
GOVERNMENT NOTICE

DEPARTMENT OF HEALTH


No. 611

2 June 2008

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

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

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


DR ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

GENERAL EXPLANATORY NOTE:

- [] words in bold type in square brackets indicate omissions from the existing enactments.
- words underlined with a solid line indicate insertions in existing enactments.

DRAFT BILL

To amend the Medicines and Related Substances Act, 1965, so as to provide for the establishment of the South African Health Products Regulatory Authority; for the certification and registration of products which include medicines, medical devices and certain foodstuffs and cosmetics, for the control of Scheduled substances; and matters incidental thereto.

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

Amendment of section 1 of Act 101 of 1965 as amended by section 1 of Act 65 of 1974, section 1 of Act 17 of 1979, section 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.

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

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

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

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

“which is intended to promote the sale of that **[medicine] product** or Scheduled substance, and ‘advertise’ has a corresponding meaning.”;

(c) insertion after the definition of ‘approved name’ of the following definition:

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

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

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

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

(e) deletion of the definition of “council”;

(f) insertion after the definition of “export” of the following definition:

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

(f) insertion of the following definition after the definition of “prescribed”:

““product” includes a medicine, cosmetic, medical device or a foodstuff.”

(g) deletion of the definition of Registrar.

(h) the deletion of subsection (3).

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

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

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

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

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

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

(2) The Authority is-

- (a) a juristic person;
- (b) subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999); and
- (c) accountable to and reports to the Minister.

(3) The Authority may exercise the powers and shall perform the functions conferred upon or assigned to it by this Act.”

Substitution of section 3 of 101 of 1965 as amended

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

“Chief Executive Officer and Other Staff of Authority

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

(2) The Chief Executive Officer-

- (a) is appointed for a term of five years and may be reappointed for one additional term of five years;
- (b) is appointed subject to the conclusion of a performance agreement with the Minister;
- (c) is accountable to and reports to the Minister;
- (d) is entitled to the benefits as may be determined by the Minister in consultation with the Minister for Public Service and Administration;

- (e) is responsible for the general administration of the Authority and for the carrying out of any functions assigned to the Authority by this Act and the Minister;
- (f) must manage and direct the activities of the Authority;
- (g) must appoint and supervise the Authority's staff; and
- (h) must compile business and financial plans and reports in terms of Act 1 of 1999.

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

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

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

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

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

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

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

Amendment of section 13 of Act 101 of 1965 as amended

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

“ Registers

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

Amendment of section 14 of Act 101 of 1965 as amended

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

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

“Prohibition on the sale of products which are subject to certification or registration and are not certified or registered”:

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

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

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

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

(b) Any such **[resolution] notice** may also relate only to **[medicines,] products** which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to **[medicines] products** which were not then so available.

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

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

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

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

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

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

“if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for certification and registration has been rejected, and is not or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been certified and registered under this Act.”

Amendment of section 15 of Act 101 of 1965 as amended

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

“Certification and Registration of products

15. (1) Every application for the certification and registration of a product shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant products and by the prescribed certification or registration fee.
- (2) As soon as possible after receipt by him or her of any such application together with any particulars and samples which accompanied the application, he or she shall inform the applicant in writing that the application is being considered."
- (3) (a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the product in question is suitable for the purpose for which it is intended and complies with the prescribed requirements and that the product is safe, of good quality and efficacious, it shall issue the applicant with a certificate to that effect.
- (b) If the Authority is not so satisfied it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may within a period of one month after the date of the notification furnish the Chief Executive Officer with his or her comments on the Authority's reasons for not being so satisfied.
- (c) If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the Authority is still not satisfied as aforesaid, it shall not issue the certificate contemplated in paragraph (a).
- (4) (a) After the Authority has issued a certificate in respect of any product, the Chief Executive Officer shall in writing, notify the applicant of that fact and submit the application to the Minister for a decision on the registration of the product.
- (b) If the Minister is satisfied that it is in the public interest to register such a product, the Minister shall approve of the registration of such product and if the Minister is not so satisfied, she or he will not approve of the registration and shall inform the Authority accordingly and the Authority shall inform the applicant.
- (c) In determining whether it is in the public interest to register a product, the Minister shall take the following into account in relation to the State:
- (i) public health interests including national epidemiological trends;
 - (ii) economic interests in relation to health policies;
 - (iii) whether the product is supportive of national health policy and goals in the long term;
 - (iv) whether the product is likely to significantly improve access to health care for vulnerable groups within society;
 - (v) the experience of other countries concerning the marketing, distribution and use of the product; and
 - (vi) generally whether the public would be best served by such registration.
- (d) Veterinary medicines shall be registered by the Minister after consultation with the Minister of Agriculture.
- (e) The Authority shall upon being informed of the Minister's decision to approve the registration, record such registration in the relevant register and issue the applicant with a certification and the certificate of registration.
- (5) Every product shall be certified and registered under such name as the Authority may approve.
- (6) The Chief Executive Officer shall allocate to every product certified or registered under this Act a certification or registration number which shall be recorded in the register opposite the name of such product and which shall be stated in the certification or certificate of registration issued in respect of such product.

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

(8) No condition shall be imposed under subsection (7) whereby the sale of the medicine in question by any person other than a pharmacist is prohibited or until after the applicant has in writing been notified by the Chief Executive Officer or the Minister, as the case may be, that the imposition of such condition is contemplated and invited to submit written representations to the Authority or the Minister, as the case may be, in regard to the matter.

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

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

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

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

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

"Amendment of entries in the register

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

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

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

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

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

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

"Transfer of certification or certificate of registration

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

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

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

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

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

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

“(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of certification or the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the [council] Authority in the prescribed manner, may be imported:”

Amendment of section 16 of Act 101 of 1965 as amended

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

“ Cancellation of certification and registration

“(1) If the Authority-

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

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

(c) in consultation with the Minister, is of the opinion that it is not in the public interest that any product shall be available to the public,

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

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

(3) If no such comments are so submitted, or if after consideration of any comments so submitted the Authority is of the opinion that the certification or the registration of the product in question should be cancelled, the Authority may-

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

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

Amendment of section 17 of Act 101 of 1965 as amended

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

"Notification or cancellation of certification or registration

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

- (a) in the case of a certification or registration of any product, the name under which such product is certified or registered, the active components of such product, the name of the person who applied for the certification or registration of such product, the number allocated to it in terms of section 15 and the conditions (if any) subject to which it is certified or registered;
- (b) in the case of a cancellation of the certification or registration of any product, the name under which such product was certified or registered, the name of the holder of the certification or certificate of registration issued in respect of such product and the number which was allocated to it in terms of section 15."

Amendment of section 18 of Act 101 of 1965 as amended

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

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

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

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

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

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

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

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

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

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

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

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

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

“Bonusing

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

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

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

“Sampling of Products

(1) No person shall sample any product.

(2) For the purposes of this section 'sample' means the free supply of products by a manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, but does not include the free supply of products for the purposes of clinical trials, donations of products to the State, tendering to the State and quality control by inspectors.

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

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

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

“Marketing of products

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

Amendment of section 19 of Act 101 of 1965 as amended

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

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

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

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

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

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

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

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

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

Amendment of section 20 of Act 101 of 1965 as amended

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

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

“Publication or distribution of false advertisements concerning products”

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

“(1) No person shall-

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any **[medicine] product**; or

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

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

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

Amendment of section 21 of Act 101 of 1965 as amended

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

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

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

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

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

Amendment of section 22 of Act 101 as amended

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the [Interim Pharmacy Council of South Africa] South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.”

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

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

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

“Publication of information relating to products or Scheduled substance”

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

“(1) Notwithstanding the provisions of section 34 the [council] Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a [medicine,] product or Scheduled substance [or medical device].”

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

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

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

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

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

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

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

“(3) The Director-General or the [council] Authority, as the case may be, may require an applicant contemplated in subsection (1) to furnish such information, in addition to any information furnished by the applicant in terms of the said subsection, as the Director-General or the [council] Authority may deem necessary.”

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

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

(e) 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.”

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

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

“22D. A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the [council] Authority, as the case may be, may allow and on payment of the prescribed fee.”

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

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

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

“(a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the [council] Authority, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;”

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

“the Director-General or the [council] Authority, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

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

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

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

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

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

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

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

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

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

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

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

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

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

Amendment of section 23 of Act 101 of 1965 as amended

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

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

“Disposal of undesirable products”

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

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

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

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

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

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

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

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

Amendment of section 24 of Act 101 of 1965 as amended

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

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

“Appeal against decision of Director-General or Authority”

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

“(1) Any person aggrieved by a decision of the Director-General **[or the council, as the case may be,]** may, within the prescribed period, in the prescribed manner and upon payment of the prescribed fee, appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned.”

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

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

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

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

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

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

Insertion of section 24A

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

“Appeal Against Decision of Authority

24A. (1) Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within 30 days of becoming aware of such decision of his or her intention to appeal and setting out the full grounds of appeal.

(2) Upon being notified the Chief Executive Officer shall meet with the appellant within 30 days of being so notified in the absence of legal representatives to try and have the matter resolved especially if the appeal involves administrative matters.

(3) Should the Chief Executive Officer and the appellant fail to resolve the matter as contemplated in subsection (2), the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Chief Executive Officer in writing to convene an appeal committee.

(4) The appeal committee contemplated in subsection (3) shall-

- (a) comprise the chairperson who shall have knowledge of the law and four other persons who shall have knowledge of the subject matter of appeal, two of them nominated by the appellant and the other two by the Chief Executive Officer; and
- (b) conduct the appeal hearing and make a decision within 30 days from the day when it first meets to hear the appeal.

(5) A party aggrieved by the decision of the appeal committee may approach the High Court for a judicial review and the High Court may confirm or set aside the decision of the appeal committee.

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

Amendment of section 25 of Act 101 of 1965 as amended

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

“ Privileges of Authority and committees

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

Amendment of section 26 of Act 101 of 1965 as amended

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

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

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

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

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

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

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

Amendment of section 27 of Act 101 of 1965 as amended

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

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

Amendment of section 28 of Act 101 of 1965 as amended

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

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

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

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

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

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

“(c) seize any such [**medicine**] product or Scheduled substance, or any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act.”

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

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

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

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

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

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

Amendment of section 29 of Act 101 of 1965 as amended

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

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

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

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

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

Amendment of section 30 of Act 101 of 1965 as amended

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

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

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

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

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

Amendment of section 31 of Act 101 of 1965 as amended

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

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

“(a) any quantity of a **[medicine] product** or Scheduled substance in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample.”

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

“(d) any statement or entry contained in any book, record or document kept by any owner of a **[medicine] product** or Scheduled substance, or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him as an admission of the facts set forth in that statement or entry, unless it is proved that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his work as manager, or in the course of his agency or employment.”

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

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

(a) substitution for the heading of the following heading

Funds of Authority

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

“(1) The funds of the **[council] Authority** shall consist of:-”

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

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

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

“(2) (a) The [council] Authority may accept money or other goods donated or bequeathed to the [council] Authority provided no condition is attached to such donation or bequest:

(b) Details of any such donation or bequest shall be specified in the relevant annual report of the [council] Authority.”

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

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

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

“(4) The [council] Authority shall open an account with a bank as defined in section 1 (1) of the Banks Act, 1990 (Act 94 of 1990), and shall deposit in that account all money referred to in subsections (1) and (2).”

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

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

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

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

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

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

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

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

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

Amendment of section 35 of Act 101 of 1965 as amended

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

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

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

(b) deletion of subparagraph (xiii)

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

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

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

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

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

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

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

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

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

(xlii) relating to the control of products;

(xliii) relating to the licensing for possessing or using certain products.”

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

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

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

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

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

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

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

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

“(8) Notwithstanding the provisions of subsection (1), the Minister may, if he or she deems it to be in the public interest, after consultation with the [executive committee appointed under section 9,] Authority make regulations relating to any matter referred to in subsection (1) or to amend or repeal any regulation made in terms of that subsection.

Amendment of section 36 of Act 101 of 1965 as amended

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

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

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

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

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

Transitional measures

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

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

Short title and commencement

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

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

1. PURPOSE OF THE BILL

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

2. OBJECTS OF THE BILL

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

3. SUMMARY

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

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

Once this has been established by the Authority, the application is then forwarded to the Minister for consideration whether the registration of the particular medicine 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 of such registration and the Authority shall duly record the registration of the medicine or product

4. DISCUSSION

CLAUSES

- 4.1 Clause 1 provides for amendments to the definitions which include the insertion of the definitions of certification; foodstuff and cosmetic. Certification means that the medicine or product is certified to be safe, of good quality and efficacious. Foodstuffs and cosmetic emphasize the requirement that there must be medicinal claims made about them for them to be regulated.
- 4.2 Clause 2 provides for the establishment of the Authority as a juristic person accountable to and reporting to the Minister and which is also subject to the Public Finance Management Act, 1999.
- 4.3 Clause 3 provides for the Chief Executive Officer (CEO) of the Authority who is appointed by the Minister for a five year term renewable once. The CEO is appointed subject to the conclusion of a performance agreement with the Minister and must compile business and financial plans as well as reports in terms of Act 1 of 1999.
- 4.4 Clause 5 provides that the CEO shall keep registers for all the products regulated in terms of the Act.

- 4.5 Clause 7 provides for certification and registration of products, that the Authority will certify products as being safe, of good quality and efficacious whereas the Minister will approve the registration of such products if it is in the public interest that such products must be registered. The registration of veterinary medicines is done in consultation with the Minister of Agriculture.
- 4.6 Clause 30 provides for appeals against the decision of the Authority, that a person aggrieved by the decision of the authority shall first seek a meeting with the CEO to resolve the matter amicably. If this is not achieved, an appeal committee comprising five persons, two nominated by the appellant and the other two by the CEO and chaired by a neutral person with knowledge of the law will hear the appeal. No provision is made for appeals against the decision of the Minister which means persons not satisfied with such decisions may directly approach the High Court.
- 4.7 The rest of the clauses are consequential amendments replacing the words "council" and "registrar" wherever they appear in the principal Act with the words "Authority" and "CEO" respectively.

5. CONSULTATION

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

6. FINANCIAL IMPLICATIONS

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

7. PARLIAMENTARY PROCEDURE

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