

REPUBLIC OF SOUTH AFRICA

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

(As amended by the Portfolio Committee on Health)
(The English text is the official text of the Bill)

(MINISTER OF HEALTH)

[B 44B—2008]

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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.

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 Chief Executive Officer and staff of the Authority; for the registration of medicines, medical devices, certain foodstuffs and cosmetics; for transitional measures; and for matters connected therewith.

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 1 of 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 5 1997 and section 1 of Act 17 of 1979

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

(a) by the substitution for the definition of “advertisement” of the following definition: 10

“ ‘**advertisement**’, in relation to any [**medicine or Scheduled substance**] product; medical device or IVD [**or Scheduled substance**], means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet or other publica- 15 tion;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that [**medicine**] product, medical device or IVD, and ‘advertise’ has a 20 corresponding meaning;”;

(b) by the insertion after the definition of “**approved name**” of the following definition:

“ ‘**Authority**’ means the South African Health Products Regulatory Authority established by section 2;” 25

- (c) by the insertion after the definition of “certificate of registration” of the following definition:
“ ‘cosmetic’ means a cosmetic as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), which contains a Scheduled substance;”; 5
- (d) by the deletion of the definition of “council”;
- (e) by the insertion after the definition of “export” of the following definition:
“ ‘foodstuff’ means a foodstuff as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), which contains a Scheduled substance;”; 10
- (f) by the insertion after the definition of “interchangeable multi-source medicine” of the following definition:
“ ‘In vitro diagnostic medical device’ (‘IVD’) means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.”; 15
- (g) by the substitution for the definition of “medical device” of the following definition:
“ ‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: 20
 (a) intended by the manufacturer to be used, alone or in combination, for human beings for:
 (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; 25
 (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
 (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process; 30
 (iv) supporting or sustaining life;
 (v) control of conception;
 (vi) disinfection of medical devices; or
 (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and 35
 (b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;” 40
- (h) by the insertion after the definition of “medical device” of the following definition:
“ ‘Medical device or IVD establishment’ means a facility used by a manufacturer, wholesaler, distributor retailer, service provider or an importer of medical devices or IVD’s for conducting business;”. 45
- (i) by the substitution for the definition of medicine of the following definition:
“ ‘medicine’ means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—
 (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in **[man]** humans; or 50
 (b) restoring, correcting or modifying any somatic or psychic or organic function in **[man]** humans, and includes any veterinary medicine”;
- (j) by the insertion after the definition of “prescribed” of the following definition:
“ ‘product’ means a medicine, a Scheduled substance, or a cosmetic or foodstuff which contains a scheduled substance;”; 55
- (k) by the deletion of the definition of “registrar”; and
- (l) by the deletion of subsection (3). 60

Substitution for section 2 of Act 101 of 1965, as substituted by section 2 of Act 65 of 1974 and amended by section 2 of Act 90 of 1997

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

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

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2. (1) The South African Health Products Regulatory 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.”.

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Substitution of section 3 of 101 of 1965, as substituted by section 3 of Act 90 of 1997

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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) A person may not be appointed as the Chief Executive Officer if such person—

- (a) is an unrehabilitated insolvent;
- (b) is mentally unfit; or
- (c) has been convicted of an offence committed after the Constitution of the Republic of South Africa, 1993 (Act No. 200 of 1993) took effect and sentenced to imprisonment without the option of a fine.

(3) The Chief Executive Officer may be removed from office for—

- (a) serious misconduct;
- (b) permanent incapacity; or
- (c) engaging in any activity that is reasonably capable of undermining the integrity of the Authority.

(4) The Chief Executive Officer—

- (a) is appointed for a term of five years and may be reappointed for one additional term of five years;
- (b) is appointed subject to the conclusion of a performance agreement with the 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 the Public Service and Administration;
- (e) is responsible for the general administration of the Authority and for the carrying out of any functions assigned to the Authority by this Act and the Minister;
- (f) must manage and direct the activities of the Authority;
- (g) must appoint and supervise staff of the Authority; and
- (h) must compile business and financial plans and reports in terms of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

(5) The Chief Executive Officer shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions.

(6) (a) The Minister shall, after consultation with the Minister for the Public Service and Administration, determine the structure and the human resources policy for the Authority.

(b) The human resources policy shall include a code of conduct applicable to the Chief Executive Officer and the staff of the Authority.

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(7) The Authority may utilise persons seconded or transferred from the public service, and such transfer must be in accordance with the Labour Relations Act, 1995 (Act No. 66 of 1995).

(8) The Chief Executive Officer and the staff of the Authority become members of the Government Employees' Pension Fund contemplated in section 2 of the Government Employees Pension Law, 1996 (Proclamation No. 21 of 1996).

(9) The Chief Executive Officer shall appoint committees, as he or she 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.

Substitution of section 13 of Act 101 of 1965, as substituted by section 3 of Act 20 of 1981

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, medical devices or IVD's; in which he or she shall record—

- (a) the registration of products, medical devices or IVD's by the Authority; and
- (b) such particulars in regard to the products, medical devices or IVD's and the holder of certificate of registration in respect of such products, medical devices or IVD's as are required by this Act.”.

Substitution of section 14 of Act 101 of 1965, as amended by section 7 of Act 94 of 1991

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

“Prohibition on the sale of [medicines] products, medical devices or IVD's which are subject to registration and are not registered

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

(2) (a) The [council] Authority may from time to time [by resolution approved by the Minister] determine that a [medicine] product, medical device or IVD, or class or category of [medicines] product, medical device or IVD or part of any class or category of [medicines] product, medical devices or IVD's mentioned in the [resolution] declaration, shall be subject to registration in terms of this Act.

(b) Any such [resolution] declaration may also relate only to [medicines,] products, medical devices or IVD's 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, medical devices or IVD's which were not then so available.

(c) Any such [resolution] declaration 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.

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

- (a) if no application for the registration of such **[medicine]** product, medical device or IVD is made within the period of six months immediately succeeding that date, on the expiration of that period; or
- (b) if application for the registration of such **[medicine]** product, medical device or IVD is made within the said period, on the date one month after the date on which a notice in respect of such **[medicine]** product, medical device or IVD is published in the *Gazette* in terms of section **15(10) 15(9)** or section 17(a).
- (4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine—
- (a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C(1)(a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or
- (b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, and referred to in section 22A, as the case may be,
- if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected, and is not or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been registered under this Act.”.

Substitution of section 15 of Act 101 of 1965 as substituted by section 9 of Act 90 of 1997

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

“Registration of products, medical devices or IVD’s

- 15.** (1) Every application for the registration of a product, medical device or IVD shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by—
- (a) the prescribed particulars;
- (b) samples of the relevant products;
- (c) where practicable, samples of medical devices or IVD’s; and
- (d) the prescribed registration fee.
- (2) As soon as possible after receipt by the Chief Executive Officer of an application contemplated in subsection (1), he or she shall inform the applicant in writing that the application is being considered.
- (3) (a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the product, medical device or IVD in question—
- (i) is suitable for the purpose for which it is intended;
- (ii) complies with the prescribed requirements;
- (iii) is safe and of good quality; and
- (iv) in the case of products, also efficacious,
- it shall issue a notice in the *Gazette* of its intention to register the product, medical device or IVD and invite, within 30 days from the date of publication of such notice, any objection based on public interest to the intended registration.
- (b) If no objection is received within the 30 days period contemplated in paragraph (a), the Authority shall register the product, medical device or IVD.
- (c) If an objection is received, the Chief Executive Officer shall inform the Minister within 14 days of receipt of such objection by the Chief Executive Officer.

(d) The Minister shall, within 30 days of being informed of an objection as contemplated in paragraph (c), convene a panel comprising three persons—

- (i) one of whom shall be appointed on account of his or her knowledge of the law as the chairperson; and
- (ii) the other two shall have the knowledge relevant to the matters raised in the objection concerned.

(e) The panel contemplated in paragraph (d) shall—

- (i) within 30 days of being convened; and
- (ii) after hearing both the applicant and the objector and any other interested persons, decide on the objection and make recommendations to the Authority.

(f) The Authority shall after receipt of the panel's recommendations, decide on whether to register the product, medical device or IVD or not and inform the applicant and the objector, if any, accordingly.

(g) An objection is based on public interest if it is based on one or more of the following grounds:

- (i) public health interest including national epidemiological trends;
- (ii) economic interests in relation to health policies; and
- (iii) the likelihood or otherwise of registration significantly improving access to health care for vulnerable groups within society.

(h) If the Authority is not satisfied as contemplated in paragraph (a), it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may within a period of 30 days after the date of the notification furnish the Chief Executive Officer with his or her comments on the Authority's reasons for not being so satisfied.

(i) 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 of registration.

(4) Every product, medical device or IVD shall be registered under such name as the Authority may approve.

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

(6) Any registration under this section—

- (a) may be made subject to such conditions as may be determined by the Authority; and
- (b) shall in the case of medicines, be valid for a period of five years.

(7) No condition shall be imposed under subsection (6)—

- (a) whereby the sale of the medicine in question by any person other than a pharmacist is prohibited; or
- (b) until after the applicant has in writing been notified by the Chief Executive Officer that the imposition of such condition is contemplated and invited to submit written representations to the Authority in regard to the matter.

(8) If no such representations are lodged by the applicant concerned within a period of 30 days after the receipt by him or her of any notification referred to in subsection (7), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall register the product, medical device or IVD concerned subject to the said condition.

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

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

(11) The Authority shall by way of rules determine—
(a) the forms which shall be used for any application for the registration of any product, medical device or IVD and the particulars which shall be furnished with any such application, or
(b) the time frames for the consideration of applications.”.

Substitution of section 15A of Act 101 of 1965

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

“Amendment of entries in register

15A. (1) The entry made in the register in respect of any product, medical device or IVD may on application by the holder of a certificate of registration issued in respect of such product, medical device or IVD be amended by the Chief Executive Officer.

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

(3) The Chief Executive Officer may, if necessary, cancel the existing registration in respect of such product, medical device or IVD and issue a new certificate of registration.”.

Substitution of section 15B of Act 101 of 1965

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

“Transfer of certificate of registration

15B. (1) A certificate of registration may with the approval of the Chief Executive Officer be transferred by the holder thereof to any other person.

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

(3) If the Chief Executive Officer grants any application submitted to him or her it in terms of subsection (2), the Chief Executive Officer shall make the necessary entries in the register relating to the person to whom the certificate of registration is transferred, cancel the existing certificate of registration and issue a new one in the prescribed form to such person.”.

Amendment of section 15C of Act 101 of 1965

10. 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 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;”.

Substitution of section 16 of Act 101 of 1965, as amended by section 14 of Act 65 of 1974 and section 4 of Act 20 of 1981

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

“Cancellation of registration

16. (1) If the Authority—

(a) is of the opinion that a holder of a certificate of registration has failed to comply with any condition subject to which any product, medical device or IVD was registered; or

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

the Authority shall cause notice in writing to be given accordingly by the Chief Executive Officer to the holder of the certificate of registration issued in respect of that product, medical device or IVD.

(2) Any such notice shall specify the grounds on which the Authority’s opinion is based, and shall indicate that the person to whom it is directed may within one month after receipt thereof submit to the Chief Executive Officer any comments he or she may wish to put forward in connection with the matter.

(3) If no such comments are so submitted, or if after consideration of any comments so submitted the Authority is of the opinion that the registration of the product, medical device or IVD in question should be cancelled, the Authority may cancel the registration thereof.

(4) If the person who is the holder of the certificate of registration issued in respect of any product, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that product, medical device or IVD before or on the prescribed date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that product, medical device or IVD.”.

Substitution of section 17 of Act 101 of 1965, as substituted by section 5 of Act 20 of 1981

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

“Notification of registration or cancellation thereof

17. The Chief Executive Officer shall give notice in the *Gazette* of the registration or cancellation of registration of any product, medical device or IVD in terms of this Act, and shall in such notice specify—

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

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

Substitution of section 18 of Act 101 of 1965, as substituted by section 7 of Act 17 of 1979 and amended by section 11 of Act 90 of 1997

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

“Labels and advertisements

18. (1) No person shall sell any [medicine or Scheduled substance] product unless the immediate container or the package in which that [medicine or Scheduled substance] product is sold bears a label stating the prescribed particulars. 5

(2) No person shall advertise any [medicine or Scheduled substance] product, medical device or IVD for sale unless such advertisement complies with the prescribed requirements. 10

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

(4) The [council] Authority may authorize a deviation from the prescribed format and contents of any label. 15

(5) The Minister may prescribe additional requirements for the labelling of [medicines] products, medical devices or IVD's.”.

Substitution of section 18A of Act 101 of 1965

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

“Bonusing 20

18A. (1) No person shall supply any product, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1).”

Substitution of section 18B of Act 101 of 1965 25

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

“Sampling of products

18B. (1) No person shall sample any product, medical devices or IVD.

(2) Use of products, medical devices or IVD's for exhibition purposes shall be as prescribed. 30

(3) For the purposes of this section ‘sample’ means the free supply of products, medical devices or IVD's by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act No. 56 of 1974), or any professional or person authorized to use the device.”. 35

Substitution of section 18C of Act 101 of 1965

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

“Marketing of products, medical devices or IVD's

18C. The Minister shall, after consultation with the relevant industries and other stakeholders, make regulations relating to the marketing of products, medical devices or IVD's and such regulations may also provide for Codes of Practice for relevant industries.”. 40

Substitution of section 19 of Act 101 of 1965, as amended by section 17 of Act 65 of 1974

17. The following section is hereby substituted for section 19 of the principal Act:

“Prohibition on sale of [medicine] products, medical devices or IVD’s which do not comply with prescribed requirements and furnishing of information regarding products to the [council] Authority 5

19. (1) No person shall sell any [medicine] product, medical device or IVD unless it complies with the prescribed requirements.

(2) The [council] Authority may by notice in writing require any person who manufactures or sells [medicines] products, medical devices or IVD’s 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 or her possession or which such person is in a position to obtain regarding such [medicine or] product, medical device or IVD. 10 15

(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.”.

Substitution of section 20 of Act 101 of 1965, as amended by section 18 of Act 65 of 1974 20

18. The following section is hereby substituted for section 20 of the principal Act:

“Publication or distribution of false advertisements concerning [medicines] products, medical devices or IVD’s

20. (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, medical device or IVD; or 25
- (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, medical device or IVD should be used for a purpose or under circumstances or manner other than that stated by the [council] Authority in terms of sub-paragraph (iii) of paragraph (a) of that section. 30 35

(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, medical device or IVD to which the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading, **[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].”.** 40 45

Substitution of section 21 of Act 101 of 1965, as amended section 6 of Act 20 of 1981

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

“Authority may authorize sale of unregistered products, medical devices or IVD’s for certain purposes

21. (1) The Authority may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular product, medical device or IVD which is not registered. 5

(2) Any product, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine. 10

(3) The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of sub-section (2).”

Substitution of section 22 of Act 101 of 1965, as amended by section 6 of Act 20 of 1981 15

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

“[Director-General] Authority to cause certain information to be furnished

22. (1) [The Director-General shall after consultation with the council] The Chief Executive Officer shall cause, in such manner as [the Director-General] he or she considers most suitable— 20

(a) as soon as practicable after any [medicine] product, medical device or IVD, other than a veterinary medicine, has been registered, medical practitioners, dentists, pharmacists and the person who applied for the registration of such [medicine] product, medical device or IVD to be informed— 25

(i) of the name and number under which such [medicine] product, medical device or IVD is registered and the conditions, if any, subject to which such [medicine] product, medical device or IVD is registered; 30

(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, medical device or IVD should be used; and 35

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

(b) as soon as practicable after the registration of any [medicine] product, medical device or IVD, 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 certificate of registration issued in respect of such [medicine] product, medical device or IVD to be informed of the cancellation of such registration. 45

(2) The provisions of subsection (1) shall apply *mutatis mutandis* in respect of any veterinary medicine, and for the purposes of such application the reference in that subsection to medical practitioners and dentist shall be deemed to be a reference to veterinarians.

Amendment of section 22A of Act 101 of 1965, as substituted by section 13 of Act 90 of 1997 and amended by section 5 of Act 59 of 2002

21. Section 22A of the principal Act is hereby amended—

- (a) by the substitution for subsection (2) of the following subsection: 5
 “(2) The Minister may, on the recommendation of the **[council]** Authority, prescribe the Scheduled substances referred to in this section.”;
- (b) by the substitution in subsection (4) for paragraph (b) of the following paragraph: 10
 “(b) to any person apparently under the age of **[14]** 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist’s assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C(1)(a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of **[14]** 12 years”; 15
- (c) by the substitution in subsection (6) for paragraph (e) of the following paragraph: 20
 “(e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of **[14]** 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist’s assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C(1)(a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of **[14]** 12 years”; 25
- (d) by the substitution in subsection (13) for paragraph (a) of the following paragraph: 30
 “(a) to the applicant’s furnishing the **[registrar]** Chief Executive Officer annually with the prescribed information;”; and
- (e) by the substitution for subsection (15) of the following subsection: 35
 “(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 No. 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.”. 40

Substitution of section 22B of Act 101 of 1965

22. The following section is hereby substituted for section 22B of the principal Act: 45

“Publication of information relating to [medicine, Scheduled substance] products, medical devices or IVD’s

22B. (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 or Scheduled substance,]** product, medical device or IVD. 50

(2) The Director-General may publish the information referred to in section (1) or release it to the public in a manner which he or she thinks fit.”. 55

Amendment of section 22C of Act 101 of 1965

23. Section 22C of the principal Act is hereby amended—

- (a) by the substitution for subsection (1) of the following subsection:
- “(1) Subject to the provisions of this section—
- (a) The Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, **[practitioner]** nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions; 5
- (b) The **[council]** Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a **[medicine]** product, medical device or IVD a licence to manufacture, act as a wholesaler of or distribute, as the case may be, such **[medicine]** product, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the **[council]** Authority may determine.”; 10 15
- (b) by the 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 determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa, **[the Allied Health Professions Council of South Africa]** and the South African Nursing Council.”; 20 25
- (c) by the 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.”; 30
- (d) by the substitution in subsection (4) for the words preceding paragraph (a) of the following words:
- “When the Director-General or the **[council]** Authority, as the case may be, grants or refuses an application for a licence-”; and 35
- (e) by the substitution for subsection (6) of the following subsection:
- “(6) No medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection (1)(b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any **[medicine]** product, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.”. 40

Substitution of section 22D of Act 101 of 1965

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

“Period of validity and renewal of licence

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.”. 45

Amendment of section 22E of Act 101 of 1965

25. Section 22E of the principal Act is hereby amended—

- (a) by the substitution in subsection (1) for paragraph (a) 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 55

- knowledge of such holder is untrue or misleading in any material respect;”;
- (b) by the substitution in subsection (1) for the words following paragraph (d) 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) by the substitution for subsection (2) of the following subsection:
- “(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)—
- (a) suspend the licence in question for such period **[as he or she or the council]** the Director-General or the Authority may determine; or
- (b) revoke the license in question.”.

Amendment of section 22F of Act 101 of 1965, as amended by section 7 of Act 59 of 2002

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

27. Section 22H of the principal Act is hereby amended by the substitution for subsections (1) and (2) of the following subsections, respectively:
- “(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.
- (c) Notwithstanding paragraphs (a) and (b), a wholesaler may purchase from or sell to, other wholesalers Schedule 0 substances.
- (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]** product was initially obtained.”.

Substitution of section 23 of Act 101 of 1965, as amended by section 22 of Act 65 of 1974

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

“Disposal of undesirable [medicines] products, medical devices or IVD’s

23. (1) If the **[council]** Authority is of the opinion that it is not in the public interest that any **[medicine] product, medical device or IVD** shall be made available to the public, it may—
- (a) by notice in writing transmitted by registered post to any person direct that person; or
- (b) by notice in the *Gazette* direct any person, to return any quantity of such **[medicine] product, medical device or IVD** which he or she has in his or her possession to the manufacturer thereof or (in the case of any imported **[medicine] product, medical device or IVD**) to the importer concerned or to deliver or send it to any other person designated by the **[council]** Authority.
- (2) The **[council]** Authority may by notice in writing direct any **medical device or IVD establishment, manufacturer or importer of any such [medicine] product, medical device or IVD** who has in his or her possession any quantity thereof (including any quantity returned, delivered or sent to him or her in pursuance of a direction under sub-section (1)), or

any other person to whom any quantity of such **[medicine]** product, medical device or IVD has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the **[council]** Authority may determine.

(3) No person shall sell any **[medicine]** product, medical device or IVD which is the subject of a notice under subsection (1) which has not been set aside on appeal.”. 5

Substitution of section 24 of Act 101 of 1965, as substituted by section 15 of Act 90 of 1997 and amended by section 9 of Act 59 of 2002

29. The following section is hereby substituted for section 24 of the principal Act: 10

“Appeal against decision of [council or] the Director-General

24. (1) Any person aggrieved by the decision of the Director-General may within the prescribed period and in the prescribed manner make written representations with regard to such decision to the Minister. 15

(2) The Minister shall, after considering representations made in terms of subsection (6), confirm, set aside or vary the decision of the Director-General.”. 15

Insertion of section 24A to Act 101 of 1965

30. The principal Act is hereby amended by the insertion after section 24 of the following section: 20

“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. 25

(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. 30

(4) The appeal committee contemplated in subsection (3) shall— 35

(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. 40

(5) A party aggrieved by the decision of the appeal committee may approach the High Court for a judicial review.”. 40

Substitution of section 25 of Act 101 of 1965, as substituted by section 10 of Act 59 of 2002

31. The following section is hereby substituted for section 25 of the principal Act: 45

“Privileges of [council] 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.”. 50

Substitution of section 26 of Act 101 of 1965, as substituted by section 24 of Act 65 of 1974, section 1 of Act 19 of 1976 and section 10 of Act 17 of 1979

32. The following section is hereby substituted for section 26 of the principal Act:

“Inspectors

26. (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. 5

(2) Every inspector shall be furnished with a certificate signed by the ~~[Director-General]~~ Chief Executive Officer and stating that he or she has been authorized as an inspector under this Act. 10

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

Substitution of section 27 of Act 101 of 1965, as substituted by section 11 of Act 17 of 1979 15

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

“Analysts, pharmacologists, engineers and pathologists

27. ~~[The Director-General]~~ Chief Executive Officer may grant such authority to such analysts, pharmacologists, engineers and pathologists or any other appropriately qualified person as he may consider necessary for the proper enforcement of this Act.”. 20

Amendment of section 28 of Act 101 of 1965

34. Section 28 of the principal Act is hereby amended—

(a) by the substitution in subsection (1)(a) for subparagraph (i) of the following subparagraph: 25

“(i) any place or premises from which a person, authorized under this Act to compound and dispense medicines or Scheduled substances, handles products, medical devices or IVD’s or from which the holder of a licence as contemplated in section 22C(1)(b) conducts a business; or”; 30

(b) by the substitution in subsection (1) for paragraphs (b) and (c) of the following paragraphs, respectively:

“(b) inspect any product, medical device or IVD, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1)(a); 35

(c) seize any such product medical device or IVD, any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act;”; 40

(c) by the addition in subsection (1) of the following paragraph:

“(d) take so many samples of any such product, medical device or IVD as he or she may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.”; and 45

(d) by the substitution for subsection (2) of the following subsection: 45

“(2) (a) Any sample taken in terms of paragraph (d) of subsection (1) shall—

(i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such ~~[medicine product or Scheduled substance,]~~ product, medical device or IVD or if there is no such person or if he or she is absent for any reason, in the presence of any other witness[, **shall**]; 50

(ii) forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit ~~[and shall]~~; and

- (iii) then be transmitted to an analyst, pharmacologist, technician or pathologist together with a certificate in the prescribed [forms] form signed by such inspector[and a].
- (b) A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such [medicine or Scheduled substance] product, medical device or IVD or his or her agent.”; and 5
- (e) by the substitution for subsection (4) of the following subsection:
 “(4) The owner of the [medicine or Scheduled substance] product, medical device or IVD from which the sample was taken may claim from the [Director-General] the Authority an amount equal to the market value thereof.”. 10

Amendment of section 29 of Act 101 of 1065, as amended by section 27 of Act 65 of 1974, section 12 of Act 94 of 1991 and section 17 of Act 90 of 1997

35. Section 29 of the principal Act is hereby amended—
- (a) by the substitution for paragraph (e) of the following paragraph: 15
 “(e) contravenes or fails to comply with any condition imposed under section [15(7)] 15(6)”;
- (b) by the substitution in paragraph (h) for the words preceding subparagraph (i) of the following words:
 “makes any false or misleading statement in connection with any [medicine or Scheduled substance] product, medical device or IVD—”; and 20
- (c) by the substitution for paragraph (i) of the following paragraph:
 “(i) sells any [medicine] product upon the container of which a false or misleading statement in connection with the contents is written; 25
 or”.

Amendment of section 30 of Act 101 of 1965, as amended by section 28 of Act 65 of 1974, section 13 of Act 94 of 1991 and section 18 of Act 90 of 1997

36. Section 30 of the principal Act is hereby amended—
- (a) by the substitution for subsection (2) of the following subsection: 30
 “(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any [medicine or Scheduled substance] product, medical device or IVD in respect of which the offence has been committed to be forfeited to the State.”; and
- (b) by the substitution for subsection (3) of the following subsection: 35
 “(3) Any [medicine or Scheduled substance] product, medical device or IVD 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 by section 29 of Act 65 of 1974, section 13 of Act 17 of 1979 and section 19 of Act 90 of 1997 40

37. Section 31 of the principal Act is hereby amended—
- (a) by the substitution in subsection (1) for paragraph (a) of the following paragraph:
 “(a) any quantity of a [medicine or Scheduled substance] product, 45
 medical device or IVD in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;”; and
- (b) by the substitution for paragraph (d) of the following paragraph: 50
 “(d) any statement or entry contained in any book, record or document kept by any owner of a [medicine product or Scheduled substance,] product, medical device or IVD or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him as an admission of the facts set forth in that statement or entry, unless [it is proved] 55

evidence to the contrary which raises a reasonable doubt shows that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his or her work as manager, or in the course of his or her agency or employment.”.

5

Amendment of section 33A of Act 101 of 1965

38. The following section is hereby substituted for section 33A of the principal Act:

“Funds of [council] Authority

- 33A.** (1) The funds of the [council] Authority shall consist of—
- (a) State funds received through the Department of Health; 10
 - (b) fees raised and interest on overdue fees;
 - (c) money accruing to the [council] Authority from any other source.
- (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. 15
- (b) Details of any such donation or bequest shall be specified in the relevant annual report of the [council] Authority.
- (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. 20
- (4) The [council] Authority shall open an account with a bank as defined in section 1(1) of the Banks Act, 1990 (Act No. 94 of 1990), and shall deposit in that account all money referred to in subsections (1) and (2).
- (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. 25
- (6) The records and annual financial statements referred to in subsection (5) shall be audited by the Auditor-General.
- (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. 30
- (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 substituted by section 15 of Act 94 of 1991 and section 22 of Act 90 of 1997

39. Section 34A of the principal Act is hereby amended by the addition of the following subsection: 40

“(3) The Chief Executive Officer may, in writing, authorise any staff member of the Authority to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function conferred or imposed on the Chief Executive Officer in terms of this Act.”.

Amendment of section 35 of Act 101 of 1965, as substituted by section 23 of Act 90 of 1997 and amended by section 12 of Act 59 of 2002 45

40. Section 35 of the principal Act is hereby amended—

- (a) by the substitution in subsection (1) for the words preceding paragraph (i) of the following words:
 - “The Minister may, in consultation with the [council] Authority, make regulations—”; 50
- (b) by the deletion in subsection (1) of paragraph (ii);
- (c) by the substitution in subsection (1) for paragraph (xii) of the following paragraph:

- (xii) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in section **[15(11)] 15(10)**.”;
- (d) by the substitution in subsection (1) for paragraph (xiii) of the following paragraph: 5
 “(xiii) relating to the responsibilities of both medical device and IVD establishments and users of medical devices and IVDs, in relation to the use, training, maintenance, calibration, post-marketing surveillance, sterilization, disinfection, recall, decomposition, decommissioning or decontamination of medical devices and IVDs.”; 10
- (e) by the substitution in subsection (1) for (xxxi) of the following paragraph: 15
 “(xxxi) prescribing the fee to be paid to the **[registrar] Authority** in respect of an application for the registration, and in respect of the registration of a **[medicine or Scheduled substance] product, medical device or IVD**, the fee to be paid annually to the **[registrar] Authority** in respect of the retention of the certification or the registration of a **[medicine or Scheduled substance] product, medical device or IVD** and the date on which such annual fee shall be paid.”; 20
- (f) by the substitution in subsection (1) for paragraph (xxxiii) of the following paragraph: 25
 “(xxxiii) relating to appeals against decisions of the Director-General or the **[council] Authority**.”;
- (g) by the substitution in subsection (1) for paragraph (xxxvii) of the following paragraph: 30
 “(xxxvii) relating to the scientific, pharmaceutical, clinical, technical and other skills required by members of staff of the Authority to evaluate the quality, efficacy and safety of products, medical devices and IVD’s.”;
- (h) by the insertion after paragraph (xxxix) of the following paragraphs, the existing paragraphs (xl) and (xli) becoming paragraphs (xliii) and (xliv), respectively: 35
 “(xl) relating to products, medical devices or IVD’s in respect of matters contemplated in paragraphs (i) up to and including paragraph (xi) and paragraphs (xxiii), (xxiv), (xxxii), (xxxiv) and (xxxviii);
 (xli) relating to the control of products, medical devices and IVD in general;
 (xlii) relating to the licensing for possessing or using certain products, medical devices or IVD’S.”;
- (i) by the substitution in subsection (2) for paragraph (b) of the following paragraph: 40
 “(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.”;
- (j) by the substitution for subsection (5) of the following subsection: 45
 “(5) Regulations made under subsection (1)(xi) may prescribe that any **[medicine] product, medical device or IVD** or any component thereof shall comply with the requirements set out in any publication which in the opinion of the **[council] Authority** is generally recognised as authoritative.”; 50
- (k) by the substitution for subsection (6) of the following subsection: 55
 “(6) Regulations may be made under this section in respect of particular products, medical devices or IVD’s or classes or categories in respect thereof other than particular classes or categories of products, medical devices or IVD’s, and different regulations may be so made in respect of different products, medical devices or IVD’s or different classes or categories of products, medical devices or IVD’s.”; and
- (l) by the substitution for subsection (8) of the following subsection: 60
 “(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.”.

Substitution of section 36 of Act 101 of 1965, as amended by section 32 of Act 65 of 1974

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

“Exclusion of any product, medical device or IVD from operation of Act

36. (1) The Minister may, on the recommendation of the Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any product, medical device or IVD from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

(2) Notwithstanding subsection (1), the exclusion of any product from the operation of section 22G shall be on the recommendation of the Pricing Committee.

Substitution of section 37A of Act 101 of 1965, as substituted by section 25 of Act 90 of 1997

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

“Amendment of Schedules

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 by the deletion therefrom of any medicine or other substance, or in any other manner.”.

Transitional measures

43. (1) Medicines and medical devices that are registered at the date of commencement of this Act shall be deemed to be certified and registered in terms of the principal 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 Act is brought into operation.

(3) Anything done by the Council which could have been done by the Authority in terms of this Act shall be deemed to have been done by the Authority.

Short title and commencement

44. 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*.

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

1. PURPOSE OF 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 BILL

The Medicines and Related Substances Amendment Bill, 2008 (“the Bill”), seeks to establish a regulatory authority for medicines and medical devices as well as other products like foodstuffs and cosmetics which contain Scheduled substances. 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 (Act No. 1 of 1999) as amended 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 Medicines Control Council will cease to exist on the commencement of the Amendment Act. The Authority will comprise full time Chief Executive Officer and staff and will be responsible for the registration of products, medical devices and IVD’s.

Any person may object to the registration of products, medical devices or IVD on public interest grounds.

4. DISCUSSION CLAUSES

4.1 **Clause 1** provides for amendments to the definitions.

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 the Public Finance Management Act, 1999 (Act No. 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 the registration of products, medical devices and IVD’s by the Authority, that before the Authority can register a product, medical device or IVD, it must first declare its intention to register such a product, medical device or IVD and afford interested persons an opportunity to object to such intended registration. Objections can only be lodged on grounds of public interest.

Once an objection is received a three member panel appointed by the Minister shall hear the objector, the applicant or any other interested person and make recommendations to the Authority and the latter still makes a decision on whether to register the product or not.”

4.6 **Clause 30** provides for appeals against decisions of the Authority, in terms whereof a person aggrieved by a 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, the other two by the CEO and chaired by a neutral person with knowledge of the law, will hear the appeal.

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, for Agriculture and Land Affairs, and of Environmental Affairs and Tourism, after consultation with the Minister of Health, identified senior officials in their respective Departments 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 in discussions with their principals so that the consensus within the Task Team would have the support and approval of their relevant Departments. The Social Sector Cluster was also consulted.

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 R137,8 m. As this will be 50% cost recovery, the budget could be R275,6 m.

7. PARLIAMENTARY PROCEDURE

7.1 The State Law Advisers and the Department of Health are of the opinion that this Bill must be dealt with in accordance with the procedure established by section 75 of the Constitution since it contains no provision to which the procedure set out in section 74 or 76 of the Constitution applies.

7.2 The State Law Advisers are of the opinion that it is not necessary to refer this Bill to the National House of Traditional Leaders in terms of section 18(1)(a) of the Traditional Leadership and Governance Framework Act, 2003 (Act No. 41 of 2003), since it does not contain provisions pertaining to customary law or customs of traditional communities.

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