such decision to the Minister.

(2) The Minister shall, after considering representations made in terms of subsection (1), confirm, set aside or vary the decision of the Director-General.

Appeal against decision of Authority

40. (1) Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within 30 days of becoming aware of such decision of his or her intention to appeal and setting out the full grounds of appeal.

(2) Upon being notified the Chief Executive Officer shall meet with the appellant within 30 days of being so notified in the absence of legal representatives to try to resolve the matter, especially if the appeal involves administrative matters.

(3) Should the Chief Executive Officer and the appellant fail to resolve the matter as contemplated in subsection (2), the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee.

(4) The appeal committee contemplated in subsection (3) shall –

- (a) comprise the chairperson who shall have knowledge of the law and four other persons who shall have knowledge of the subject matter of appeal but with no financial or business interests in the affairs of the parties to the appeal, two of them nominated by the appellant and the other two by the Chief Executive Officer; and
- (b) conduct the appeal hearing and make a decision within 30 days from the day when it first meets to hear the appeal.

(5) A party aggrieved by the decision of the appeal committee may approach the High Court for a judicial review.

Privileges of Authority and committees

41. The Authority, persons contracted by the Authority to perform work for the Authority, committees appointed in terms of this Act or their members are not liable in respect of anything done in good faith under this Act.

Inspectors

42. (1) The Chief Executive Officer may authorize such persons as inspectors as he or she may consider necessary for the proper enforcement of this Act.

(2) Every inspector shall be furnished with a certificate signed by the Chief Executive Officer and stating that he or she has been authorized as an inspector under this Act.

(3) An inspector shall, before he or she exercises or performs any power or function under this Act, produce and exhibit to any person affected by such exercise or performance, the certificate referred to in subsection (2).

Analysts, pharmacologists, engineers, technicians and pathologists

43. The Chief Executive Officer may grant such authority to such analysts, pharmacologists, engineers, technicians and pathologists or any other appropriately qualified person as he or she may consider necessary for the proper enforcement of this Act.

Powers of inspectors

44. (1) An inspector may, at all reasonable times –
- (a) enter upon-
 - (i) any place or premises from which a person, authorized under this Act to compound or dispense medicines or scheduled substances, dispenses or handles medicines, scheduled substances, medical devices or IVDs or from which the holder of a licence as contemplated in 32(1)(b) conducts a business; or
 - (ii) any place, premises, vessel or aircraft if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed

thereon or therein or that an attempt has been made or is being made to commit such an offence thereon or therein; or

- (iii) any private dwelling, with the consent of the occupier or under the authority of a warrant issued in terms of subsection (5) or without a warrant in terms of subsection (6);
- (b) inspect any medicine, scheduled substance, medical device or IVD, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1) (a);
- (c) seize any such medicine, scheduled substance, medical device or IVD, any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act;
- (d) take so many samples of any such medicine or scheduled substance, medical device or IVD as he or she may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.

(2)(a) Any sample taken in terms of paragraph (d) of subsection (1) shall –

- (i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine, scheduled substance, medical device or IVD, or if there is no such person or if he or she is absent for any reason, in the presence of any other witness;
- (ii) forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit; and
- (iii) then be transmitted to an analyst, pharmacologist, technician, engineer, scientist, pathologist or expert designated by the Authority together with a certificate in the prescribed form signed by such inspector.

(b) A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such medicine, scheduled substance, medical device or IVD or his or her agent.

(3) The analyst, pharmacologist, engineer, scientist, pathologist or expert designated by the Authority to whom a sample has been transmitted in terms of the provisions of subsection (2) shall with all convenient speed test, examine or analyse the sample delivered to him or her, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.

(4) The owner of the medicine, scheduled substance, medical device or IVD from which the sample was taken may claim from the Authority an amount equal to the market value thereof.

(5) Where on application to a magistrate it appears to such magistrate from information on oath that there are reasonable grounds to believe that –

- (a) the conditions for entry described in subsection (1) (a) exist in relation to a private dwelling;
 - (b) entry to that private dwelling is necessary for any purpose relating to the administration or enforcement of this Act; and
 - (c) entry to the private dwelling has been refused or that entry thereto will be refused,
- a magistrate may issue a warrant authorizing the inspector named therein to enter that private dwelling subject to such conditions as may be specified in the warrant.

(6) If an inspector believes on reasonable grounds that –

- (a) a warrant would be issued to him or her under subsection (5) if he or she applies for such a warrant; and
- (b) a delay in obtaining such warrant would defeat the object of the entry, search and seizure,

he or she may without a warrant enter and search any premises for any medicines, scheduled substance, book, record or document relevant to the administration or enforcement of this Act and seize or take samples as contemplated in subsection (1) (c).

CHAPTER 7 ADMINISTRATION OF ACT

Offences

45. Any person who –

- (a) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this Act; or
- (b) contravenes or fails to comply with the provisions of section 15(1), 22, 23 or 24; or
- (c) contravenes the provisions of section 26(1) or fails to comply with a notice issued under section 26(2); or
- (d) contravenes the provisions of section 27(1); or
- (e) contravenes or fails to comply with any condition imposed under section 16(6);
- (f) fails to comply with any direction given under section 38 or contravenes the provisions of section 38(3); or
- (g) with fraudulent intent tampers with any sample taken in terms of this Act; or
- (h) makes any false or misleading statement in connection with any medicine, scheduled substance, medical device or IVD –

- (i) in an application for the registration thereof; or
 - (ii) in the course of the sale thereof; or
- (i) sells any medicine, scheduled substance, medical device or IVD upon the container of which a false or misleading statement in connection with the contents is written; or
- (j) for purposes of business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act; or
- (k) contravenes any provision of section 30, 32(5) and (6), 35, 36 or 37 or contravenes or fails to comply with any condition imposed thereunder;
- (l) contravenes or fails to comply with the provisions of section 49;
- (m) manufactures, sells or uses a veterinary medicine in contravention of a prohibition referred to in section 53, or contravenes, or fails to comply with, a condition imposed in terms of the said section,
- shall be guilty of an offence.

Penalties

46. (1) Any person who is convicted of an offence referred to in section 45 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine, scheduled substance, medical device or IVD in respect of which the offence has been committed to be forfeited to the State.

(3) Any medicine, scheduled substance, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with as the Chief Executive Officer may direct.

(4) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section.

Procedure and evidence

- 47.** (1) In any criminal proceedings under this Act –
- (a) any quantity of a medicine, scheduled substance, medical device or IVD in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample; and

- (c) a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section *twenty-eight* and purporting to be signed by the analyst, pharmacologist or pathologist who carried out such test, examination or analysis, shall be accepted as *prima facie* proof of the facts stated therein;
- (d) any statement or entry contained in any book, record or document kept by any owner of a medicine, scheduled substance, medical device or IVD or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him or her as an admission of the facts set forth in that statement or entry, unless evidence to the contrary which raises a reasonable doubt shows that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his or her work as manager, or in the course of his or her agency or employment.

(3) The court in which any such certificate is adduced in evidence may in its discretion cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question or may cause written interrogatories to be submitted to him for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, shall be admissible in evidence in such proceedings.

Act or omission by manager, agent or employee

48. (1) Whenever any manager, agent or employee of any person (hereinafter called the employer) does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then unless it is proved that –

- (a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the employer; and
- (b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and
- (c) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or omit to do acts, whether lawful or unlawful, of the character of the act or omission charged,

the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

(2) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

(3) Any such manager, agent or employee may be so convicted and sentenced in addition to the employer.

Preservation of secrecy

49. No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer.

Delegation of powers

50. (1) The Minister may in writing authorise the Director-General or any officer of the Department of Health to exercise any of the powers conferred upon the Minister by this Act other than the powers referred to in sections 13, 39(1) and 51, or to exercise or perform any of the duties or functions conferred or imposed on the Minister in terms of this Act.

(2) The Director-General may in writing authorize any officer of the Department of Health to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function, excluding any power, duty or function referred to in subsection (1), conferred or imposed on the Director-General by or in terms of this Act.

(3) The Chief Executive Officer may, in writing, authorise any staff member of the Authority to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function conferred or imposed on the Chief Executive Officer in terms of this Act.

Regulations

51. (1) The Minister may, in consultation with the Authority, make regulations –

- (i) prescribing the categories of persons by whom application may be made for the registration of any medicine, medical device or IVD or to whom a certificate of registration may be transferred;
- (ii) prescribing the forms which shall be used for any application for the registration of any medicine, medical device or IVD and the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine, medical device or IVD in question or any component of such medicine, medical device or IVD is manufactured and the premises at which such medicine, medical device or IVD or any such component is manufactured);
- (iii) providing for the classification of medicines, medical devices or IVDs into classes or categories for the purposes of this Act;
- (iv) prescribing the samples of any medicine, medical device or IVD and the quantity thereof which shall accompany any application for the registration of a medicine, medical device or IVD;
- (v) prescribing the form in which the medicines, medical devices or IVDs register shall be kept and the particulars which shall be entered therein in respect of any registered medicine, medical device or IVD, as the case may be;
- (vi) prescribing the form of any certificate of registration of any medicine, medical device, or IVD;
- (vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine, scheduled substance, medical device or IVD may be sold;
- (viii) prescribing the manner in which any package containing any medicine, scheduled substance, medical device or IVD shall be labelled, packed or sealed;
- (ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine, scheduled substance, medical device or IVD sold, and the manner in which such particulars shall be furnished;
- (x) prescribing the particulars which shall appear in any advertisement relating to any medicine, scheduled substance, medical device or IVD, or prohibiting the inclusion of any specified particulars in such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organisation or a specified category of organisations;

- (xi) prescribing the requirements with which any medicine, or any component thereof, medical device or IVD shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;
- (xii) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in section 15 (10);
- (xiii) relating to the responsibilities of both medical device and IVD establishments and users of medical devices and IVDs, in relation to the use, training, maintenance, calibration, post-marketing surveillance, sterilization, disinfection, recall, decomposition, decommissioning or decontamination of medical devices and IVDs;
- (xiv) prescribing the particulars which shall appear on a prescription or an order for a medicine or a scheduled substance, the number of issues of a medicine or a scheduled substance that may be made on any such specified prescription or order, the manner in which any such prescription or order shall be issued and the period for which any such prescription or order shall be retained;
- (xv) prescribing the forms of licences, registers, prescription books, records and other documents which shall be kept or used in respect of medicines, scheduled substances, medical devices or IVDs, the manner in which they shall be kept, the particulars which shall be entered therein and the place where and the period for which they shall be retained;
- (xvi) requiring the furnishing of returns, reports and information in respect of scheduled substances and plants from which any such substance can be extracted, derived, produced or manufactured, and in respect of any medicine or other substance of which any such scheduled substance is a component;
- (xvii) as to the transshipment or the exportation from or importation into the Republic of any medicine, scheduled substance, medical device or IVD, specifying the ports or places at which such medicine, scheduled substance, medical device or IVD may be brought into the Republic;
- (xviii) authorising and regulating or restricting the transmission through the Republic of medicines, scheduled substances, medical devices or IVDs;
- (xix) prescribing the manner in which packages containing medicines, scheduled substances, medical devices or IVDs shall be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they shall be kept;
- (xx) authorising and regulating the purchase, acquisition, keeping or use of preparations of cocaine by managers or persons in charge of factories or

- workshops in connection with the treatment of eye injuries or for other essential purposes;
- (xxi) authorising and regulating the purchase, acquisition, keeping or use of scheduled substances by particular persons or categories of persons;
 - (xxii) Authorising and regulating the possession by persons entering or departing from the Republic of specified quantities of medicines, scheduled substances, medical devices or IVDs for personal medicinal use;
 - (xxiii) as to the disposal or destruction of a medicine, scheduled substance, medical device or IVD, and the records which shall be kept in respect thereof;
 - (xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines, scheduled substances, medical devices or IVDs, and the manner in which medicines, scheduled substances, medical devices or IVDs shall be kept and controlled in different categories of hospitals;
 - (xxv) prescribing the methods in accordance with which samples may be taken under this Act and the form of the certificates to be issued by inspectors in respect of such samples;
 - (xxvi) prescribing the methods to be employed and the form of the certificates to be issued in connection with the testing, examination or analysis of samples taken under this Act;
 - (xxvii) authorising, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device, IVD or class of medical devices, IVDs or medicines in respect of its safety, quality and efficacy;
 - (xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines, medical devices or IVDs;
 - (xxix) as to the summary seizure and disposal of any medicine, scheduled substance, medical device or IVD found in the possession or custody of any person not entitled under this Act to keep or use it;
 - (xxx) as to the disposal or destruction of a medicine, scheduled substance, medical device or IVD which has become unfit for use, and the report to be furnished in respect thereof;
 - (xxxi) prescribing the fee to be paid to the Authority in respect of an application for the registration, and in respect of the registration of a medicine, medical device or IVD, the fee to be paid annually to the Authority in respect of the retention of the certification or the registration of a medicine, medical device or IVD and the date on which such annual fee shall be paid;

- (xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, medical devices or IVDs, the issuing of permits and certificates under this Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the safety, quality and efficacy of medicines, scheduled substances, medical devices or IVDs for the purpose of registration, the evaluation of technical amendments and changes to the particulars contained in registers and the testing for batch release of biological medicines;
- (xxxiii) relating to appeals against decisions of the Director-General or the Authority;
- (xxxiv) relating to the conditions under which medicines, scheduled substances, medical devices or IVDs may be sold;
- (xxxv) relating to the repackaging of medicines in patient-ready packs;
- (xxxvi) relating to the safety, quality and efficacy of any interchangeable multi-source medicine;
- (xxxvii) relating to the scientific, pharmaceutical, clinical and other skills required by a member of the council or by a member of the executive committee of the council to evaluate the quality, efficacy and safety of medicines;
- (xxxvii) relating to the scientific, pharmaceutical, clinical, technical and other skills required by members of staff of the Authority to evaluate the quality, efficacy and safety of medicines, medical devices and IVDs;
- (xxxviii) relating to the safety, quality and efficacy of imported medicines, scheduled substances, medical devices and IVDs;
- (xxxix) relating to the control and conduct of clinical trials;
 - (xl) relating to medicines, scheduled substances, medical devices or IVDs in respect of matters contemplated in paragraphs (i) up to and including paragraph (xi) and paragraphs (xxiii), (xxiv), (xxxii), (xxxiv) and (xxxviii);
 - (xli) relating to the control of medicines, scheduled substances, medical devices and IVDs in general;
 - (xlii) relating to the licensing for possessing or using certain medicines, scheduled substances, medical devices or IVDs;
 - (xliii) relating to time frames for the consideration of applications by the Authority;
 - (xliv) with regard to any matter which in terms of this Act shall or may be prescribed; and
 - (xlv) generally for the efficient carrying out of the objects and purposes of this Act, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.

(2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the *Gazette*, together with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

(3) The provisions of subsection (2) shall not apply in respect of-

- (a) any regulation which, after the provisions of that subsection have been complied with, has been amended by the Minister in consequence of comments or representations received by him or her in pursuance of the notice issued thereunder; or
- (b) any regulation in respect of which the Minister is, after consultation with the Authority, of the opinion that the public interest requires it to be made without delay.

(4) A regulation under subsection (1) (xxxi) and (xxxii) shall be made only in consultation with the Minister of Finance.

(5) Regulations made under subsection (1) (xi) may prescribe that any medicines, scheduled substances, medical device or IVD or any component thereof shall comply with the requirements set out in any publication which in the opinion of the Authority is generally recognised as authoritative.

(6) Regulations may be made under this section in respect of particular medicines, scheduled substances, medical devices or IVDs or classes or categories of medicines, scheduled substances or medical devices or IVDs or in respect of medicines, scheduled substances, medical devices or IVDs other than particular classes or categories thereof, and different regulations may be so made in respect of different medicines, scheduled substances, medical devices or IVDs or different classes or categories thereof.

(7) (a) Regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith of a fine, or imprisonment for a period not exceeding 10 years.

(b) Notwithstanding anything to the contrary in any law contained a magistrate's court shall be competent to impose any penalty provided for in paragraph (a).

(8) Notwithstanding the provisions of subsection (1), the Minister may, if he or she deems it to be in the public interest, after consultation with the Authority, make regulations relating to any matter referred to in subsection (1) or amend or repeal any regulation made in terms of that subsection.

Exclusion of medicine, scheduled substance, medical device and IVD from Act

52. (1) The Minister may, on the recommendation of the Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any medicine, schedule substance, medical device or IVD from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

(2) Notwithstanding subsection (1), the exclusion of any medicine or scheduled substance from the operation of sections 23 and 36 shall be effected by the Minister on the recommendation of the Pricing Committee.

Prohibition of manufacture, sale or use of certain veterinary medicines

53. Notwithstanding anything to the contrary in this Act or in any other law contained, the Minister may by notice in the *Gazette* for any reason other than the safety, quality or therapeutic efficacy of a veterinary medicine –

- (a) prohibit the manufacture, sale or use of any veterinary medicine containing a substance mentioned in the notice; or
- (b) prohibit such manufacture, sale or use, except in accordance with such conditions as may be specified in the notice,

and may in like manner repeal or amend such notice.

**CHAPTER 8
MISCELLANEOUS MATTERS****Amendment of Schedules**

54. Notwithstanding the provisions of section 51(2), the Minister may, on the recommendation of the Authority, from time to time by notice in the *Gazette* amend any Schedule prescribed under section 30(2) by the inclusion therein or the deletion therefrom of any medicine or other substance, or in any other manner.

Operation of Act in relation to other laws

55. The provisions of this Act shall be in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.

Transitional provisions

56. (1) For the purposes of this section –

- (a) “Authority” means the South African Health Products Regulatory Authority established by section 2 of this Act;
- (b) “commencement date” means the date on which this Act takes effect;
- (c) “Council” means the Medicines Control Council established by section 2 of the Medicines and Related Substances Control Act 101 of 1965; and
- (d) “Department” means the national Department of Health.

(2) (a) The Council continues to perform the functions which it performed before the commencement date but ceases to exist the day immediately before the date of the first meeting of the Board appointed by the Minister in terms of section 6 of this Act.

(b) The date of the first meeting of the Board referred to paragraph (a) must be determined by the Minister.

(c) Anything done by the Council that could have been done by the Authority in terms of this Act must be regarded as having been done by the Authority.

(3) Medicines, medical devices and IVDs that are registered on the commencement date must be regarded as having been registered in terms of this Act and the Chief Executive Officer must enter them in the relevant register.

(4) (a) The Minister must, at least 30 days before the commencement date, designate all the employees of the Department who are engaged in the regulation of medicines and health technologies and in radiation control as employees to be transferred to the Authority.

(b) An employee contemplated in paragraph (a) must be informed in writing of the designation as soon as possible after designation.

(c) The transfer of the designated employees must be in accordance and subject to –

- (i) the relevant labour legislation;
- (ii) the Public Service Act, 1994 (Proclamation No. 103 of 1994); and
- (iii) any collective agreement reached between employers and employees.

(d) For the purposes of the Income Tax Act, 1962 (Act No. 58 of 1962), no change of employer must be regarded as having taken place when employment is taken up at the Authority by a person contemplated in this subsection.

(e) Any person transferred to the Authority in terms of this subsection remains subject to any decision, proceeding, ruling and direction applicable to that person immediately before the transfer date to the extent that such decision, proceeding, ruling and direction remain applicable.

(f) Any proceedings against a person transferred to the Authority that were pending immediately before the transfer date must be disposed of as if that person had not been transferred.

(5) (a) Registration of any medicine, medical device or IVD which was pending registration before the commencement date, must be dealt with by the Authority as if this Act has not been passed.

(b) Any appeal in terms of section 24 of the Medicines and Related Substances Act 101 of 1965 that is pending on the commencement date must be dealt with as if this Act had not been passed.

(c) Decisions, guidelines and procedures made and adopted by the Department that are in force on the commencement date and that deals with matters in respect of which the Authority may make rules and guidelines in terms of this Act, remain in force until amended or repealed by the Authority.

(6) (a) The ownership and control of all movable property of which the ownership and control vested in the State immediately before the commencement date and which has been used for the purposes or in connection with the exercise or performance of the powers and duties of the employees transferred to the Authority in terms of this section must be transferred to the Authority.

(b) In the event of the movable property being held under a lease or pledge or any form of security, such lease or pledge or other security are transferred on the commencement date to the Authority.

(c) On production of a certified register by the Director-General of the Department that movable property that constitutes part of the resources of the employees contemplated in subsection (4)(a) is owned by the State, the Authority must make such entries or endorsements in or on any relevant register or other document to register that movable property in its name, and the Director-General must remove that removable property from its asset register.

(d) From the commencement date all contractual rights, obligations, assets and liabilities of the Department in respect of that part of the Department under which the employees contemplated in subsection (4)(a) fall vest in and must be transferred to the Authority.

(e) Any litigation resulting from any cause of action in relation to the assets, rights, obligations or liabilities transferred to the Authority in terms of paragraph (a) which arose –

- (i) before the commencement date, must be conducted by or against the Department; and

(ii) on or after the commencement date must be conducted by or against the Authority.

(f) If there is any uncertainty about which movable property must be transferred to the Authority, the matter must be finally determined by the Minister, in consultation with the Minister of Finance.

(7) The fees to be charged by the Authority for services rendered to any applicant in respect of any medicine, scheduled substance, medical device and IVD must, from the commencement date, be as contained in the regulations in force and used by the Department immediately before the commencement date until the relevant regulations have been amended or substituted by the Minister in terms of the principal Act as amended by this Act.

(8) (a) All debt owing to the Department for medicines regulation immediately before the date of commencement of this Act is payable to the Authority and must be managed under the same conditions that applied immediately prior to that commencement date.

(b) The Authority may alter the conditions under which the debt is managed after giving the debtors three months' notice of the proposed changes.

(c) The bank account held by the Department for medicine regulation and all amounts in the account must be transferred to the Authority on the commencement date.

State bound

57. This Act binds the State.

Repeal of laws

58. The laws set out in Schedule 1 are hereby repealed to the extent set out in the third column thereof.

Short title and commencement

59. This Act is called the Medicines and Related Substances Act, 2017 and takes effect on a date fixed by the President by proclamation in the *Gazette*.

SCHEDULE**LEGISLATION REPEALED**

| No and year | Title | Extent of repeal |
|--------------------|---|--|
| 101 of 1965 | Medicines and Related Substances Act, 1965 | The whole |
| 29 of 1968 | Drugs Control Amendment Act, 1968 | The whole |
| 88 of 1970 | Drugs Control Amendment Act, 1970 | The whole |
| 95 of 1971 | Drugs Laws Amendment Act, 1971 | The whole |
| 65 of 1974 | Drugs Control Amendment Act, 1974 | The whole |
| 19 of 1976 | Medicines and Related Substances Control Amendment Act, 1976 | The whole |
| 36 of 1977 | Health Laws Amendment Act, 1977 | Sections 1, 2 and 3 |
| 17 of 1979 | Medicines and Related Substances Control Amendment Act, 1979 | The whole |
| 20 of 1981 | Medicines and Related Substances Control Amendment Act, 1981 | The whole |
| 94 of 1991 | Medicines and Related Substances Control Amendment Act, 1991 | Sections 1 to 8, 10 to 18, 20, 22 and 26 |
| 118 of 1993 | Health and Welfare Matters Amendment Act, 1993 | Section 11 |
| 88 of 1996 | Abolition of Restrictions on the Jurisdiction of Courts Act, 1996 | Section 32 |
| 90 of 1997 | Medicines and Related Substances Control Amendment Act, 1997 | The whole |
| 59 of 2002 | Medicines and Related Substances Amendment Act, 2002 | The whole |
| 72 of 2008 | Medicines and Related Substances Amendment Act, 2008 | The whole |
| 14 of 2015 | Medicines and Related Substances Amendment Act, 2015 | The whole |

Annexure H

Provincial Departments of Health Legislation

| | No and year | Short title | Provisions still in force |
|---------------------|-------------|--|--|
| Eastern Cape | | | |
| 1. | 18 of 1946 | Hospitals Ordinance [Cape of Good Hope] | The whole |
| 2. | 15 of 1955 | Hospitals Amendment Ordinance [Cape of Good Hope] | Sections 3 and 4 |
| 3. | 3 of 1956 | Hospitals Amendment Ordinance [Cape of Good Hope] | Sections 1, 4(2) and 6 |
| 4. | 63 of 1977 | Health Act | <p>The administration of the whole Act, excluding-</p> <p>(a) sections 14, 20 (2), (3) and (4), 30 (2) (b), 30 (3), 32 to 40, 42 and 45 to 49 and 55;</p> <p>(b) section 30 (4), in so far as it is to section 30 (2) (b);</p> <p>(c) sections 50, 53, 56, 57 and 58 in so far as they are applicable to the provisions referred to in paragraph (a) above;</p> <p>(d) section 54, in so far it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government.</p> <p>The whole of this Act, excluding sections 14, 15, 16(b) to (d) inclusive, 17, 18, 20, 24, 30, 31, 32 to 40, 44, 45 to 49, 50, 51, 53, 55, 56, 57 and 58 in so far as they are applicable to sections 32 to 40, 45 to 49 and 55, was repealed by section 43(1) of the Eastern Cape Provincial Health Act 10 of 1999 with effect from 1 March 2000.</p> |
| 5. | 10 of 1999 | Eastern Cape Provincial Health Act | The whole |
| 6. | 6 of 2001 | Application of Health Standards in Traditional Circumcision Act (Eastern Cape) | The whole |
| Free State | | | |
| 1. | 63 of 1977 | Health Act | <p>The administration of the whole of this Act, excluding –</p> <p>(a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;</p> <p>(b) section 30(4), in so far as it is applicable to section 30(2)(b);</p> <p>(c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;</p> |

| | No and year | Short title | Provisions still in force |
|----------------------|-------------|---|--|
| | | | (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government. |
| 2. | 13 of 1996 | Free State Hospitals Act | The whole |
| 3. | 11 of 1998 | Free State School Health Services Act | The whole |
| 4. | 15 of 1998 | Free State Nursing Education Act | The whole |
| 5. | 1 of 2004 | Free State Initiation School Health Act | The whole |
| 6. | 3 of 2009 | Provincial Health Act [Free State] | The whole |
| Gauteng | | | |
| 1. | 20 of 1943 | Transvaal Board for the Development of Peri-Urban Areas Ordinance [Transvaal] | The whole |
| 2. | 14 of 1958 | Hospitals Ordinance [Transvaal] | The whole |
| 3. | 63 of 1977 | Health Act | The administration of the whole of this Act, excluding – (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55; (b) section 30(4), in so far as it is applicable to section 30(2)(b); (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above; (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government. |
| 4. | 4 of 1999 | Hospitals Ordinance Amendment Act [Gauteng] | The whole |
| 5. | 8 of 2000 | The Gauteng District Health Services Act | Date of commencement to be proclaimed |
| 6. | 6 of 2002 | Gauteng Ambulance Services Act | The whole |
| KwaZulu-Natal | | | |
| 1. | 13 of 1938 | Provincial Hospitals Ordinance [Natal] | Section 9 |
| 2. | 22 of 1955 | Provincial Hospitals Service Ordinance [Natal] | The whole |
| 3. | 13 of 1961 | Provincial Hospitals Ordinance [Natal] | The whole |
| 4. | 63 of 1977 | Health Act | The administration of the whole of this Act, excluding – (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55; (b) section 30(4), in so far as it is applicable to section 30(2)(b); (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) |

| | No and year | Short title | Provisions still in force |
|-------------------|-------------|--|--|
| | | | above; (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government. |
| 5. | 3 of 1979 | Provincial Hospitals Service Appointment of Dr. G. P. Wilson Ordinance [Natal] | The whole |
| 6. | 11 of 1986 | KwaZulu Act on Medical and Surgical Treatment | The whole |
| 7. | 1 of 2009 | KwaZulu-Natal Health Act | The whole |
| Limpopo | | | |
| 1. | 63 of 1977 | Health Act | The administration of the whole of this Act, excluding – (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55; (b) section 30(4), in so far as it is applicable to section 30(2)(b); (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above; (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government. |
| 2. | 13 of 1984 | Health Act (Venda) | The whole |
| 3. | 3 of 1996 | Limpopo College of Nursing Act | The whole |
| 4. | 5 of 1998 | Limpopo Province Health Services Act | The whole |
| Mpumalanga | | | |
| 1. | 20 of 1943 | Transvaal Board for the Development of Peri-Urban Areas Ordinance [Transvaal] | The whole |
| 2. | 14 of 1958 | Hospitals Ordinance [Transvaal] | The whole |
| 3. | 63 of 1977 | Health Act | The administration of the whole of this Act, excluding – (a) sections 14, 20(2), (3) and (4), 30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55; (b) section 30(4), in so far as it is applicable to section 30(2)(b); (c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above; (d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government. |
| 4. | 12 of 1983 | Health Act [Bophuthatswana] | The whole |

| | No and year | Short title | Provisions still in force |
|----------------------|-------------|---|---|
| Northern Cape | | | |
| 1. | 18 of 1946 | Hospitals Ordinance [Cape of Good Hope] | The whole |
| 2. | 15 of 1955 | Hospitals Amendment Ordinance [Cape of Good Hope] | Sections 3 and 4 |
| 3. | 3 of 1956 | Hospitals Amendment Ordinance [Cape of Good Hope] | Sections 1, 4(2) and 6 |
| North-West | | | |
| 1. | 20 of 1943 | Transvaal Board for the Development of Peri-Urban Areas Ordinance [Transvaal] | Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 2. | 18 of 1946 | Hospitals Ordinance [Cape of Good Hope] | Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 3. | 11 of 1955 | Ambulance Personnel Transfer and Pensions Ordinance [Cape of Good Hope] | Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 4. | 15 of 1955 | Hospitals Amendment Ordinance [Cape of Good Hope] | Administration of sections 3 and 4 Schedule indicating which legislation has been repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 5. | 3 of 1956 | Hospitals Amendment Ordinance [Cape of Good Hope] | Administration of sections 1, 4(2) and 6 Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 6. | 14 of 1958 | Hospitals Ordinance [Transvaal] | Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 7. | 63 of 1977 | Health Act | The administration of the whole of this Act, excluding – (a) sections 14, 20(2), (3) and (4), |

| | No and year | Short title | Provisions still in force |
|---------------------|---------------|--|---|
| | | | <p>30(2)(b), 30(3), 32 to 40 inclusive, 42, 45 to 49 inclusive and 55;</p> <p>(b) section 30(4), in so far as it is applicable to section 30(2)(b);</p> <p>(c) sections 50, 53, 56, 57 and 58, in so far as they are applicable to the provisions referred to in paragraph (a) above;</p> <p>(d) section 54, in so far as it relates to land or premises owned or occupied by an institution within the jurisdiction of the national government.</p> <p>Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province.</p> |
| 8. | 4 of 1984 | Training of Nurses and Midwives Ordinance [Cape of Good Hope] | Schedule indicating which legislation was repealed by the North West Health, Developmental Social Welfare and Hospital Governance Institutions Act 2 of 1997 is not available. It is unclear whether this ordinance is still in operation in the North-West Province. |
| 9. | 11 of 1995 | Health Laws Rationalisation Act [North-West] | The whole |
| 10. | 2 of 1997 | North West Health, Developmental Social Welfare and Hospital Governance Institutions Act | The whole |
| Western Cape | | | |
| 1. | 15 of 1955 | Hospitals Amendment Ordinance [Cape of Good Hope] | Sections 3 and 4 |
| 2. | 3 of 1956 | Hospitals Amendment Ordinance [Cape of Good Hope] | Sections 1, 4 (2) and 6 |
| 3. | Act 7 of 2001 | Western Cape Health Facility Boards | The whole |
| 4. | Act 6 of 2002 | Western Cape Health Amendment | The whole |
| 5. | 7 of 2007 | Western Cape Health Care Waste Management Act | The whole |
| 6. | 5 of 2008 | Western Cape Health Service Fees Act | The whole |
| 7. | 6 of 2008 | Western Cape Ambulance Personnel Transfer and Pensions Ordinance Repeal Act | The whole |
| 8. | 3 of 2010 | Western Cape Ambulance Services Act | The whole |
| 9. | 5 of 2010 | Western Cape District Health Councils Act | The whole |
| 10. | 6 of 2010 | Western Cape Health Care Waste Management Amendment Act | The whole |
| 11. | 7 of 2012 | Western Cape Health Facility Boards Amendment Act | The whole |

| | No and year | Short title | Provisions still in force |
|-----|--------------------|--|---------------------------------------|
| 12. | 9 of 2013 | Western Cape District Health Councils Amendment Act | The whole |
| 13. | 2 of 2014 | Western Cape Independent Health Complaints Committee Act | The whole |
| 14. | 4 of 2016 | Western Cape Health Facility Boards and Committees Act 4 of 2016 | Date of commencement to be proclaimed |