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CONTENTS

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. 611 **2 June 2008**

PUBLICATION OF BILLS IN TERMS OF PARLIAMENTARY RULES (NA RULE 241 / NCOP RULE 186)

The Minister of Health intends to table the bills following hereunder in Parliament this year. The Bills and their respective memorandums setting out the objects of the Bills are hereby published as required by National Assembly Rule 241(1) and the National Council of Provinces Rule 186(1).

1. The Medical Schemes Amendment Bill, 2008
2. The National Health Amendment Bill, 2008; and
3. The Medicines and Related Substances Amendment Bill, 2008.

DR ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing enactments.

_____ Words underlined with a solid line indicate insertions in existing enactments.

DRAFT BILL

To amend the Medical Schemes Act, 1998, so as to provide for risk equalisation among medical schemes; to amend and insert certain definitions; to provide for the establishment of a risk equalisation fund; to extend the functions of the Council for Medical Schemes in relation to risk equalisation; to provide for the application of risk equalisation to medical schemes; to provide for the provision of information by medical schemes to the Council for Medical Schemes for purposes of risk equalisation; to provide for the methodology and procedures for risk equalisation; to amend the provisions relating to benefits and contributions provided by medical schemes; to amend the provisions relating to the composition of boards of trustees and eligibility of persons to serve as trustees or principal officers; to define the respective functions of boards of trustees and principal officers; to specify the powers of the High Court in relation to election processes; to amend the provisions relating to disclosure of trustee remuneration; to provide for good corporate governance guidelines and associated disclosure requirements; to amend the provisions relating to the powers of the Minister to make regulations; to amend the provisions relating to offences; to rearrange some of the existing sections; and to provide for matters in connection therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows: —

Amendment of section 1 of Act 131 of 1988, as amended by section 1 of Act 55 of 2001, section 1 of Act 62 of 2002, section 40 of Act 65 of 2002, and section 25 of Act 52 of 2003.

1. Section 1 of the Medical Schemes Act, 1988 (hereinafter referred to as the principal Act), is hereby amended by the —

(a) insertion after the definition of "Appeal Board" of the following definition:

" **'basic benefits'** means those benefits contemplated in section 32J(1);";

(b) insertion after the definition of "beneficiary" of the following definitions:

" **'benefit'** means the liability accepted by a medical scheme to render a relevant health service or to defray fees or charges in respect of provision of relevant health service;

'supplementary benefit option' means those additional benefits offered by a medical scheme in respect of which its members may choose to enroll;";

(c) insertion after the definition of "dependant" of the following definition:

'financial transfer' means a financial transfer from the Fund to a medical scheme or from a medical scheme to the Fund, as the case may be;";

(d) insertion after the definition of "Master" of the following definition:

" **'material relationship'** means a relationship with, or interest in, a natural or juristic person which, in the view of a reasonable person would interfere with the independent judgment of

" **'material relationship'** means a relationship with, or interest in, a natural or juristic person which, in the view of a reasonable person would interfere with the independent judgment of the officer of the medical scheme or prejudice the interests of the medical scheme or its members;";

(f) substitution for the definition of "principal officer" of the following definition:

" **'principal officer'** means **[the principal officer]** a person appointed in terms of section **[57(4)(a)]** 57C(1);";

(g) insertion after the definition of "restricted membership scheme" of the following definitions:

" **'risk equalisation'** means the system of financial transfers to ensure the sharing of expected costs of providing benefits contemplated in section 19B;

'risk equalisation risk factor' means a risk factor to be used in the calculation of financial transfers, as contemplated in section 19L(1);

'risk equalised benefits' means the benefits in respect of which risk equalisation will take place, as contemplated in section 19B;";

(h) insertion after the definition of "Service" of the following definitions:

'supplementary benefit option' means those additional benefits offered by a medical scheme in respect of which its members may choose to enroll;";

" **'the Fund'** means the bank account contemplated in section 19C(1);";

(i) substitution for the definition of "this Act" of the following definition:

" **'this Act'** includes the regulations**[.]**;";

Amendment of section 7 of Act 131 of 1998, as amended by section 2 of Act 55 of 2001.

2. Section 7 of the principal Act is hereby amended by the insertion of the following paragraphs after paragraph *(f)*:

" *(fA)* manage the administration of the Fund in accordance with the provisions of this Act;

(fB) consult on a regular basis with relevant stakeholders in relation to the implementation of risk equalisation ;".

Amendment of section 13 of Act 131 of 1998

3. Section 13 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

"(2) The financial year of the Council shall end on **[31 December]** 31 March in each year."

Insertion of Chapter 3A in Act 131 of 1998

4. The principal Act is hereby amended by the insertion after section 19 of the following Chapter:

"**CHAPTER 3A**
RISK EQUALISATION

Part 1: General provisions

Scope and purpose of risk equalisation

19A. (1) Subject to the provisions of this Chapter, risk equalisation shall apply to each medical scheme and each such medical scheme shall comply with the terms and conditions of risk equalisation.

Risk equalised benefits

19B. The benefits in respect of which risk equalisation will apply shall be those prescribed in terms of section 67(1)(g), subject to such limitations as may be prescribed.

Part 2: Risk Equalisation Fund

Establishment of Risk Equalisation Fund

19C. (1) The Council shall cause a bank account, to be known as the "Risk Equalisation Fund," to be opened at a financial institution.
(2) The Council must annually report on the Fund as part of the report contemplated in section 14.
(3) The costs of managing the Fund shall be paid for from the revenue of the Council raised in terms of section 12(1) and the Council for Medical Schemes Levies Act, 2000 (Act No. 58 of 2000), and not from financial transfers to the Fund.

Fund to vest in and to be administered by Council

19D. (1) Money in the Fund shall vest in the Council.
(2) The Fund is under the control and management of the Council, which —
(a) must utilise the money in the Fund in accordance with section 19F only;
(b) is responsible for accounting for money received in, and payments made from, the Fund; and
(c) must cause the necessary accounting and other related records to be kept.

Revenue of Fund

19E. The Fund shall consist of—
(a) financial transfers paid to the Fund in terms of section 19O;
(b) interest and dividends derived from the investment of money standing to the credit of the Fund;
(c) administrative penalties paid in terms of section 19S; and
(d) other money lawfully paid into the Fund.

Allocation of money in Fund

19F. (1) All money paid to the Fund shall be appropriated for expenditure by the Council in accordance with subsection (2).
(2) The Council must appropriate expenditure for financial transfers to medical schemes in accordance with the risk equalisation methodology set out in this Chapter.
(3) With the exception of claims by medical schemes in respect of financial transfers, no person shall in respect of any liability of the Council have or obtain recourse or any right against money standing to the credit of the Fund.

Investment of money not immediately required

19G. (1) Any money of the Fund which is not required for immediate allocation may be invested in accordance with the Public Finance Management Act, 1999 (Act No. 1 of 1999) and may be withdrawn when required.
(2) Any unexpended balance of the money of the Fund at the end of any financial year shall be carried forward as a credit to the next financial year.

Separate financial records and financial statements

19H. (1) The Council must cause separate accounting records for the Fund to be maintained must prepare separate annual financial statements for the Fund in accordance with general accepted accounting practice.
(2) The Fund and the records referred to in subsection (1) must be audited by the Auditor-General.
(3) The audited records referred to in subsection (1) must be incorporated into the report contemplated in section 14.

Part 3: Information required for risk equalisation

Information for calculation of financial transfers

19I. (1) Every medical scheme must at such intervals and in the form determined by the Registrar submit to the Registrar such information as may be necessary for purposes of:
(a) ascertaining the number of beneficiaries of each medical scheme;
(b) allocating beneficiaries to various age categories;
(c) allocating beneficiaries to various risk equalisation risk factors;
(d) auditing the correctness of information supplied by the medical scheme; and
(e) preventing fraud.
(2) Information collected in terms of subsection (1) shall include, in respect of every beneficiary of a medical scheme —
(a) personal particulars, including full names, gender, identity number or passport number in the case of a non-resident, date of birth and, where applicable, date of death;
(b) the unique medical scheme number of the beneficiary and any other unique identifier assigned to the beneficiary for purposes of risk equalisation;
(c) details of beneficiary status, including whether the beneficiary is a principal member, adult dependant or child dependant and relationship to the principal member, where applicable;
(d) date and details of the enrolment and, where applicable, termination of enrolment of the beneficiary, including details of the medical scheme from or to which the member transferred, where applicable;
(e) the name of the benefit option on which the beneficiary is enrolled and date and details of change of benefit option, where applicable;
(f) details of any waiting periods applicable to the beneficiary;
(g) information related to the health status and claims history of beneficiaries, specifically in relation to health conditions or other factors identified as risk equalisation risk factors in terms of section 19L(1).
(3) The Registrar shall ensure that —
(a) personally identifiable information is subject to strict confidentiality;
(b) health status data and personally identifiable information are never submitted simultaneously by a medical scheme in terms of section (1) and are stored and maintained in a manner that prevents simultaneous access to health status and personally identifiable information.
(4) A request for access to information submitted in terms of this section shall be dealt with in terms of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), provided that the information provided in terms thereof shall under no circumstances be capable of being personally identified.

Verification of information

19J. (1) The Registrar may in relation to information provided in accordance with section 19I, on written notice require a medical scheme to submit to him or her -

(a) the information as specified in the notice; or

(b) a report by an auditor or by any other person with appropriate professional skill, designated by the Registrar, on any matter specified in the notice.

(2) The Registrar may at any time inspect the business of a medical scheme if the Registrar has reason to believe that information submitted by a medical scheme in accordance with section 19I is incorrect or false. The provisions of section 44, with the necessary changes, apply to an inspection under this subsection.

(3) *(a)* Despite the provisions of any other law, the auditor of a medical scheme must inform the Registrar in writing of any matter relating to the affairs of a medical scheme of which the auditor became aware of in the performance of his or her functions as auditor of that medical scheme, that, in the opinion of the auditor relates to the medical scheme's participation in the risk equalisation fund or may negatively impact on the medical scheme's ability to pay a financial transfer which it may be required to pay in terms of this Chapter.

(b) An auditor must inform the principal officer of a medical scheme of any information referred to in paragraph *(a)*, provided to the Registrar.

(c) The furnishing in good faith by an auditor of information in terms of paragraph *(a)* may not be held to constitute a contravention of any provision of the law or breach of any provision of a code of professional conduct to which such auditor may be subject.

Part 4: Risk equalisation methodology

Formula for risk equalisation

19K. (1) The Minister shall, in consultation with the Minister of Finance, prescribe the formula for the determination of the quantum of financial transfers.

(2) The formula prescribed in terms of subsection (1) shall —

(a) provide for a method of determining the expected cost per beneficiary in a medical scheme of providing the risk equalized benefits, taking into consideration:

(i) the prevalence of risk equalisation risk factors amongst the beneficiaries, identified in accordance with the criteria published in terms of section 19M(1)(b); and

(ii) the weighted values assigned to these risk factors, as published in terms of section 19M(1)(a);

(b) provide for a method of determining the expected cost per beneficiary among all medical schemes of providing the risk equalized benefits taking into consideration the factors in subparagraphs (a)(i) and (ii) above;

(c) as far as reasonably possible, result in the expected cost to a medical scheme, per beneficiary, of providing the risk equalized benefits, being equivalent to the average expected cost per beneficiary among all medical schemes, assuming a reasonable level of efficiency in the delivery of those benefits.

Risk equalisation risk factors

19L. (1) The Minister shall from time to time prescribe the risk factors to be used in the calculation of financial transfers, which shall be demographic variables, health status indicators and other factors capable of predicting the cost to medical schemes of the risk equalised benefits.

(2) When prescribing the risk equalisation risk factors, the Minister shall take into consideration for those factors to —

(a) be objective, repeatable and auditable;

(b) be measurable without significant measurement errors;

(c) be measurable using data that are readily available to medical schemes;

(d) not readily be susceptible to manipulation, and

(e) discourage the selection by a medical scheme of beneficiaries with only preferred risks.

Publication of information related to risk equalization risk factors

19M. (1) The Council shall from time to time after consultation with the Minister—

(a) assign and publish weighted values to each of the risk equalization risk factors based upon their importance in predicting costs of risk equalized benefits; and

(b) publish criteria to identify and verify the existence of a risk equalisation risk factor in a beneficiary, taking into account the need, as far as possible, to —

(i) accurately identify beneficiaries with one or more of the risk equalisation risk factors; and

(ii) prevent opportunities for misrepresentation and manipulation of the risk equalisation system.

Determination of amount of financial transfers

19N. (1) The Registrar shall evaluate and assess the information submitted to him or her in terms of the Chapter and applying the formula prescribed in terms of section 19K, determine the amount of financial transfers payable by a medical scheme to the Fund or by the Fund to a medical scheme, as the case may be.

(2) The Registrar may adjust the amount of a financial transfer calculated in terms of this section to -

(a) correct an error;

(b) take account of the outcome of an appeal;

(c) take account of more accurate information obtained in relation to the number of beneficiaries and prevalence of risk factors within a medical scheme; or

(d) distribute interest accrued on monies standing to the credit of the Fund or administrative penalties which have been paid into the Fund proportionate to the value of financial transfers payable in respect of medical schemes.

(3) If a medical scheme fails to submit the information it is required to submit to the Registrar in terms of section 19(1)(1), or the Registrar has reason to believe that the information submitted by the medical scheme is incomplete or incorrect such that an accurate calculation of the financial transfer in respect of that medical scheme is not possible, the Registrar may make a determination of the amount of a financial transfer to be paid in respect of that medical scheme taking into consideration one or more of the following factors—

(i) the most recent previous uncontested data submission of the medical scheme;

(ii) the industry average of the relevant data;

(iii) the age profile of the medical scheme; and

(iv) any other factor the Registrar may reasonably consider relevant to the determination.

(4) Notwithstanding the provisions of this section —

(a) the liability of the Council in relation to financial transfers payable to medical schemes shall not under any circumstances exceed the amount standing to the credit of the Fund at the time that such financial transfers are paid; and

(b) if, due to bad debt from medical schemes or for any other reason, the amount standing to the credit of the Fund is insufficient to pay a medical scheme the full quantum of a financial transfer calculated in terms of this section:

(i) the amount of a financial transfer payable from the Fund to the medical scheme will be adjusted downwards proportionately to the amounts that would otherwise have been paid to it; and

(ii) to the extent that the monies owed to the Fund are subsequently partially or fully recovered, such monies will at that stage be paid to the medical scheme proportionately to the amounts which it would otherwise have been due in terms of this section.

Effecting of financial transfers

19O. (1) Financial transfers shall be effected on a quarterly basis, based upon the cumulative assessments of the three months in that quarter, or if the Registrar provides 12 months' written notice to medical schemes, financial transfers shall take place on a monthly basis.
(2) Every medical scheme must pay the financial transfers as determined by the Registrar to the Fund on being notified by the Registrar in writing of the amount of the financial transfer, within the period and in the manner stated in the notice.
(3) The Registrar shall, within such period as may be prescribed following the date on which financial transfers to the Fund are due in terms of subsection (1), make the required financial transfers to those medical schemes to which payments are due.
(4) Interest at the rate determined by the Minister of Finance under the Public Finance Management Act, is payable on any late payments by a medical scheme of a financial transfer.
(5) If a medical scheme fails to pay a financial transfer or pay it within the specified period, the Registrar may, by way of civil action in a competent court recover the amount owed by the medical scheme.

Progressive implementation of financial transfers

19P. The Council may recommend to the Minister a schedule for the progressive implementation of financial transfers, taking into account the potential impact of the financial transfers on the financial soundness and viability of medical schemes in general.

Projections on financial transfers

19Q. The Registrar must annually 4 months before the start of a calendar year, inform each medical scheme of the projections on financial transfers relating to that medical scheme for that calendar year.

Part 5: Appeals and Penalties

Appeals

19R. Notwithstanding the provisions of this Act or any other law, if an appeal is lodged against a decision made in terms of the provisions of this chapter, such appeal shall not suspend any obligation to pay a financial transfer determined in terms of section 19N pending the outcome of an appeal.

Administrative penalties

19S. (1) Notwithstanding the fact that adjustments may be made to financial transfers to take account of errors in calculations of financial transfers, a medical scheme shall also be liable to pay a penalty equivalent to 5% of the difference between the amount of an erroneously calculated financial transfer made in respect of that medical scheme and the correct amount of the financial transfer that ought to have been paid if it is determined that the erroneous calculation of the amount of the financial transfer was as a result of –

(a) the non-submission by that medical scheme of information required in terms of section 19I; or

(b) the submission by that medical scheme of incomplete or incorrect information required in terms of section 19I.

(2) An administrative penalty imposed or payable under this section must be paid within the period specified by the Council.
(3) If a medical scheme fails to pay an administrative penalty within the specified period, the Registrar may, by way of civil action in a competent court, recover the amount of the administrative penalty from the medical scheme.
(4) The Council shall pay any penalties received in terms of this section into the Fund."

Amendment of section 29 of Act 131 of 1998, as amended by section 9 of Act 55 of 2001

5. Section 29 of the principal Act is hereby amended by the —

(a) substitution in subsection (1) for the words preceding paragraph *(a)* of the following words:

"**[(1)]** 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, subject to the provisions of this Act:";

(b) substitution in subsection (1) for paragraph *(h)* of the following paragraph:

"*(h)* **[Subject to the provisions of this Act, the]** The manner in which and the circumstances under which a medical scheme shall be terminated or dissolved.";

(c) substitution in subsection (1) for paragraph *(n)* of the following paragraph:

"*(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]** in accordance with the provisions of Chapter 5B.";

(d) substitution in subsection (1) for paragraph *(p)* of the following paragraph:

"*(p)* **[No limitation shall apply to the re-imbursement of any relevant health service obtained by a member from a public hospital where this service complies with the general scope and level as contemplated in paragraph *(o)* and may not be different from the entitlement in terms of a service available to a public hospital patient]** The reimbursement for services obtained from a public hospital in accordance with the provisions of section 34A."

(e) deletion in subsection (1) of paragraph *(r)*;

(f) substitution in subsection (1) for paragraph *(s)* of the following paragraph:

"*(s)* The **[continuation, subject to such conditions as may be prescribed, of the membership of a member, who retires from the service of his or her employer or whose employment is terminated by his or her employer on account of age, ill-health or other disability and his or her dependants]** admission and continuation of membership of members and dependants contemplated in subsection (1) of section 32C, in accordance with the provisions of that section."

(g) deletion in subsection (1) of paragraphs *(t)* and *(u)*; and

(h) deletion of subsections (2) and (3).

Deletion of section 29A in Act 131 of 1998

6. The principal Act is hereby amended by the deletion of section 29A.

Insertion of Chapter 5A in Act 131 of 1998

7. The principal Act is hereby amended by the insertion after section 32 of the following Chapters:

"**CHAPTER 5A**
ADMISSION OF BENEFICIARIES

Open enrolment

32A. A medical scheme shall not —

(a) exclude any applicant or a dependant of an applicant, subject to the conditions as may be prescribed, from membership except for a restricted membership scheme as provided for in this Act;

(b) exclude any applicant or a dependant of an applicant who would otherwise be eligible for membership to a restricted membership scheme; or

(c) impose waiting periods other than as provided for in section 32B.

Waiting periods

32B. (1) A medical scheme may impose upon a person in respect of whom an application is made for membership or admission as a dependant, and who was not a beneficiary of a medical scheme for a period of at least 90 days preceding the date of application –

(a) a general waiting period of up to three months; and

(b) a condition-specific waiting period of up to 12 months.

(2) A medical scheme may impose upon any person in respect of whom an application is made for membership or admission as a dependant, and who was previously a beneficiary of a medical scheme for a continuous period of up to 24 months, terminating less than 90 days immediately prior to the date of application –

(a) a condition-specific waiting period of up to 12 months, except in respect of any treatment or diagnostic procedures covered within the prescribed minimum benefits;

(b) in respect of any person contemplated in this subsection, where the previous medical scheme had imposed a general or condition-specific waiting period, and such waiting period had not expired at the time of termination, a general or condition-specific waiting period for the unexpired duration of such waiting period imposed by the former medical scheme.

(3) A medical scheme may impose upon any person in respect of whom an application is made for membership or admission as a dependent, and who was previously a beneficiary of a medical scheme for a continuous period of more than 24 months, terminating less than 90 days immediately prior to the date of application, a general waiting period of up to three months, except in respect of any treatment or diagnostic procedures covered within the prescribed minimum benefits.

(4) A medical scheme may not impose a general or a condition-specific waiting period on a beneficiary who changes from one benefit option to another within the same medical scheme unless that beneficiary is subject to a waiting period on the current benefit option, in which case any remaining period may be applied.

(5) A medical scheme may not impose a general or a condition-specific waiting period on a child-dependant born during the period of membership.

(6) A medical scheme may not impose a general or condition-specific waiting period on a person in respect of whom application is made for membership or admission as a dependant, and who was previously a beneficiary of a medical scheme, terminating less, than 90 days immediately prior to the date of application, where the transfer of membership is required as a result of –

(a) change of employment; or

(b) an employer changing or terminating the medical scheme of its employees, in which case such transfer shall occur at the beginning of the financial year, or reasonable notice must have been furnished to the medical scheme to which an application is made for such transfer to occur at the beginning of the financial year.

(7) A medical scheme may require an applicant to provide the medical scheme with a medical report in respect of any proposed beneficiary only in respect of a condition for which medical advice, diagnosis, care or treatment was recommended or received within the 12 month period ending on the date on which an application for membership was made.
(8) In respect of members who change medical schemes in terms of subsection (6), where the former medical scheme had imposed a general or condition-specific waiting period and such waiting period had not expired at the time of termination, the medical scheme to which the person has applied may impose a general or condition-specific waiting period for the unexpired duration of such waiting period imposed by the former medical scheme.

Continuation membership

32C. (1) A medical scheme shall allow —
(a) the continuation, subject to such conditions as may be prescribed, of the membership of a member, who retires from the service of his or her employer or whose employment is terminated by his or her employer on account of age, ill-health or other disability and his or her dependants;
(b) the continued membership of a member's dependants, subject to conditions as may be prescribed, after the death of that member, until such dependant becomes a member of, or is admitted as a dependant of a member of another medical scheme.
(2) If the members of a medical scheme who are members of that medical scheme by virtue of their employment by a particular employer terminate their membership of the said medical scheme with the object of obtaining membership of another medical scheme or of establishing a new medical scheme, such other or new medical scheme shall admit to membership, without a waiting period or the imposition of new restrictions on account of the state of his or her health or the health of any of his or her dependants, any member or a dependant of such first mentioned medical scheme who is a person contemplated in subsection (1).

Cancellation or suspension of membership

32D. A medical scheme shall not cancel or suspend a member's membership or that of any of his or her dependants, except on the grounds of —
(a) failure to pay, within the time allowed in the medical scheme's rules, the membership fees required in such rules;
(b) failure to repay any debt due to the medical scheme;
(c) submission of fraudulent claims;
(d) committing any fraudulent act; or
(e) the non-disclosure of material information.

CHAPTER 5B
CONTRIBUTIONS

Community rating requirement

32E. A medical scheme shall apply community rating in the determination of its contributions, which for the purposes of this Act means —
(a) the medical scheme does not determine contributions on the basis of :
(i) the age of a person, except to the extent allowed in this Chapter; and
(ii) the gender, race, marital status, ethnic or social origin or sexual orientation of a person; and
(iii) pregnancy or disability of a person; and
(iv) state of health of a person or frequency of utilization of relevant health services.
(b) the only discounts available, if any, are discounts allowed under section 32H;

(c) contributions may be differentiated on the basis of income categories only to the extent that this does not result in direct or indirect contravention of the requirements set out in paragraph *(a)*;

(d) the contribution payable to the medical scheme meets the contribution requirements in sections 32F and 32G.

Contributions requirement for basic benefits

32F. (1) The contributions payable in respect of the basic benefits of a medical scheme shall be based on the average expected costs of providing the basic benefits to the beneficiaries of the scheme, taking into account projections of financial transfers contemplated in section 19Q, subject to such regulations relating to categories of beneficiaries as may be prescribed.

(2) Regulations contemplated in subsection (1) shall not allow variations in contribution which result in unfair discrimination as contemplated in section 24(2)(e).

Contribution requirement for supplementary benefit options

32G. (1) The contributions payable in respect of a supplementary benefit option of a scheme shall be based on the average expected costs of providing the basic benefits to the beneficiaries participating in that supplementary benefit option, subject to such regulations relating to categories of beneficiaries as may be prescribed.

(2) Regulations contemplated in subsection (1) shall not allow variations in contribution which result in unfair discrimination as contemplated in section 24(2)(e).

Discounts for choice of provider

32H. A medical scheme may provide in its rules for a discount to apply off the contribution payable by a member in respect of the basic benefits or a supplementary benefit option because the member agrees to the choice of a particular provider or provider network for the provision of specified services to that member and his or her dependants, provided that —

(a) such choice promotes greater efficiency in the delivery of benefits and does not give rise to unfair discrimination against beneficiaries of the medical scheme; and

(b) the discount shall be disclosed in the rules of a medical scheme as a uniform percentage of the relevant contributions and is approved by the Registrar in terms of section 33."

Amendment of heading of Chapter 6 in Act 131 of 1998

8. The principal Act is hereby amended by the substitution for the heading of Chapter 6 of the following heading:

"CHAPTER 6
[BENEFIT OPTIONS] BENEFITS".

Insertion of section 32J in Act 131 of 1998

9. The principal Act is hereby amended by the insertion in Chapter 6, immediately preceding section 33, of the following section:

"**Basic benefits and supplementary benefit options**

32J. (1) A medical scheme shall provide to every beneficiary of the medical scheme:

(a) benefits which have been prescribed in terms of section 67(1)*(g)*; and

(b) any additional benefits which the medical scheme offers in respect of services rendered to a beneficiary while that beneficiary is an in-patient in a hospital.

(2) A medical scheme may offer to its members the choice of enrolling in a supplementary benefit options, provided that —

(a) a supplementary benefit option does not offer benefits contemplated in subsection (1); and

(b) the dependants of a member shall enroll in the same supplementary benefit option as the member."

Amendment of section 33 of Act 131 of 1998

10. Section 33 of the principal Act is hereby amended by the —

(i) substitution for subsection (1) of the following subsection:

"(1) A medical scheme shall apply to the Registrar for the approval of its basic benefits and any supplementary benefit option **[if such a medical scheme provides members with more than one benefit option]**.";

(j) deletion in subsection (2) of paragraphs *(a)* and *(b)*;

(k) substitution in subsection (2) for paragraph *(d)* of the following paragraph:

"*(d)* will not jeopardise the financial soundness of the medical scheme or of any **[existing]** supplementary benefit option within the medical scheme.".

Insertion of section 34A in Act 131 of 1998

11. The principal Act is hereby amended by the insertion after section 34 of the following section:

"**Services obtained from public hospitals**

34A. (1) A medical scheme shall not apply any limitation to the reimbursement of any relevant health service obtained by a beneficiary from a public hospital where this service complies with the general scope and level as contemplated in paragraph *(o)* of section 29.
(2) If a beneficiary obtains a service contemplated in paragraph *(o)* of section 29 from a public hospital, the entitlement of the beneficiary to receive this service may not be different from the entitlement in terms of a service available to a public hospital patient.".

Amendment of section 35 of Act 131 of 1998, as amended by section 12 of Act 55 of 2001

12. Section 35 of the principal Act is hereby amended by the substitution in subsection (12) for the words preceding paragraph *(a)* of the following words:

"(12) The Registrar may, when he or she has received the information referred to in subsection (11)**[, and in concurrence with the Council]** —".

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

13. Section 36 of the principal Act is hereby amended by the —

(a) 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 No. 80 of 1991)]** Auditing Professions Act 2005 (Act No. 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 first approved by the Registrar.";

(b) 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(1) of the Auditing Professions Act, 2005, also furnish a copy thereof to the Registrar;";

(c) substitution in subsection (5)*(c)* for subparagraph (ii) 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)*(b)* of the Public Accountants' and Auditors' Act, 1991]** 45(1) of the Auditing Professions Act, 2005, submit such a report to the Registrar; and";

(d) 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; and"

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

14. Section 37 of the principal Act is hereby amended by the —

(a) 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.";

(b) substitution in subsection (4) for paragraph *(a)* of the following paragraph:

"*(a)* be prepared in accordance with **[general accepted accounting practice]** International Financial Reporting Standards, which is the set of accounting standards issued from time to time by the International Accounting Standards Board;".

Amendment of section 44 of Act 131 of 1998, as amended by section 17 of Act No 55 of 2001

15. Section 44 of the principal Act is hereby amended by the —

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

"(2) The Registrar, or such other person authorized 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 under section 2 of the Inspection of Financial Institutions Act, **[1984 (Act No. 38 of 1984)]** 1988 (Act No. 80 of 1998), as if he or she has been appointed an inspector under that Act.";

(b) 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]** 1998.";

(c) substitution in subsection (6) for the words preceding paragraph *(a)* of the following words:

"(6) The Registrar may direct that any statement furnished to him or her under subsection **[(4)]** (5), or any document so furnished and which relates to the financial affairs of that medical scheme, shall be accompanied by a report thereon by the auditor of the medical scheme, and in which the auditor shall state —";

(d) substitution for subsection (7) of the following subsection:

"(7) The Registrar may, if he or she, on account of any statement, document or information furnished to him or her by virtue of subsection **[(4)]** (5), deems it necessary in the interests of the members of the medical scheme concerned, **[and, after consultation with the Financial Services Board established by section 2 of the Financial Services Board Act, 1990 (Act No. 97 of 1990),]** by notice in writing direct the medical scheme to furnish to him or her a report compiled by an actuary, in the form and relating to the matters specified by the Registrar in the notice.";

(e) substitution in subsection (10) for the words preceding paragraph *(a)* of the following words:

"(10) The Registrar may, for the purposes of paragraph *(a)* of subsection **[(8)]** (9), by notice in writing direct the medical scheme concerned —";

(f) substitution for subsection (11) of the following subsection:

"(11) The Registrar may, if a medical scheme fails to amend its rules as directed by the Registrar under subsection **[(9)]** (10)*(a)* within the period specified in the notice concerned, amend such rules, and such amendment shall be deemed to be an amendment within the meaning of section 31."

Amendment of section 51 of Act 131 of 1998, as amended by section 19 of Act 55 of 2001

16. Section 51 of the principal Act is hereby amended by the —

(a) substitution in subsection (5) for paragraph *(d)* of the following paragraph:

"*(d)* order that the medical scheme be placed under judicial management in terms of section 52; **[or]**

(b) substitution in subsection (5) for paragraph *(e)* of the following paragraph:

"*(e)* order that the whole or any part of the business of the medical scheme be wound up in terms of section 53**[.]**; or";

(c) insertion in subsection (5) of the following paragraph after paragraph *(e)*:

"*(f)* in the case of an application brought on the basis of material irregularities relating to the conduct of elections for trustees of a medical scheme —

(i) declare the results of the election to be flawed in certain material respects and issue such directions to the medical scheme concerned as the High Court may deem desirable to remedy such flaws; or

(ii) declare the results of the election to be invalid and order the medical scheme concerned to hold another election subject to such conditions as the High Court may deem desirable.".

Amendment of section 56 of Act 131 of 1998, as amended by section 22 of Act No. 55 of 2001

17. Section 56 of the principal Act is hereby amended by the —

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

"(2) The provisions of the **[Financial Institutions (Investment of Funds) Act, 1984 (Act No. 39 of 1984)]** Financial Institutions (Protection of Funds) Act, 2001 (Act No. 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.";

(b) substitution in subsection (3) for the words preceding paragraph *(a)* of the following words:

"(3) In the application of the **[Financial Institutions (Investment of Funds) Act, 1984 (Act No. 39 of 1984)]** Financial Institutions (Protection of Funds) Act, 2001, as provided for by subsection (1) —" ;

(c) substitution in subsection (3) for paragraph *(a)* of the following paragraph:

"*(a)* a reference to a company and the registrar in section 1 of the **[Financial Institutions (Investment of Funds) Act, 1984 (Act No. 39 of 1984)]** Financial Institutions (Protection of Funds) Act, 2001, shall be construed as a reference also to a board of trustees and the Registrar, respectively;"

Amendment of heading of Chapter 12 of Act 131 of 1998

18. The principal Act is hereby amended by the substitution for the heading of Chapter 12 of the following heading:

"CHAPTER 12
[GENERAL] GOVERNANCE".

Insertion of Part 1 heading in Chapter 12 of Act 131 of 1998

19. The principal Act is hereby amended by the insertion, immediately preceding section 57, of the following Part heading:

"*Part 1: Board of Trustees*"

Amendment of section 57 of Act 131 of 1998, as amended by section 23 of Act 55 of 2001

20. Section 57 of the principal Act is hereby amended by the —

(a) substitution for the heading of section 57 of the following heading:

"**57. [General provisions on governance] Governance by board of trustees**";

(b) substitution for subsection (1) of the following subsection:

"(1) Every medical scheme shall have a board of trustees consisting of persons who are fit and proper to **[manage]** direct the business contemplated by the medical scheme in accordance with the applicable laws and the rules of such medical scheme.";

(c) substitution for subsection (2) of the following subsection:

"(2) **[At least 50 per cent of the members of the board of trustees shall be elected from amongst members]** The board of trustees of a medical scheme is accountable for the performance of its functions and those of its principal officer, to —

(a) the members of the medical scheme; and

(b) the Council and the Registrar, to the extent provided for in this Act.";

(d) deletion of subsections (3), (4), (5), (6), (7) and (8).

Insertion of sections 57A and 57B in Act 131 of 1998

21. The principal Act is hereby amended by the insertion after section 57 of the following sections:

"**Composition of board of trustees**

57A. (1) At least 50 per cent of the members of the board of trustees shall be elected by members of the medical scheme from amongst members of the medical scheme.

(2) Members of a board of trustees who are not elected in terms of subsection (1) shall —

(a) in the case of restricted membership schemes, be appointed in terms of the rules of the medical scheme; and

(b) in the case of all other medical schemes, be appointed by those members of the board of trustees who were elected in terms of subsection (1).

(3) The election of a trustee by the members of a medical scheme shall not be valid unless all the members of the medical scheme had reasonable opportunity to vote in the election of that trustee.

(4) A person shall not serve as a trustee for more than a total of six years in any one medical scheme.

(5) A person shall not be a member of the board of trustees of a medical scheme if that person —

(a) is an employee, director, officer, consultant or contractor of any person contracted by the medical scheme to provide administrative, marketing, or managed health care services, or of the holding company, subsidiary, joint venture or associate of such person;

(b) is a broker or an employee, director, or officer of a person which provides broker services; or

(c) otherwise has a material relationship with any person contracted by the medical scheme to provide administrative, marketing, broker, managed health care or other services, or with its holding company, subsidiary, joint venture or associate."

Duties of board of trustees

57B. The duties of the Board of trustees shall be to —

(a) provide strategic direction and oversight to the medical scheme;

(b) ensure that —

(i) the resources of the schemes are used in an effective, efficient, economical and transparent manner;

(ii) proper registers, books and records of all operations of the medical scheme are kept, and that proper minutes are kept of all resolutions passed by the board of trustees;

(iii) proper control systems are employed by or on behalf of the medical scheme;

(iv) adequate and appropriate information is communicated to the members regarding their rights, benefits, contributions and duties in terms of the rules of the medical scheme;

(v) all reasonable steps are taken for contributions to be paid timeously to the medical scheme in accordance with this Act and its rules;

(vi) an appropriate level of professional indemnity insurance and fidelity guarantee insurance is taken out and maintained;

(vii) the rules, operation and administration of the medical scheme comply with the provisions of this Act and all other applicable laws; and

(viii) all reasonable steps are taken to protect the confidentiality of medical records concerning any member's state of health;

(c) approve the budget, policies and procedures in terms of which the operational and financial management of the medical scheme is carried out;

(d) approve all contracts and expenditure with a value above levels predetermined by the Board of trustees;

(e) where applicable, negotiate and enter into contracts for the administration of the scheme by an intermediary accredited in terms of section 58 and for the provision of managed health care by an intermediary accredited in terms of regulation 15B of the General Regulations made in terms of this Act;

(f) obtain expert advice on legal, accounting and business matters as required, or on any other matter of which the members of the board of trustees may lack sufficient expertise; and

(g) monitor the performance of the principal officer of the medical scheme and hold the principal officer accountable for the functions delegated to him or her by the Board of trustees.

Insertion of Parts 2 and 3 in Chapter 12 of Act 131 of 1998

22. The principal Act is hereby amended by the insertion after section 57B of the following Parts of Chapter 12:

"*Part 2: Principal Officers*

Appointment of principal officer

57C. (1) The board of trustees shall —

(a) appoint a principal officer who is a fit and proper person to hold such office; and

(b) within 30 days of such appointment, give notice thereof in writing to the Registrar.

(2) A person shall not be a principal officer of a medical scheme if that person —

(a) is an employee, director, officer, consultant or contractor of any person contracted by the medical scheme to provide administrative, marketing, or managed health care services, or of the holding company, subsidiary, joint venture or associate of such person;

(b) is a broker or an employee, director, or officer of a person which provides broker services;

(c) is the principal officer of another medical scheme; or

(d) otherwise has a material relationship with any person contracted by the medical scheme to provide administrative, marketing, broker, managed health care or other services, or with its holding company, subsidiary, joint venture or associate.

(3) The principal officer of a medical scheme may participate in all meetings of the board of trustees, or any of its committees, but shall not be a voting member of the board of trustees.

Responsibilities of principal officer

57D. (1) A principal officer is responsible under the authority of the board of trustees of the medical scheme for the executive management of the business of the medical scheme.

(2) The Board of trustees of a medical scheme shall, in writing, delegate to the principal officer such duties as may be necessary to enable the principal officer to effectively manage the business of the medical scheme.

Part 3: General provisions on governance

Corporate Governance

57E. (1) The board of trustees and principal officer of a medical scheme shall establish and maintain an adequate and effective process of corporate governance, which shall be consistent with the nature, complexity and risks inherent in the activities and the business of the medical scheme concerned.

(2) The Council may, from time to time, publish in such manner as it deems fit —

(a) guidelines for good corporate governance to assist the trustees and principal officers of medical schemes to establish and maintain adequate and effective processes of corporate governance, as contemplated by subsection (1); and

(b) requirements for the periodic disclosure by the board of trustees of a medical scheme to the Registrar and the members of the medical scheme of the extent to which those guidelines have been met, together with reasons for failure to comply with those guidelines.

(3) A medical scheme shall, at such intervals and in such manner and format as the Council may from time to time determine, make such disclosures as are contemplated in paragraph *(b)* of subsection (2)."

Duty of care

57F. The board of trustees and principal officer shall —

(a) take all reasonable steps to ensure that the interests of beneficiaries in terms of the rules of the medical scheme and the provisions of the Act are protected at all times;

(b) act with due care, diligence, skill and good faith;

(c) take all reasonable steps to avoid conflicts of interest; and

(d) act with impartiality in respect of all beneficiaries.

Disclosure

57G. (1) The members of the Board of trustees and principal officer shall disclose annually in the annual financial statements of the medical scheme details of any payments, gifts or considerations made to them in that particular year by —

(a) the medical scheme concerned;

(b) any person contracted by the medical scheme to provide administrative, marketing, brokerage, managed care or other services, or the holding company, subsidiary, joint venture or associate of such person; and

(c) and any other person if such payments, gifts or considerations were made by virtue of their holding office within the medical scheme.

(2) A disclosure as contemplated in subsection (1) shall include:

(a) the identity of the source of the payment, gift or consideration;

(b) the reason for the payment, gift or consideration;

(c) the date on which the payment, gift or consideration was given; and

(d) the quantum of money or otherwise the value of the payment, gift or consideration.

Suspension or removal from office

57H. (1) If a Board of trustees suspends or removes from office the principal officer or trustee of a medical scheme and that principal officer or trustee believes that the suspension or removal from office is as a result of him or her duly performing his or her functions in terms of this Act, or exposing inappropriate or unlawful conduct on the part of any officer of the medical scheme or any

third party contracted to provide services to the medical scheme, the principal officer or trustee concerned may complain in writing to the Registrar.

(2) On receipt of a written complaint in terms of subsection (1) –

(a) the Registrar shall investigate the basis of the complaint; and

(b) if he or she finds that the complaint has merit, the Registrar or the Council shall take such steps as may be necessary in terms of the powers provided for by this Act to address the concerns raised in the complaint.".

Notices to medical scheme

57I. Any notice required or permitted to be given to a medical scheme in terms of this Act shall, if given to the principal officer, be deemed to have been duly given to the medical scheme.

Insertion of heading for Chapter 13 in Act 131 of 1998

23. The principal Act is hereby amended by the insertion, after section 57I, of the following Chapter heading:

"CHAPTER 13
GENERAL"

Amendment of section 63 of Act 131 of 1998, as amended by section 25 of Act 55 of 2001

24. Section 63 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection:

"(1) No transaction involving the amalgamation of the business of a medical scheme with any business of any other person **[irrespective of whether that other person is or is not a medical scheme]** or the transfer of any business from a medical scheme to any other **[medical scheme]** person (irrespective of whether that other person is or is not a medical scheme)or the transfer of any business from any other person to a medical scheme, shall be of any force, unless such amalgamation or transfer is carried out in accordance with the provisions of this section.".

Amendment of section 66 of Act 131 of 1998, as amended by section 27 of Act 55 of 2001

25. Section 66 of the principal Act is hereby amended by the –

(a) substitution in subsection (1) for paragraph *(e)* of the following paragraph:

"*(e)* renders a statement, account or invoice to a member or any other person, knowing that such statement, account or invoice is false and which may be used by such member or other person to claim from a medical scheme any benefit or a benefit greater that then benefit to which he or she is entitled in terms of the rules of the medical scheme **[; or]**;";

(b) substitution in subsection (1) for the words following paragraph *(e)* of the following words:

"shall, subject to the provisions of **[subsection]** subsections (1A) and (2), be guilty of an offence, and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and imprisonment.";

(c) insertion after subsection (1) of the following subsection:

" (1A) Notwithstanding the provisions of subsection (1), any person who –

(a) in any way unlawfully obstructs or attempts to delay or prevent a payment being made from a medical scheme to the risk equalisation fund;

(b) makes or causes or allows to be made any false entry or statement to the Council which may affect the quantum of a financial transfer, or signs off on or submits any such

statement or entry to the Council without reasonable grounds for believing the same to be true;

(c) prepares or maintains or authorises the preparation or maintenance of any false books of account or other records of falsifies or authorises the falsification of any books of account or other records, which causes, may cause or is intended to cause an error in the value of a financial transfer; or

(d) in any other way makes use of any fraud, art or contrivance whatsoever, or authorizes the use of any such fraud, art or contrivance which causes, may cause or is intended to cause an error in the value of a financial transfer,

shall be guilty of an offence and is liable on conviction to a fine not exceeding R1000000 or to imprisonment for a period not exceeding 10 years, or to both such fine and imprisonment."

Amendment of section 67 of Act 131 of 1998, as amended by section 28 of Act 55 of 2001 and section 3 of Act 62 of 2002

26. Section 67 of the principal Act is hereby amended by the —

(check consequential amendments)

(a) insertion in subsection (1) of the following paragraphs after paragraph *(o)*:

" *(oA)* duties of a principal officer;

(oB) requirements and criteria for the determination of the fit and proper status of a trustee, principal officer and any other person required to be fit and proper to perform any function or duty in terms of this Act;

(oC) the conduct of elections for members of the board of trustees of a medical scheme, including conditions and requirements relating to —

(i) oversight of election processes;

(ii) timing and location of elections;

(iii) processes for the nomination of persons standing for election as trustees;

(iv) advance notice to members concerning elections and voting processes; and

(v) any other matter affecting the fairness of elections;

(oD) the sound operation of risk equalization, including;

(i) limitations to the benefits in respect of which risk equalisation will apply, as contemplated in section 19B;

(ii) the formula for the determination of the quantum of financial transfers, as contemplated in section 19K;

(iii) periods within which the Registrar shall make financial transfers to medical schemes, as contemplated in terms of section 19O(3); and

(iv) the amounts of administrative penalties as contemplated in terms of section 19S(3);

(oE) the determination of contributions for basic benefits and supplementary benefit options, as contemplated in sections 32F and 32G."

(b) insertion after subsection (1) of the following subsection:

"(1A) The Minister may prescribe variations from the requirements of the regulations prescribed in terms of subsection (1) to be applied to medical scheme products which cater specifically for low income persons, provided that the variations so prescribed are –

(a) reasonably necessary to create conditions for the emergence of such medical scheme products in the market; and

(b) in the best interests of low income consumers.".

Insertion of Schedule 3 of Act 131 of 1998

27. The principal Act is hereby amended by the insertion after Schedule 2 of the following Schedule:

"Schedule 3

TRANSITIONAL ARRANGEMENTS RELATING TO AMENDMENTS EFFECTED BY MEDICAL SCHEMES AMENDMENT ACT, 2007

Definitions

1. In this Schedule —

"the amending Act" means the Medical Schemes Amendment Act, 2007;

"the principal Act" means the Medical Schemes Act, 1998.

Trustees

1. A person who, immediately prior to commencement of the amending Act was lawfully a trustee of a medical scheme but who is not eligible to serve as a trustee of the medical scheme as a consequence of amendments to the principal Act by the amending Act, shall vacate such office within a period of twelve calendar months after the commencement of the amending Act.

2. A board of trustees which, immediately prior to commencement of the amending Act was lawfully constituted, but which is no longer lawfully constituted as a consequence of amendments to the principal Act by the amending Act shall, within a period of twelve calendar months after the commencement of the amending Act —

(a) change the constitution of the board of trustees to comply with the principal Act as amended by the amending Act; and

(b) to the extent necessary, amend the rules of the medical scheme accordingly.

Principal officers

3. A person who immediately prior to commencement of the amending Act was lawfully a principal officer of a medical scheme but who is not eligible to serve as a principal officer of the medical scheme in terms of section 57C of this Act as a consequence of amendments to the principal Act by the amending Act, shall vacate such office within a period of twelve calendar months after the commencement of the amending Act."

Application of this Act

28. Subject to the transitional clauses contained in schedule 3 inserted in Act 131 of 1998 by section 27 of this Act, the amendments effected by this Act to Act 131 of 1998 shall apply to all relevant contractual or other business activities or arrangements notwithstanding the fact that such contractual or other business activities or arrangements may have been initiated or entered into prior to the coming into operation of any provision of this Act.

Short title and commencement

29. (1) This Act is called the Medical Schemes Amendment Act, 2008, and comes into operation on a date to be fixed by the President by proclamation in the *Gazette*.

(2) Different dates may be fixed under subsection (1) in respect of different provisions of this Act.

(3) Notwithstanding the coming into effect of this Act, financial transfers shall not commence until such time as the Minister of Health, in concurrence with the Minister of Finance, provides written approval therefor after consideration of:

(a) the adequacy of the systems in place in the Council for Medical Schemes to effectively manage risk equalisation transfers;

(b) the quality of data available for purposes of administering the risk equalisation fund; and

(c) any other matter relevant to such approval.

EXPLANATORY MEMORANDUM ON THE OBJECTS OF THE MEDICAL SCHEMES AMENDMENT BILL, 2008

1. The Medical Schemes Amendment Bill 2008 ("the Bill"), seeks to amend the Medical Schemes Act, 1998 (Act No.131 of 1998) ("the principal Act") to provide for —

   (a) the establishment of a risk equalisation fund, and for the implementation of risk equalisation among medical schemes;

   (b) a benefit structure within medical schemes that reduces complexity and facilitates greater cross-subsidisation across the membership of the medical scheme;

   (c) revisions to the governance framework within medical schemes to promote improved corporate governance;

   (d) certain measures to facilitate the emergence of risk-pooled medical scheme products for low income beneficiaries; and

   (e) various incidental matters.

2. CLAUSE BY CLAUSE ANALYSIS OF THE BILL

Clause 1
Clause 1 deals with definitions and inserts the definitions of basic benefits, benefit, supplementary benefit option, financial transfer, material relationship, risk equalisation, risk equalisation risk factor, risk equalised benefits, and the Fund. The definition of principal officer is amended to make reference to the section which places an obligation on trustees to appoint a principal officer (see discussion of Chapter 12, Part 2, below).

Clause 2
Clause 2 amends section 7 of the principal Act, by extending the functions of the Council for Medical Schemes (CMS), to include control of the management and administration of the Risk Equalisation Fund (the Fund) in accordance with the provisions of the Act, and to place an obligation on the Council to engage in effective consultation in relation to the implementation of the REF.

Clause 3
The financial year of the Council is changed from 31 December to 31 March in order to bring the Act in line with the requirements of the Public Finance Management Act (PFMA).

Clause 4
In clause 4, the Bill inserts a new chapter 3A in the principal Act, which becomes sections 19A to 19S. The Chapter is divided into 5 Parts: 1: General Provisions; 2: Risk Equalisation Fund; 3: Information Required for Risk Equalisation; 4: Risk Equalisation Methodology; and part 5: Appeals and Penalties.

PART 1

Section 19A
Section 19A makes it clear that risk equalisation shall apply to schemes and schemes have a consequent obligation to comply with the requirements of risk equalisation.

Section 19B
Section 19B provides for prescribed minimum benefit, that these are prescribed by the Minister.

PART 2

Part 2 of Chapter 3A (sections 19C to 19H) deals with the institutional framework of the Fund, with specific focus on ensuring proper governance, control and accountability for the administration of the Fund.

Section 19C
The Council is required to establish a Fund, and open a bank account for the Fund. The Council's statutory requirements for reporting are also extended to include reporting on the Fund.

Section 19D
The section provides that the money in the Fund shall be managed by the Council.

Section 19E
Section 19E defines the sources of revenue which may lawfully form part of the Fund.

Section 19F
Section 19F provides that the moneys in the Fund may be appropriated only for risk equalisation transfers.

Section 19G
Section 19G provides for investment of monies not immediately required and for unexpended balances of the Fund to be carried forward to successive financial years.

Section 19H
Section 19H provides for separate accounting records to be kept by the Council in respect of the Fund, and for audits to be conducted by the Auditor-General.

PART 3

Section 19I
Section 19I requires medical schemes to submit information to the Registrar, which may be required for purposes of risk equalisation. The section also protects personal information.

Section 19J
Section 19J provides for various measures to allow for proper verification of information submitted by schemes for purposes of risk equalisation, including: the submission of additional information by medical schemes, reports by an auditor, and conducting of inspections. Specific duties of auditors are also set out in this clause.

PART 4

Section 19K
The section enables the Minister to prescribe a formula for the determination of the quantum of financial transfers.

Section 19L
The section provides for the publication by the Council of information relating to risk equalisation risk factors.

Section 19M
The section provides for the publication of information related to risk equalisation risk factors.

Section 19N
Section 19N provides for the determination of amounts of financial transfers.

Section 19O
Section 19O provides for the effecting of financial transfers.

Section 19P
Section 19P makes provision for the possibility of the progressive implementation of risk equalisation to be determined by the Minister on the recommendation of the Council. This would entail incremental annual increases in the percentage of financial transfers that are payable, taking into account the interest of the financial soundness and viability of medical schemes in general.

Section 19Q
Section 19Q provides for the Registrar to timeously provide medical schemes with projections on financial transfers.

Section 19R
This provision makes it clear that if an appeal is lodged against a decision made in terms of the provisions of this chapter, such appeal shall not suspend any obligation to pay a financial transfer pending the outcome of an appeal.

Section 19S
Section 19S makes provision for administrative penalties to be imposed by the Registrar on medical schemes for any failure to comply with risk equalisation provisions of the Act.

Clause 5
The clause provides for matters that must be included in rules of medical schemes.

Clause 6
The clause provides for the deletion of section 29A of the principal Act which is replaced by new section 32B.

Clause 7
Clause 7 introduces Chapter 5A which generally provides for admission of beneficiaries. Following hereunder are specific provisions.

CHAPTER 5A: ADMISSION OF BENEFICIARIES

Section 32A
Section 32A incorporates the existing section 29(3) of the Act, without substantive amendment, providing for open enrolment.

Section 32B
Section 32B incorporates, without amendment, the existing section 29A of the Act, providing for waiting periods.

Section 32C
Section 32C provides for continuation of membership.

Section 32D
Section 32D provides for cancellation and suspension of membership.

Section 32E
Section 32 E provides for community rating by medical schemes.

Section 32F
Section 32F provides for contribution requirements for basic benefits.

Section 32G
Section 32 G provides for contribution requirements for supplementary benefits.

Section 32H
Section 32H provides for discounts for choice of provider.

Clause 8
The clause provides for a new heading to chapter 6.

Clause 9
The clause provides for a new section 32J which provides for basic benefits and supplementary benefit options.

Clause 10.
This clause provides for consequential amendments to section 33.

Clause 11
The clause provides for a new section 34A that provides for matters relating services obtained from public hospitals.

Clause 12
The clause seeks to amend section 35(12) of the principal Act by allowing the Registrar to act in certain matters without the concurrence of the Council.

Clause 13
The clause provides for changes references in section 36 to the now repealed Public Accountants' and Auditors' Act, 1991 to the relevant provisions of the new Auditing Professions Act, 2005.

Clause 14
The amendment to section 37 updates the standards for annual financial statements to come in line with International Financial Reporting Standards.

Clause 15
References in section 44(2) & (3) to the now repealed Inspection of Financial Institutions Act 1984 has been changed to reflect a corresponding reference to the 1998 Act. Erroneous cross references in subsections (6), (7), (10) and (11) of section 44 have also been corrected. These are purely technical corrections.

Clause 16
The clause provides for powers of the High Court in relation to flawed election processes, these powers are now integrated in section 51 of the Act where they are considered to be more appropriately located.

Clause 17
Section 56 of the Act is amended by replacing references to the now repealed Financial Institutions (Investment of Funds) Act, 1984, with references to the Financial Institutions (Protection of Funds) Act, 2001.

Clause 18
Clause 18 amends the heading of Chapter 12 from "General" to "Governance". The Chapter heading "General" is reinserted by clause 23 after section 57 I.

Clause 19
Clause 19 inserts the heading for Part 1: Board of Trustees.

Clause 20
The amendment to section 57(1), consistent with the governance model described above, are intended to emphasise the governance role of trustees, as opposed to management, by the Board. The amendment to section 57(2) establishes the accountability of the Board to its members and, to the extent provided for in the Act, to the Registrar and the Council.

Clause 21
The clause introduces sections on corporate governance in general and specifically provides for section 57A, which provides for the composition of boards of trustees and section 57B, which provides for duties of board of trustees.

Clause 22
This clause provides for matters relating to principal officers in general and specifically provides for their appointment, corporate governance, duty of care, disclosure, and suspension and removal from office. It is important to note that the amendment seeks to ensure that a principal officer or trustee who is aggrieved by a suspension or termination, and who believes that it has resulted from him or her duly performing his or her duties, or otherwise exposing inappropriate or unlawful conduct, to complain in writing to the Registrar. The Registrar then has a duty to investigate and, if there is found to be merit in the complaint, invoke such powers as may already be provided for in the Act to remedy the situation.

Clause 23
In accordance with the restructuring of this area of the Act, the Chapter heading for Chapter 13: General is inserted by this clause.

Clause 24
The clause simply seeks to clarify the existing section 63.

Clause 25
Section 66 of the Act is amended to make provision for specific offences and penalties in relation to fraudulent or obstructive measures designed to frustrate or subvert the effective application of risk equalisation among medical schemes.

Clause 26
The amendments to section 67 of the Act create enabling provisions for the Minister to make regulations relating to additional matters.

Clause 27
Clause 27 provides for transitional measures in relation to trustees and principal officers. It also provides for the short title of the Act and the fixing of the commencement date. It also provides for a trigger for the risk equalisation financial transfers to be in the hands of the Ministers of Health and Finance, based on consideration of the adequacy of risk equalisation systems, the quality of data for purposes of risk equalisation and any other relevant matter.

Clause 28
Clause 28 provides for contractual or other business activities or arrangements notwithstanding the fact that such contractual or other business activities or arrangements may have been initiated or entered into prior to the coming into operation of any provision of this Act.

Clause 29
Clause 29 provides for the short title and commencement of the Act, that this Act is called the Medical Schemes Amendment Act, 2008, and comes into operation on a date to be fixed by the President by proclamation in the *Gazette*.

GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing enactments

DRAFT BILL

To amend the National Health Act, 2003, so as to provide for some definitions; the appointment and functions of the Facilitator and Assistant Facilitators; support and remuneration for the Facilitator and Assistant Facilitators; conflict of interest; collective negotiations and individual bargaining on prices; resolution of disputes; limitation of liability; exemption for medicines; short title and commencement of the Act; and matters incidental thereto.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:-

Insertion of chapter 10A in Act 61 of 2003

1. The National Health Act, 2003 (Act No. 61 of 2003) ("hereinafter referred to as "the principal Act") is hereby amended by the insertion after chapter 10 of the following chapter:

"Chapter 10A

Definitions

89A. In this chapter-

(a) *"prescribed minimum benefits"* mean prescribed minimum benefits as provided for in the regulations made in terms of the Medical Schemes Act, 1998 (Act No. 131 of 1998) published under GN R570 of 5 June 2000 as amended; and

(b) *"prices"* mean tariffs, fees or any form of reimbursement for health services rendered, procedures performed and consumable and disposable items utilised by health establishments, health care providers or health workers.

Objects of Chapter

89B. The object of this chapter is to create a framework that-

(a) enables health care providers, health establishments and medical schemes to-

(i) negotiate collectively on prices; and

(ii) bargain individually on prices; and

(b) ensures transparency and fairness in the determination of prices.

Facilitator, Assistant Facilitators, appointment and functions

89C. (1) The Minister shall-

(a) by notice in the Gazette, invite nominations on the appointment of a Facilitator for Health Pricing ("the Facilitator");

(b) after receiving nominations as contemplated in paragraph (a), appoint a Facilitator and two or more but not exceeding five Assistant Facilitators from such nominations;

(c) in an instance where no nominations are received after an invitation, on his or her own accord, appoint the Facilitator and Assistant Facilitators; and

(d) ensure that persons appointed as the Facilitator or Assistant Facilitators when severally considered, have qualifications or experience in mediation and dispute resolution, health economics; law; commerce; health or public administration.

(2) The Facilitator-

(a) is appointed on a contract with a fixed term; and

(b) must not have an direct interest, financial or otherwise in the affairs of any of the parties taking part in the negotiations or bargaining processes contemplated in section 89F..

(3) The Facilitator must-

(a) in the prescribed manner-

(i) facilitate the collective negotiations contemplated in section 89F(2)(a);

(ii) record and submit to the Minister for publication agreements reached at such collective negotiations; and

(b) where called upon by the parties or a party to individual bargaining, assist such parties during the bargaining process.

(4) The Facilitator may at the request of a party to collective bargaining, require any other party to furnish the party requesting information with any specified information to assist the latter party to make informed choices during the bargaining process.

(5) In facilitating the collective negotiation process, the Facilitator must ensure that the process is conducted in a manner that-

(a) is fair and transparent to the parties involved; and

(b) enables the parties to share information that is necessary for them to make informed decisions.

(6) The Facilitator shall-

(a) in an instance where parties to collective negotiations fail to agree on prices, confirm that the parties have failed to agree and refer this matter for arbitration in terms of section 89I; and

(b) confirm in writing to the Minister at the end of both collective negotiations and individual bargaining processes that such processes were transparent and fair to the parties involved; and

(7) Assistant Facilitators shall assist the Facilitator in the performance of his or her functions.

Support and remuneration

89D. (1) The Director-General shall, with the concurrence of the Facilitator, designate staff of the national department as the secretariat for the Facilitator.

(2) The Minister must, in consultation with the Minister of Finance, determine remuneration for the Facilitator and Assistant Facilitators.

Conflict of interest

89E. Persons nominated for the position of the Facilitator or Assistant Facilitators must upon request by the Minister, submit to the Minister a written statement in which it is declared whether or not they have any direct or indirect interest financially or otherwise, which-

(a) may constitute a conflict of interest in respect of their functions; or

(b) could reasonably be expected to compromise themselves in the performance of their functions.

Negotiations and Bargaining

89F. (1) The Minister must, within 60 days of publication of the reference price lists (RPL) contemplated in section 90(1)(v), by notice in the Gazette, invite health care providers, health establishments and medical schemes (hereinafter jointly referred to as "the parties") to negotiate and bargain on prices.

(2) The parties may-

(a) negotiate collectively in instances where the parties are represented by representative organizations or associations; and

(b) bargain individually in instances where the parties represent themselves as individual entities.

(3) The parties to both collective negotiations and individual bargaining-

(a) may conduct such negotiations or bargaining separately according to their specific area of interest; and

(b) must use the RPL as a source of reference for negotiations and bargaining.

Prescribed minimum benefits

89G. (1) In collective negotiations, the parties must agree on maximum prices that can be charged, using the RPL as a source of reference.

(2) Where the parties to both collective negotiations and individual bargaining have reached agreements on prices, health care providers and health establishments shall not charge prices in excess of those agreed upon if the prices are in respect of prescribed minimum benefits.

(3) In an instance where-

(i) negotiations or bargaining as contemplated in section 89F(2) fail and the parties are unable to reach agreement on prices; and

(ii) such prices are in respect of prescribed minimum benefits,

the parties must inform the Facilitator who shall then refer the matter for arbitration in terms of section 89H.

(4) A determination made by the arbitrator is also binding in respect of users who are not members or dependants of members of medical schemes.

Non-Prescribed minimum benefits

89H. The parties negotiating and bargaining on prices that do not relate to prescribed minimum benefits must also use the RPL as a source of reference.

Arbitration, resolution of disputes

89I. (1) A party or parties to the bargaining process or the Facilitator may in the prescribed manner refer a dispute arising from the bargaining process to the Minister.

(2) The Minister shall within 30 days of receipt of the notice of the dispute, refer the dispute to an arbitrator agreeable to both parties and appointed by the Minister.

(3) Where the parties fail to agree on the appointment of the arbitrator, the Minister shall, after consultation with the Minister of Justice and Constitutional Development, appoint the arbitrator.

(4) The arbitrator shall make a determination on the dispute within 30 days and inform the parties, the Facilitator where the dispute was referred for resolution by the Facilitator and the Minister of such determination.

(5) The costs of arbitration shall be borne by the parties to the dispute, with the arbitrator having the power to make an appropriate cost order having taken into account the conduct of the parties during arbitration.

Limitation of liability

89J. The Facilitator and the secretariat are not liable for any loss suffered by any person as a result of any act performed or omitted in good faith in the course of exercising the functions in terms of this Chapter.

Exemption, Medicines

89K. The provisions of this Chapter do not apply to the sale of medicines.

Amendment of section 90 of Act 61 of 2003

2. Section 90 of the principal Act is hereby amended by the substitution in subsection (1) of paragraph (v) of the following paragraph:

"(v) the processes of determination and publication by the Director-General of one or more reference price lists for services rendered, procedures performed, and consumable and disposable items utilised by categories of health establishments, health care providers or health workers in the private health sector which may be used-

(i) by a medical scheme as a reference to determine its own benefits; and

(ii) by health establishments, health care providers or health workers in the private health sector as a reference to determine their own fees,

[but which are not mandatory;] and"

Short title and commencement

3. This Act is called the National Health Amendment Act, 2008 and shall come into operation on a date fixed by the President by proclamation in the Gazette.

EXPLANATORY MEMORANDUM ON THE OBJECTS OF THE NATIONAL HEALTH AMENDMENT BILL, 2008

1. PURPOSE OF THE BILL

The purpose of the Bill is to introduce a new chapter in the National Health Act, 2003 that provides for a framework for health pricing.

2. CLAUSE BY CLAUSE ANALYSIS OF THE BILL

The Bill seeks to introduce Chapter 10A in the National Health Act, 2003 (Act No. 61 of 2003), so as to specifically, clause by clause, provide for the following:

2.1 Clause 89A

It provides for the insertion of new definitions of some of the words used in the new chapter.

2.2 Clause 89B

It makes provision for the objects of the Chapter, which is to provide for a framework to enable health care providers, health establishments and medical schemes ("stakeholders") to negotiate and bargain on prices.

2.3 Clause 89C

The clause provides for the actual appointment of the Facilitator and Assistant Facilitators by the Minister from nominations by interested persons. It further provides for the functions of the Facilitator which include facilitating collective negotiations by stakeholders; recording and submitting to the Minister agreements reached on prices; assisting the parties during the negotiations process; ensuring that negotiations are conducted in a transparent and fair manner; and confirming to the Minister that indeed such negotiations were conducted in a transparent and fair manner.

2.4 Clause 89D

The clause provides for the support for and remuneration of the Facilitator, that the Director-General shall designate staff of the Department to serve as the Secretariat for the Facilitator and that the Facilitator's remuneration is determined by the Minister in consultation with the Minister of Finance.

2.5 Clause 89E

The clause deals with conflict if interest, that the Facilitator must make a declaration to the Minister in this regard.

2.6 Clause 89F

The clause provides for the actual negotiations and bargaining on prices, that the parties may negotiate collectively as organizations or associations and bargain individually as individual entities; that negotiations must start after the publication by the Department of the reference price lists and that these lists must serve as a price reference for the parties during the negotiations process; that where the parties have reached agreements on prices, health care providers and health establishments shall not charge prices in excess of those agreed upon.

2.7 Clause 89G

The Clause provides for an eventuality where the parties fails to agree on prices, that in such an instance, if the services rendered relate to prescribed minimum benefits, health care providers and health establishments shall not charge prices in excess of those appearing on the reference price lists. This requirement also extends to patients who are not members of medical schemes. Provision is made for specialists that these may charge in excess of prices appearing on the reference price lists.

2.8 Clause 89H

The Clause provides for non-prescribed minimum benefits, that whatever the parties charge must be in relation to the reference price lists.

2.9 Clause 89I

The Clause provides for the resolution of disputes, that where disputes arise during the negotiations process, such disputes may be referred to the Minister and that the Minister shall appoint an arbitrator agreeable to both parties to resolve the dispute and that where the parties cannot agree on the arbitrator, the Minister may appoint one after consultation with the Minister of Justice and Constitutional Development.

2.10 Clause 89J

The clause provides for limitation of liability for the Facilitator and the secretariat for acts performed in good faith in the performance of their functions.

2.11 Clause 89K

The Clause exempts medicines from the provisions of the new chapter because medicines' prices are already regulated in terms of other legislation.

3. CONSULTATION

The provisions of the Bill resulted from consultative processes between the National Department and Provinces as well as stakeholders in the private health care industry. The Bill was also published for comment.

4. FINANCIAL IMPLICATIONS

The financial implications have been estimated and the necessary budget will be allocated.

5. PARLIAMENTARY PROCEDURE

This Bill must be dealt with in accordance with the procedure established by section 76 of the Constitution.

1

GENERAL EXPLANATORY NOTE:

[ ] words in bold type in square brackets indicate omissions from the existing enactments.

..... words underlined with a solid line indicate insertions in existing enactments.

DRAFT BILL

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 certification and registration of products which include medicines, medical devices and certain foodstuffs and cosmetics, for the control of Scheduled substances; and matters incidental thereto.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:-

Amendment of section 1 of Act 101 of 1965 as amended by section 1 of Act 65 of 1974, section 1 of Act 17 of 1979, section 1of Act 20 of 1981, section 1 of Act 94 of 1991, section 49 of Act 94 of 1991, section 1 of Act 49 of 1996, section 1 of Act 90 of 1997 and section 1 of Act 17 of 1979.

1. Section 1 of the Medicines and Related Substances Act 101 of 1965 (hereinafter referred to as the principal Act) is hereby amended by the-

(a) substitution, in the definition of advertisement, for the words appearing before paragraph (a) of the following words:

"advertisement', in relation to any **[medicine]** product or Scheduled substance, means any written, pictorial, visual or other descriptive matter or verbal statement or reference-"

(b) substitution, in the definition of advertisement, of the words following upon paragraph (c) of the following words:

"which is intended to promote the sale of that **[medicine]** product or Scheduled substance, and 'advertise' has a corresponding meaning;":

(c) insertion after the definition of 'approved name" of the following definition:

"Authority" means the South African Health Products Regulatory Authority established in terms of section 2 of this Act";

(d) insertion after the definition of "certificate of registration" of the following definitions:

" " certification" means certification by the Authority that a product is safe, of good quality and efficacious in relation to its effect on human or animal health, as the case may be";

"cosmetic" means a cosmetic as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972 in respect of which medicinal claims are made.

(e) deletion of the definition of "council";

(f) insertion after the definition of "export" of the following definition:

"foodstuff" means a foodstuff as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 in respect of which medicinal claims are made.;"

(f) insertion of the following definition after the definition of "prescribed":

""product" includes a medicine; cosmetic; medical device or a foodstuff;"

(g) deletion of the definition of Registrar;

(h) the deletion of subsection (3).

(i) substitution for subsection (4) of the following subsection:

"(4) International tendering for **[medicines]** products shall be allowed in the prescribed manner and on the prescribed conditions"

Substitution of section 2 of Act 101 of 1965, as amended

2. The followings section is hereby substituted for section 2 of the principal Act:

"Establishment, powers and functions of the South African Health Products Regulatory Authority

2. (1) The South African Health Products Regulatory Authority (the Authority) is hereby established.

(2) The Authority is-

(a) a juristic person;
(b) subject to the Public Finance Management Act, 1999 (Act No. 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."

Substitution of section 3 of 101 of 1965 as amended

3. The following section is hereby substituted for section 3 of the principal Act

"Chief Executive Officer and Other Staff of Authority

3. (1) The Minister must appoint a suitably qualified person as the Chief Executive Officer of the Authority.

(2) 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 Minister;
(c) is accountable to and reports to the Minister;
(d) is entitled to the benefits as may be determined by the Minister in consultation with the Minister for 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 the Authority's staff; and
(h) must compile business and financial plans and reports in terms of Act 1 of 1999.

(3) 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.

(4) The Minister, after consultation with the Minister for the Public Service and Administration, shall determine the human resources policy for the Authority and such policy shall include a code of conduct applicable to the Chief Executive Officer and staff of the Authority.

(5) 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 No. 66 of 1995).

(6) 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 No. 21 of 1996).

(7) The Chief Executive Officer may, subject to the approval of the Minister, appoint committees as it may deem necessary, to investigate and report to it on any matter within the purview of the Authority in terms of this Act.

Repeal of sections 4, 5, 6, 7, 8, 9 and 12 of Act 101 of 1965.

4. Sections 4, 5, 6, 7, 8, 9 and 12 of the principal Act are hereby repealed.

Amendment of section 13 of Act 101 of 1965 as amended

5. The following section is hereby substituted for section 13 of the principal Act:

" **Registers**

13. The Chief Executive Officer shall keep separate registers for products, in which he or she shall record products' certification by the Authority and registration as approved by the Minister, and in which he or she shall enter all such particulars in regard to such products and the holder of certification or certificate of registration in respect of such products as are required by this Act to be entered therein."

Amendment of section 14 of Act 101 of 1965 as amended

6. Section 14 of the principal Act is hereby amended by the-

(a) substitution for the heading of section 14 of the following heading:

"Prohibition on the sale of products which are subject to certification or registration and are not certified or registered";

(b) substitution for subsection (1) of the following subsection:

"(1) Save as provided in this section or sections 21 and 22A, no person shall sell any **[medicine,]** product which is subject to certification and registration by virtue of a **[resolution]** notice published in terms of subsection (2) unless it is certified and registered.

(c) substitution for subsection (2) of the following subsection:

"(2) (a) The **[council]** Authority may from time to time by **[resolution approved by]** notice, with the approval of the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines; a cosmetic, medical device or foodstuff mentioned in the **[resolution]** notice shall be subject to certification and registration in terms of this Act.

(b) Any such **[resolution]** notice may also relate only to **[medicines,]** products 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]** products which were not then so available.

(c) Any such **[resolution]** notice shall be published in the Gazette by the **[registrar]** Chief Executive Officer and shall come into operation on the date on which it is so published."

(d) Substitution for subsection (3) of the following subsection:

"(3) In the case of a **[medicine,]** product which was available for sale in the Republic immediately prior to the date of publication in the Gazette of the **[resolution]** notice by virtue of which it is subject to certification and registration in terms of this Act, the provisions of subsection (1) shall come into operation-

(a) if no application for the certification and registration of such **[medicine]** product, is made within the period of six months immediately succeeding that date, on the expiration of that period; or

(b) if the application for the certification and registration of such **[medicine,]** product is made within the said period, on the date one month after the date on which a notice in respect of such **[medicine]** product, is published in the Gazette in terms of section 15 (10) or section 17 (a)."

(c) substitution for the words following upon paragraph (b) of subsection (4) of the following words:

"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 certification and 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 certified and registered under this Act."

Amendment of section 15 of Act 101 of 1965 as amended

7. The following section is hereby substituted for section 15 of the principal Act:

"Certification and Registration of products

15. (1) Every application for the certification and registration of a product shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant products and by the prescribed certification or registration fee.

(2) As soon as possible after receipt by him or her of any such application together with any particulars and samples which accompanied the application, 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 product in question is suitable for the purpose for which it is intended and complies with the prescribed requirements and that the product is safe, of good quality and efficacious, it shall issue the applicant with a certificate to that effect.

(b) If the Authority is not so satisfied 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 one month 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 not issue the certificate contemplated in paragraph (a).

(4) (a) After the Authority has issued a certificate in respect of any product, the Chief Executive Officer shall in writing, notify the applicant of that fact and submit the application to the Minister for a decision on the registration of the product;

(b) If the Minister is satisfied that it is in the public interest to register such a product, the Minister shall approve of the registration of such product and if the Minister is not so satisfied, she or he will not approve of the registration and shall inform the Authority accordingly and the Authority shall inform the applicant;

(c) In determining whether it is in the public interest to register a product, the Minister shall take the following into account in relation to the State:

(i) public health interests including national epidemiological trends;
(ii) economic interests in relation to health policies;
(iii) whether the product is supportive of national health policy and goals in the long term;
(iv) whether the product is likely to significantly improve access to health care for vulnerable groups within society;
(v) the experience of other countries concerning the marketing, distribution and use of the product; and
(vi) generally whether the public would be best served by such registration.

(d) Veterinary medicines shall be registered by the Minister after consultation with the Minister of Agriculture.

(e) The Authority shall upon being informed of the Minister's decision to approve the registration, record such registration in the relevant register and issue the applicant with a certification and the certificate of registration..

(5) Every product shall be certified and registered under such name as the Authority may approve.

(6) The Chief Executive Officer shall allocate to every product certified or registered under this Act a certification or registration number which shall be recorded in the register opposite the name of such product and which shall be stated in the certification or certificate of registration issued in respect of such product.

(7) Any certification or registration under this section, shall be valid for a period of five years and may be made subject to such conditions as may with regard to the succeeding provisions of this section be determined by the Authority or the Minister respectively.

(8) No condition shall be imposed under subsection (7) 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 or the Minister, as the case may be, that the imposition of such condition is contemplated and invited to submit written representations to the Authority or the Minister, as the case may be, in regard to the matter.

(9) If no such representations are lodged by the applicant concerned within a period of one month after the receipt by him or her of any notification referred to in subsection (8), or if after consideration of any such representations the Authority or the Minister, as the case may be, is still of the opinion that the condition in question should be imposed, the Authority or the Minister, as the case may be, shall certify or register the product concerned subject to the said condition.

(10) Notice of the rejection of an application for certification or registration under this section in respect of a product referred to in subsection (3) of section 14 shall be given in the Gazette by the Chief Executive Officer.

(11) The Chief Executive Officer shall as soon as possible after the date of expiry of the appropriate period referred to in section 14(3) publish in the Gazette the prescribed particulars in respect of all applications for certification and registration received by him or her prior to such date."

Amendment of section 15A of Act 101 of 1965 as amended

8. The following section is hereby substituted for section 15A of the principal Act:

"**Amendment of entries in the register**

(1) The entry made in the register with respect to any product may on application by the holder of certification or certificate of registration issued in respect of such product be amended by the Chief Executive Officer and with the approval of the Minister if such amendment relates to the registration of the product.

(2) Application for the amendment of an entry in the register shall be made to the Chief Executive Officer on the prescribed form and shall be accompanied by the prescribed application fees.

(3) The Chief Executive Officer shall as soon as possible after the receipt of any such application submit the application to the Authority for consideration.

(4) If the Authority or the Minister, as the case may be, grants approval in respect of any application submitted to it in terms of subsection (3) the Chief Executive Officer shall make the required amendments in the register and, if necessary, cancel the existing certification or registration in respect of such product and issue a new certification or certificate of registration on the prescribed form to the applicant in respect of such product."

Amendment of section 15B of Act 101 of 1965 as amended

9. The following section is hereby substituted for section 15B of the principal Act:

"**Transfer of certification or certificate of registration**

"(1) Certification or certificate of registration may with the approval of the Authority be transferred by the holder thereof to any other person.

(2) Application for approval of the transfer of certification or a certificate of registration shall be made to the Chief Executive Officer on the prescribed form and shall be accompanied by the certification or certificate of registration in question and the prescribed application fees.

(3) The Chief Executive Officer shall as soon as practicable after the receipt of any such application submit the application to the Authority for consideration.

"(4) If the Authority grants any application submitted to it in terms of subsection (3) the Chief Executive Officer shall make the necessary entries in the register relating to the person to whom certification or the certificate of registration is transferred, cancel the existing certification or certificate of registration and issue a new one on the prescribed form to such person in respect of the relevant product"

Amendment of section 15C of Act 101 of 1965 as amended

9. Section 15C of the principal Act is hereby amended by the substitution for paragraph (b) of the following paragraph:

"(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 certification or the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the **[council]** Authority in the prescribed manner, may be imported;"

Amendment of section 16 of Act 101 of 1965 as amended

10. The following section is hereby substituted for section 16 of the principal Act:

" Cancellation of certification and registration

"(1) If the Authority-

(a) is of the opinion that any person has failed to comply with any condition subject to which any product was certified or registered; or

(b) is of the opinion that any product does not comply with any prescribed requirement; or

(c) in consultation with the Minister, is of the opinion that it is not in the public interest that any product 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 certification or certificate of registration issued in respect of that product.

(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 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 certification or the registration of the product in question should be cancelled, the Authority may-

(a) cancel the certification thereof; and
(b) in consultation with the Minister, cancel the registration thereof..

(4) If the person who is the holder of the certification or certificate of registration issued in respect of any product fails to pay the prescribed annual fee in respect of the retention of the certification or registration of that product 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 product."

Amendment of section 17 of Act 101 of 1965 as amended

11. The following section is hereby substituted for section 17 of the principal Act:

"Notification or cancellation of certification or registration

17. The Chief Executive Officer shall give notice in the Gazette of the certification or registration or cancellation of the certification or the registration of any product in terms of this Act, and shall in such notice specify-

(a) in the case of a certification or registration of any product, the name under which such product is certified or registered, the active components of such product, the name of the person who applied for the certification or registration of such product, the number allocated to it in terms of section 15 and the conditions (if any) subject to which it is certified or registered;

(b) in the case of a cancellation of the certification or registration of any product, the name under which such product was certified or registered, the name of the holder of the certification or certificate of registration issued in respect of such product and the number which was allocated to it in terms of section 15."

Amendment of section 18 of Act 101 of 1965 as amended

12. Section 18 of the principal Act is hereby amended by the-

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

"(1) No person shall sell any **[medicine]** product or Scheduled substance unless the immediate container or the package in which that **[medicine]** product or Scheduled substance is sold bears a label stating the prescribed particulars."

(b) substitution for subsection (2) of the following subsection:

"(2) No person shall advertise any **[medicine]** product or Scheduled substance for sale unless such advertisement complies with the prescribed requirements."

(c) substitution for subsection (3) of the following subsection:

"(3) The label referred to in subsection (1) shall be approved by the **[council]** Authority."

(d) substitution for subsection (4) of the following subsection:

"(4) The **[council]** Authority may authorise a deviation from the prescribed format and contents of any label."

(c) substitution for subsection (5) of the following subsection:

"(5) The Minister may prescribe additional requirements for the labelling of **[medicines]** products."

Amendment of section 18A of Act 101 of 1065 as amended

13. The following section is hereby substituted for section 18A of the Principal Act:

"Bonusing

18A. No person shall supply any **[medicine]** product according to a bonus system, rebate system or any other incentive scheme."

Amendment of section 18B of Act 101 of 1965 as amended

14. The following section is hereby substituted for section 18B of the principal Act:

"Sampling of Products

(1) No person shall sample any product.

(2) For the purposes of this section 'sample' means the free supply of products by a 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, but does not include the free supply of products for the purposes of clinical trials, donations of products to the State, tendering to the State and quality control by inspectors.

(3) The use of products or Scheduled substances for exhibition purposes shall be as prescribed."

Amendment of section 18C of Act 101 of 1965 as amended

15. The following section is hereby substituted for section 18C of the principal Act:

"Marketing of products

18C. The Minister may, after consultation with the relevant industries and other stakeholders, make regulations relating to the marketing of products and such regulations may also provide for Codes of Practice for relevant industries."

Amendment of section 19 of Act 101 of 1965 as amended

16. Section 19 of the principal Act is hereby amended by the-

(a) substitution for the heading of the following heading:

" Prohibition on sale of products which do not comply with prescribed requirements and furnishing of information regarding products to the Authority"

(b) substitution for subsection (1) of the following subsection:

"(1) No person shall sell any **[medicine]** product unless it complies with the prescribed requirements.

(c) substitution for subsection (2) of the following subsection:

"(2) The **[council]** Authority may by notice in writing require any person who manufactures or sells products or administers or prescribes any medicine or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his possession or which such person is in a position to obtain regarding such medicine or product."

(d) substitution for subsection (3) of the following subsection:

"(3) The **[council]** Authority may, if so requested by any person to whom a notice under subsection (2) is addressed, extend the period stipulated in such notice."

Amendment of section 20 of Act 101 of 1965 as amended

17. Section 20 of the principal Act is hereby amended by the-

(a) substitution of the heading of the following heading:

"Publication or distribution of false advertisements concerning products"

(b) substitution for subsection (1) of the following subsection:

"(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]** product; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any **[medicine]** product is other than that stated by the **[council]** Authority in terms of sub-paragraph (ii) of paragraph (a) of section twenty-two or state or suggest that any **[medicine]** product should be used for a purpose or under circumstances or in a manner other than that stated by the **[council]** Authority in terms of sub-paragraph (iii) or paragraph (a) of that section."

(c) substitution for subsection (2) of the following subsection:

"(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of sub-section (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the **[medicine]** product 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, unless it is proved that the accused failed on demand by the **[registrar]** Chief Executive Officer or an inspector or a member of the South African Police to furnish the name and address of the person at whose instance the advertisement was published, distributed or so brought to the notice of the public."

Amendment of section 21 of Act 101 of 1965 as amended

18. The following section is hereby substituted for section 21 of the principal Act:

"Authority may authorize sale of uncertified or unregistered products for certain purposes"

(1) The Authority may in consultation with the Minister in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular product which is not certified or registered."

(2) Any product sold in pursuance of any authority granted under sub-section (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 in consultation with the Minister may at any time by notice in writing withdraw any authority granted in terms of sub-section (1) if effect is not given to any determination made in terms of sub-section (2)."

Amendment of section 22 of Act 101 as amended

19. Section 22 of the principal Act is hereby amended by the...

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

(1) **The Director-General shall after consultation with the council** The Chief Executive Officer shall cause, in such manner as he or she **[the Director-General]** considers most suitable-

(a) as soon as practicable after any **[medicine]** product, other than a veterinary medicine, has been registered, medical practitioners, dentists, pharmacists and the person who applied for the registration of such **[medicine]** product to be informed-

(i) of the name and number under which such **[medicine]** product is certified or registered and the conditions, if any, subject to which such **[medicine]** product is certified or registered;

(ii) of the therapeutic efficacy and effect of such **[medicine]** product;

(iii) of the purpose for which, the circumstances under which and the manner in which such **[medicine]** product should be used; and

(iv) regarding any other matter concerning such **[medicine]** product which, in the opinion of the **[council]** Chief Executive Officer may be of value to them;

(b) as soon as practicable after the certification or registration of any **[medicine]** product, other than a veterinary medicine, has been cancelled in terms of section 16, medical practitioners, dentists, pharmacists, the public in general and the holder of the certification or certificate of registration issued in respect of such **[medicine]** product to be informed of the cancellation of such certification or registration.

Amendment of section 22A of Act 101 of 1965 as amended

20. Section 22A of the principal Act is hereby amended by the-

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

"(2) The Minister may, on the recommendation of the **[council]** Authority, prescribe the Scheduled substances referred to in this section."

(b) substitution for paragraph (a) of subsection (13) of the following paragraph:

"(a) to the applicant's furnishing the **[registrar]** Chief Executive Officer annually with the prescribed information"

(c) substitution for subsection (15) of the following subsection"

"(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the **[Interim Pharmacy Council of South Africa]** 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."

Amendment of section 22B of Act 101 of 1965 as amended

21. Section 22B of the principal Act is hereby amended by the-

(a) substitution for the heading of the following heading:

"Publication of information relating to products or Scheduled substance

(b) substitution for subsection (1) of the following subsection:

"(1) Notwithstanding the provisions of section 34 the **[council]** 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,]** product or Scheduled substance **[or medical device]**."

Amendment of section 22C OF Act 101 of 1965 as amended

22. Section 22C of the principal Act is hereby amended by the-

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

"(b) the **[council]** Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a **[medicine or medical device]** product a licence to manufacture, act as a wholesaler of or distribute, as the case may be, such **[medicine or medical device]** a product, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the **[council]** Authority may determine."

(b) substitution for subsection (2) of the following section:

"(2) A licence referred to in subsection (1) (a) shall not be issued unless the applicant has successfully completed a supplementary course prescribed under the Pharmacy Act, 1974 (Act 53 of 1974), by the **[Interim Pharmacy Council of South Africa]** South African Pharmacy Council."

(c) substitution for subsection (3) of the following subsection:

"(3) The Director-General or the **[council]** 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 **[council]** Authority may deem necessary."

(d) substitution for the words appearing before paragraph (a) of the following words:

"(4) When the Director-General or the **[council]** Authority, as the case may be, grants or refuses an application for a licence-"

(c) substitution for subsection (6) of the following subsection:

"(6) No manufacturer, wholesaler or distributer referred to in subsection (1) (b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any **[medicine or medical device]** product unless he or she is the holder of a licence contemplated in the said subsection."

Amendment of section 22D of Act 101 of 1965 as amended

23. The following section is hereby substituted for section 22D of the principal Act:

"22D. A licence issued under section 22C 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 **[council]** Authority, as the case may be, may allow and on payment of the prescribed fee."

Amendment of section 22E of Act 101 of 1965as amended

24. Section 22E of the principal Act is hereby amended by the-

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

"(a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the **[council]** 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) substitution for the words following upon paragraph (d) of subsection (1) of the following words:

"the Director-General or the **[council]** 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.

(c) substitution for the words appearing before paragraph (a) of subsection (2) of the following words:

"(2) The Director-General or the **[council]** Authority, as the case may be, may after considering the reasons furnished to him or her in terms of subsection (1)-

(d) substitution for paragraph (a) of subsection (2) of the following paragraph:

"(a) Suspend the licence in question for such period as he or she or the **[council]** Authority may determine; or

Amendment of section 22F of Act 101 of 1965 as amended

25. Section 22F of the principal Act is hereby amended by the substitution for paragraph (c) of subsection (4) of the following paragraph:

" (c) where the product has been declared not substitutable by the **[council]** Authority."

Amendment of section 22H of Act 101 of 1965 as amended

26. Section 22H of the principal Act is hereby amended by the-

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

"(1) (a) No wholesaler shall purchase **[medicines]** products from any source other than from the original manufacturer or from the primary importer of the finished product.

(b) A wholesaler shall sell **[medicines]** products only into the retail sector.

(2) Subsection (1) shall not be construed as preventing the return of **[medicines]** products for credit purposes only, to the manufacturer or wholesaler from which that **[medicine]** was initially obtained."

Amendment of section 23 of Act 101 of 1965 as amended

27. Section 23 of the principal Act is hereby amended by the-

(a) substitution for the heading of the following heading:

"Disposal of undesirable products"

(b) substitution for the words appearing before paragraph (a) of subsection (1) of the following words:

"(1) If the **[council]** Authority is of the opinion that it is not in the public interest that any **[medicine]** product shall be made available to the public, it may-"

(c) substitution for the words following upon paragraph (b) of subsection (1) of the following words:

" to return any quantity of such **[medicine]** product which he has in his possession to the manufacturer thereof or (in the case of any imported **[medicine]** product) to the importer concerned or to deliver or send it to any other person designated by the **[council]** Authority."

(d) substitution for subsection (2) of the following subsection:

"(2) The **[council]** Authority may by notice in writing direct any manufacturer or importer of any such **[medicine]** product who has in his possession any quantity thereof (including any quantity returned, delivered or sent to him in pursuance of a direction under sub-section (1)), or any other person to whom any quantity of such **[medicine]** product has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the **[council]** Authority may determine."

(e) substitution for subsection (3) of the following subsection:

"(3) No person shall sell any **[medicine]** product which is the subject of a notice under subsection (1) which has not been set aside on appeal."

Amendment of section 24 of Act 101 of 1965 as amended

28. Section 24 of the principal Act is hereby amended by the-

(a) substitution for the heading of the following heading:

"Appeal against decision of Director-General or Authority"

(b) substitution for subsection (1) of the following subsection:

"(1) 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 and upon payment of the prescribed fee, appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned."

(c) substitution for subsection (3) of the following subsection:

"(3) The appeal committee may after hearing the appeal-

(a) confirm, set aside or vary the relevant decision of the Director-General; **[or the council]** and

(b) direct the Director-General **[or the council, as the case may be,]** to execute the decision of the appeal committee."

(d) substitution for subsection (4) of the following subsection:

"(4) The decision of the appeal committee shall be in writing and a copy thereof shall be furnished to the appellant as well as to the Director-General **[or the council, as the case may be]**."

Insertion of section 24A

29. The principal Act is hereby amended by the insertion after section 24 of the following section:

"Appeal Against Decision of Authority

24A. (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 and have the matter resolved 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 Chief Executive Officer 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, 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 and the High Court may confirm or set aside the decision of the appeal committee.

(6) In setting aside the decision of the appeal Committee, the High Court cannot substitute its decision for that of the appeal committee but can refer the matter back to the appeal committee for a final decision.

Amendment of section 25 of Act 101 of 1965 as amended

30. The following section is hereby substituted for section 25:

" Privileges of Authority and committees

25. The Authority, persons contracted by the Authority to perform work for the Authority, committees appointed in terms of this Act or its members are not be liable in respect of anything done in good faith under this Act."

Amendment of section 26 of Act 101 of 1965 as amended

31. Section 26 of the principal Act is hereby amended by the-

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

"(1) The **[Director-General]** Chief Executive Officer may authorize such persons as inspectors, as he may consider necessary for the proper enforcement of this Act."

(b) substitution for subsection (2) of the following subsection:

"(2) Every inspector shall be furnished with a certificate signed by the **[Director-General]** Chief Executive Officer and stating that he has been authorized as an inspector under this Act."

(c) substitution for subsection (3) of the following subsection:

"(3) An inspector shall, before he exercises or performs any power or function under this Act, produce and exhibit to any person affected **[hereby]** by such exercise or performance, the certificate referred to in subsection (2)."

Amendment of section 27 of Act 101 of 1965 as amended

32. The following section is hereby substituted for section 27 of the Act:

"27. **[The Director-General]** Chief Executive Officer may grant such authority to such analysts, pharmacologists and pathologists as he may consider necessary for the proper enforcement of this Act"

Amendment of section 28 of Act 101 of 1965 as amended

33. Section 28 of the principal Act is hereby amended by the-

(a) substitution for subparagraph (i) of subsection (1) of the following subparagraph:

"(i) any place or premises from which a person authorised under this Act to compound and dispense medicines or Scheduled substances, handles products or from which the holder of a licence as contemplated in section 22C (1) (b) conducts business; or"

(b) substtution for paragraph (b) of subsection (1) of the following paragraph:

(b) inspect any **[medicine]** product or Scheduled substance, or any book, record or document found in or upon such premises, place, vehicle, vessel or aircraft;

(c) substitution for paragraph (c) of subsection (1) of the following paragraph:

"(c) seize any such **[medicine]** product or Scheduled substance, or 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) substitution for paragraph (d) of subsection (1) of the following paragraph:

"(d) take so many samples of any such **[medicine]** product or Scheduled substance as he may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act."

(e) substitution for subsection (2) of the following subsection:

"(2) Any sample taken in terms of paragraph (d) of subsection (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such **[medicine]** product or Scheduled substance, or if there is no such person or if he is absent for any reason, in the presence of any other witness, shall forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit and shall then be transmitted to an analyst, pharmacologist or pathologist together with a certificate in the prescribed form signed by such inspector and a copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such **[medicine]** product or Scheduled substance or his agent."

(f) substitution for subsection (4) of the following subsection:

(4) The owner of the **[medicine]** product or Scheduled substance from which the sample was taken may claim from the **[Director-General]** the Authority an amount equal to the market value thereof.

Amendment of section 29 of Act 101 of 1065 as amended

34. Section 29 of the principal Act is hereby amended by the-

(a) substitution in paragraph (h) of the words appearing before subparagraph (i) of the following words:

"(h) makes any false or misleading statement in connection with any **[medicine]** product or Scheduled substance-

(b) substitution for paragraph (i) of the following paragraph:

"(i) sells any **[medicine]** product or Scheduled substance upon the container of which a false or misleading statement in connection with the contents is written; or"

Amendment of section 30 of Act 101 of 1965 as amended

35. Section 30 of the principal Act is hereby amended by the-

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

"(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any **[medicine]** product or Scheduled substance in respect of which the offence has been committed to be forfeited to the State."

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

"(3) Any **[medicine]** product or Scheduled substance forfeited under this Act shall be destroyed or otherwise dealt with as the **[Director-General]** Chief Executive Officer may direct."

Amendment of section 31 of Act 101 of 1965 as amended

36. Section 31 of the principal Act is hereby amended by the-

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

" (a) any quantity of a **[medicine]** product or Scheduled substance 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;"

(b) substitution for paragraph (d) of the following paragraph:

"(d) any statement or entry contained in any book, record or document kept by any owner of a **[medicine]** product or Scheduled substance, 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 as an admission of the facts set forth in that statement or entry, unless it is proved 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 work as manager, or in the course of his agency or employment."

Amendment of section 33A of Act 101 of 1965 as amended

37. Section 33A of the principal Act is hereby amended by the-

(a) substitution for the heading of the following heading

"Funds of Authority

(b) substitution in subsection (1) for the words appearing before paragraph (a) of the following words:

"(1) The funds of the **[council]** Authority shall consist of-"

(c) substitution for paragraph (c) of subsection (1) of the following paragraph:

"(c) money accruing to the **[council]** Authority from any other source."

(d) substitution for subsection (2) of the following subsection:

"(2) (a)The **[council]** Authority may accept money or other goods donated or bequeathed to the **[council,]** 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 **[council]** Authority."

(e) substitution for subsection (3) of the following subsection:

"(3) The **[council]** Authority shall utilise its funds for the defrayal of expenses incurred by the **[council]** Authority in the performance of its functions under this Act."

(f) substitution for subsection (4) of the following subsection:

"(4) The **[council]** 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 referred to in subsections (1) and (2)."

(g) substitution for subsection (5) of the following subsection:

"(5) The **[council]** Authority shall keep full and proper records of all money received or expended, of its assets and liabilities and of its financial transactions."

(h) substitution for subsection (7) of the following subsection:

"(7) The **[council]** Authority may invest money which is deposited in terms of subsection (4) and which is not required for immediate use in any manner as it may deem fit."

(i) substitution for subsection (8) of the following subsection:

"(8) Any money which at the close of the **[council's]** Authority's financial year stands to the credit of the **[council]** Authority in the account referred to in subsection (4) and money which has been invested in terms of subsection (7), shall be carried forward to the next financial year as a credit in the account of the **[council]** Authority."

Amendment of section 34A of Act 101 of 1965 as amended

38. Section 34A of the principal Act is hereby amended by the addition of the following subsection:

"(3) The Chief Executive Officer may in writing authorize 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."

Amendment of section 35 of Act 101 of 1965 as amended

39. Section 35 of the principal Act is hereby amended by the-

(a) substitution for the words appearing before subparagraph (i) of subsection (1) of the following words:

"(1) The Minister may, in consultation with the **[council]** Authority, make regulations-"

(b) deletion of subparagraph (xiii)

(c) substitution for subparagraph (xxxi) of the following subparagraph:

"(xxxi) prescribing the fee to be paid to the **[registrar]** Authority in respect of an application for the certification or the registration, and in respect the certification or the registration of a **[medicine]** product or Scheduled substance **[or medical device]**, the fee to be paid annually to the **[registrar]** Authority in respect of the retention of the certification or the registration of a **[medicine]** product or, Scheduled substance **[or medical device]** and the date on which such annual fee shall be paid;"

(d) substitution for subparagraph (xxxiii) of subsection (1) of the following subparagraph:

"(xxxiii) relating to appeals against decisions of the Director-General or the **[council]** Authority;

(e) substitution for subparagraph (xxxvii) of the following subparagraph:

"(xxxvii) relating to the scientific, pharmaceutical, clinical and other skills required by **[member of the council or by a member of the executive committee of the council]** members of staff of the Authority to evaluate the **[quality, efficacy and safety]** the certification of **[medicines]** products;"

(f) insertion of the following subparagraphs after subparagraph (xxxix), the existing subparagraphs (xl) and (xli) becoming subparagraphs (xliv) and (xlv) respectively:

"(xl) relating to products in respect of matters contemplated in subparagraphs (ii) up to and including subparagraph (xi); subparagraphs (xxiii); (xxiv); (xxxii); (xxxiv) and (xxxviii);

(xli) relating to certification of products in respect of matters contemplated in subparagraphs (i); (ii); (iv); (v); (vi); (xii); (xxvii) and xxxii);

(xlii) relating to the control of products;

(xliii relating to the licensing for possessing or using certain products;"

(g) substitution for paragraph (b) of subsection (2) of the following paragraph:

"(b) any regulation in respect of which the Minister is, after consultation with the **[council]** Authority, of the opinion that the public interest requires it to be made without delay.

(h) substitution for subsection (5) of the following subsection:

" (5) Regulations made under subsection (1)(xi) may prescribe that any **[medicine]** product or any component thereof shall comply with the requirements set out in any publication which in the opinion of the **[council]** Authority is generally recognized as authoritative."

(i) substitution for subsection (6) of the following subsection:

"(6) Regulations may be made under this section in respect of particular **[medicines]** products or Scheduled substances or classes or categories of **[medicines]** products or Scheduled substances

or in respect of **[medicines]** products or Scheduled substances other than particular classes or categories of **[medicines]** products or Scheduled substances, and different regulations may be so made in respect of different **[medicines]** products or Scheduled substances or different classes or categories of **[medicines]** products or Scheduled substances."

(j) substitution for subsection (8) of the following subsection:

"(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 **[executive committee appointed under section 9,]** Authority make regulations relating to any matter referred to in subsection (1) or to amend or repeal any regulation made in terms of that subsection.

Amendment of section 36 of Act 101 of 1965 as amended

40. The following section is hereby substituted for section 36 of the principal Act:

"36. The Minister may, on the **[unanimous]** recommendation of the **[members present at any meeting of the council]** Authority, by notice in the Gazette exclude, subject to such conditions as he may determine, any **[medicine]** product from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice."

Amendment of section 37A of Act 101 of 1965 as amended

41. The following section is hereby substituted for section 37A of the principal Act:

"37A. Notwithstanding the provisions of section 35 (2), the Minister may, on the recommendation of the **[council]** Authority, from time to time by notice in the Gazette amend any Schedule prescribed under section 22A (2) by the inclusion therein or the deletion therefrom of any medicine or other substance, or in any other manner.

Transitional measures

42. (1) Medicines and medical devices that are registered at the date of commencement of this Amendment Act shall be deemed to be certified and registered in terms of the Act and the Chief Executive Officer shall enter them in the relevant register.

(2) The Medicines Control Council shall cease to exist the day before this Amendment Act is brought into operation.

Short title and commencement

43. This Act is called the Medicines and Related Substances Amendment Act, 2008 and comes into operation on a date fixed by the President by proclamation in the Gazette.

EXPLANATORY MEMORANDUM ON THE OBJECTS OF THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2008

1. PURPOSE OF THE BILL

The purpose of the Bill is to amend the Medicines and Related Substances Act, 1965 to provide for a new medicines regulatory authority that will replace the Medicines Control Council.

2. OBJECTS OF THE BILL

The Medicines and Related Substances Amendment Bill, 2008 ("the Bill") South seeks to introduce the establishment of regulatory authority for medicines and medical devices as well as other products like foodstuffs and cosmetics which have some medicinal components in them or in respect of which medicinal claims are made. This new regulatory authority, the South African Health Products Regulatory Authority ("the Authority") will replace the current Medicines Control Council.

3. SUMMARY

The Bill establishes the Authority as a juristic person that is subject to the Public Finance Management Act, 1999 and is accountable to and reports to the Minister. The Authority is headed by a Chief Executive Officer who is also accountable to and reports to the Minister.

The Bill further introduces a two-tier registration system for all the products regulated under it. First, an applicant must apply for certification by the Authority. Certification means that the Authority confirms that a medicine or product is safe, of good quality and efficacious.

Once this has been established by the Authority, the application is then forwarded to the Minister for consideration whether the registration of the particular medicine of product will be in the public interest. If the Minister concludes that registration of such medicine or product is in the public interest, the Minister will approve of such registration and the Authority shall duly record the registration of the medicine or product

4. DISCUSSION

CLAUSES

4.1 Clause 1 provides for amendments to the definitions which include the insertion of the definitions of certification; foodstuff and cosmetic. Certification means that the medicine or product is certified to be safe, of good quality and efficacious. Foodstuffs and cosmetic emphasize the requirement that there must be medicinal claims made about them for them to be regulated.

4.2 Clause 2 provides for the establishment of the Authority as a juristic person accountable to and reporting to the Minister and which is also subject to the Public Finance Management Act, 1999.

4.3 Clause 3 provides for the Chief Executive Officer (CEO) of the Authority who is appointed by the Minister for a five year term renewable once. The CEO is appointed subject to the conclusion of a performance agreement with the Minister and must compile business and financial plans as well as reports in terms of Act 1 of 1999.

4.4 Clause 5 provides that the CEO shall keep registers for all the products regulated in terms of the Act.

4.5 Clause 7 provides for certification and registration of products, that the Authority will certify products as being safe, of good quality and efficacious whereas the Minister will approve the registration of such products if it is in the public interest that such products must be registered. The registration of veterinary medicines is done in consultation with the Minister of Agriculture.

4.6 Clause 30 provides for appeals against the decision of the Authority, that a person aggrieved by the decision of the authority shall first seek a meeting with the CEO to resolve the matter amicably. If this is not achieved, an appeal committee comprising five persons, two nominated by the appellant and the other two by the CEO and chaired by a neutral person with knowledge of the law will hear the appeal. No provision is made for appeals against the decision of the Minister which means persons not satisfied with such decisions may directly approach the High Court.

4.7 The rest of the clauses are consequential amendments replacing the words "council" and "registrar" wherever they appear in the principal Act with the words "Authority" and "CEO" respectively.

5. CONSULTATION

The Ministers of Finance, of Trade and Industry, of Agriculture and Land Affairs, of Environmental Affairs and Tourism, after consultation with the Minister of Health identified a senior official to represent their Departments on the Ministerial Task Team. The Task Team's recommendations were achieved by consensus. Members of the various Departments were asked to engage discussions with their principals so that the consensus within the Task Team would have the support and approval of their relevant Departments.

6. FINANCIAL IMPLICATIONS

It is recommended that there be a 50% cost recovery from the revenue generated from fees charged by the Authority. Partial or total cost recovery is practiced by some regulatory authorities in order to ensure financial viability and feasibility, affordability and sustainability. Projected financial calculations indicate that this is feasible. The projected fees that could be accrued are estimated at R137.8m. As this will be 50% cost recovery, the budget could be R275.6m.

7. PARLIAMENTARY PROCEDURE

This Bill must be dealt with in accordance with the procedure established by section 76 of the Constitution.