

REPUBLIC OF SOUTH AFRICA

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

*(As introduced in the National Assembly (proposed section 75);
explanatory summary of Bill published in Government Gazette No. 31114 of 2 June 2008)
(The English text is the official text of the Bill)*

(MINISTER OF HEALTH)

[B 44—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 certification and registration of products which include medicines, medical devices, certain foodstuffs and cosmetics; for the control of Scheduled substances; 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 1997 and section 1 of Act 17 of 1979 5

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]** product 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 publication; 15

(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 or Scheduled substance, and ‘advertise’ has a corresponding meaning;” 20

(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;”;

(c) by the insertion after the definition of “**certificate of registration**” of the following definitions: 25

“**‘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, and ‘certify’ must be interpreted accordingly;
- ‘**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 a medicinal claim is made;”;
- (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), in respect of which a medicinal claim is made;”;
- (f) by the insertion after the definition of “**prescribed**” of the following definition:
 “**‘product’** means medicine or medical device, or any cosmetic or foodstuff in respect of which a medical claim is made;”;
- (g) by the deletion of the definition of “**registrar**”;
- (h) by the deletion of subsection (3); and
- (i) by the 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 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

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.”.

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

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 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).

(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) (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.

(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.

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 in which he or she shall record—

- (a) certification of products by the Authority;
- (b) the registration of a product as approved by the Minister; and
- (c) such particulars in regard to the products and the holder of certification or certificate of registration in respect of such products 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 which are subject to certification or registration and are not certified or registered

14. (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.

(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, a medical device or a 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.

(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 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).

(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 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.”.

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:

“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 product and by the prescribed certification or 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 the application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the product 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) is effective,

it shall issue the applicant with a certificate to that effect.

(b) If the Authority is not satisfied as contemplated in paragraph (a) it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may, within a period of one month after the date of such notification, furnish the

Chief Executive Officer with his or her comments on the decision of the Authority.

(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, it shall reject the application.

(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.

(c) If the Minister is not satisfied as contemplated in paragraph (b), he or she shall not approve of the registration and shall inform the Authority accordingly and the Authority shall inform the applicant.

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

- (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.

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

(f) 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) 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.

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

(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 that he or she may 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 section 14(3) 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.”.

Substitution of section 15A of Act 101 of 1965

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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 may on application by the holder of a certification or certificate of registration issued in respect of such product be amended by the Chief Executive Officer and, if such amendment relates to the registration of the product, with the approval of the Minister.

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(2) An 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.

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(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.”.

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Substitution of section 15B of Act 101 of 1965

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

“Transfer of certification or certificate of registration

15B. (1) A certification or certificate of registration may with the approval of the Authority be transferred by the holder thereof to any other person.

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(2) An 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.

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(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.”.

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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: 45

“(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 50

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: 5

“Cancellation of certification and registration

16. (1) If the Authority—

- (a) is of the opinion that a holder of a certification or certificate of registration has failed to comply with any condition subject to which any product was certified or registered; 10
- (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 made 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. 15

(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. 20

(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— 25

- (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.”. 30

Substitution of section 17 of Act 101 of 1965, as substituted by section 5 of Act 20 of 1981 35

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

“Notification of certification or registration or cancellation thereof

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— 40

- (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; 45
- (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.”. 50

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]** 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. 5

(2) No person shall advertise any **[medicine]** product or Scheduled substance 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 authorise 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.”.

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

Substitution of section 18B of Act 101 of 1965

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

“Sampling of products 25

18B. (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 (Act No. 56 of 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. 30

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

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.”. 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 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 unless it complies with the prescribed requirements.

(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 or her possession or which such person is in a position to obtain regarding such medicine or product. 10

(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.”. 15

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

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

“Publication or distribution of false advertisements concerning [medicines] products

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; 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 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) of paragraph (a) of that section. 30

(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 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].” 35 40

Substitution of section 21 of Act 101 of 1965, as amended section 6 of Act 20 of 1981 45

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

“[Council] Authority may authorise sale of uncertified or unregistered [medicine] products for certain purposes

21. (1) The Authority may in consultation with the Minister in writing authorise 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. 50

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

(3) The Authority 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 of 1965, as amended by section 6 of Act 20 of 1981

20. Section 22 of the principal Act is hereby amended by the 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 the **[Director-General]** Chief Executive Officer 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 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:

“(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 (13) for paragraph (a) of the following paragraph:

“(a) to the applicant’s furnishing the **[registrar]** Chief Executive Officer annually with the prescribed information;”;

(c) by the 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 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.”.

Substitution of section 22B of Act 101 of 1965

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

“Publication of information relating to [medicine,] products or Scheduled substance [or medical device]

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,] product or Scheduled substance [or medical device].

(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.”.

Amendment of section 22C of Act 101 of 1965

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

(a) by the substitution in subsection (1) for paragraph (b) 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) 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 prescribed under the Pharmacy Act, 1974 (Act No. 53 of 1974), by the [Interim Pharmacy Council of South Africa] South African Pharmacy Council.”;

(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.”;

(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

(e) by the substitution for subsection (6) of the following subsection:

“(6) No 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 or medical device] product unless he or she is the holder of a licence contemplated in the said subsection.”.

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.”.

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 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 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.
- (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**

- 23.** (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—
- (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** which he or she has in his or her 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**.

(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 or her 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. 5

(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.”.

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 10

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

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

24. (1) Any person aggrieved by a decision of the **[council]** Director-General 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. 15

(2) An appeal committee contemplated in subsection (1) shall consist of no fewer than three persons: Provided that— 20

- (a) the chairperson shall be appointed on account of his or her knowledge of the law;
- (b) the skills of the other two members shall be relevant to the case concerned;
- (c) no member shall have a direct or indirect interest in the affairs of the appellant or respondent. 25

(3) The appeal committee may after hearing the appeal—

- (a) confirm, set aside or vary the relevant decision of the **[council]** Director-General; and
- (b) direct the **[council]** Director-General to execute the decision of the appeal committee. 30

(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 **[council]** Director-General.

(5) To the members of the appeal committee who are not in the full-time employment of the State shall be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine. 35

(6) 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. 40

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

Insertion of section 24A to Act 101 of 1965 45

30. 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. 50

(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) 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.

(b) In setting aside the decision of the appeal committee, the High Court may not substitute its decision for that of the appeal committee but must refer the matter back to the appeal committee for a final decision.”.

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:

“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 personnel are not be liable in respect of anything done in good faith under this Act.”.

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.

(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.

(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

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

“Analysts, pharmacologists and pathologists

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

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:
 - “(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 a business; or”;
- (b) by the substitution in subsection (1) for paragraphs (b) and (c) of the following paragraphs, respectively:
 - “(b) inspect any product or Scheduled substance, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1)(a);
 - (c) seize any such 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) by the addition in subsection (1) of the following paragraph:
 - “(d) take so many samples of any such product or Scheduled substance as he or she may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.”; and
- (e) by the substitution for subsection (2) of the following subsection:
 - “(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, 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~~;
 - (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 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] product** or Scheduled substance or his or her agent.”; and
- (f) by the 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 1965, 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 in paragraph (h) for the words preceding subparagraph (i) of the following words:
 - “makes any false or misleading statement in connection with any **[medicine] product** or Scheduled substance—”; and
- (b) by the 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 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:

“(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.”; and

(b) by the 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 by section 29 of Act 65 of 1974, section 13 of Act 17 of 1979 and section 19 of Act 90 of 1997

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] 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.”; and

(b) by the 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]** 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.”.

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;
- (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.

(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.

(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.

(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.

(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:

"(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

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

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

"The Minister may, in consultation with the **[council]** Authority, make regulations—";

(b) by the deletion in subsection (1) of subparagraph (xiii);

(c) by the substitution in subsection (1) 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 of 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) by the substitution in subsection (1) for subparagraph (xxxiii) of the following subparagraph:

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

(e) by the substitution in subsection (1) for subparagraph (xxxvii) of the following subparagraph:

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

(f) by the insertion after subparagraph (xxxix) of the following subparagraphs, the existing subparagraphs (xI) and (xIi) becoming subparagraphs (xIiv) and (xIv), respectively:

"(xI) relating to products in respect of matters contemplated in subparagraphs (ii) up to and including subparagraph (xi) and subparagraphs (xxiii), (xxiv), (xxxii), (xxxiv) and (xxxviii);
 (xIi) relating to certification of products in respect of matters contemplated in subparagraphs (i), (ii), (iv), (v), (vi), (xii), (xxvii) and (xxxii);
 (xIii) relating to the control of products;
 (xIiii) relating to the licensing for possessing or using certain products;";

- (g) by the substitution in subsection (2) for paragraph (b) 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.”; 5
- (h) by the 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 recognised as authoritative.”; 10
- (i) by the 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.”; and 15
- (j) by the 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.”. 20 25

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 drug from operation of 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 or she 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.”. 30

Substitution of section 37A of Act 101 of 1965, as substituted by section 25 of Act 90 of 1997 35

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.”. 40

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. 45
- (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. 50

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 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.

After certification by the Authority, the application is then forwarded to the Minister for consideration whether the registration of the particular medicine or 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 the 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.
- 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 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 be registered. The registration of veterinary medicines is done in consultation with the Minister for Agriculture and Land Affairs.

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

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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