GENERAL NOTICE

NOTICE 216 OF 2012

DEPARTMENT OF HEALTH

PUBLICATION OF MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2012

The Minister of Health intends to introduce table the Medicines and Related Substances Amendment Bill, 2012 in Parliament, this year.

Interested persons are invited to submit any substantiated comments or representations on the proposed draft amendment to the regulations, to the Director – General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Cluster Manager: Legal Services), within three months of the date of publication of this notice.

The Bill is attached and further copies can be obtained from Ms Hyldia Phasha of the Department of Health: Legal Services at

18th Floor Civitas Building
Corner Andries and Struben Streets
Pretoria
Tel: (012) 395 8492

OR

Government Printers- Pretoria

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2012

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 delete and insert certain words in certain definitions; to insert certain definitions and to effect certain technical corrections; to provide for certain transitional matters; and to provide for matters connected therewith.

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

Amendment of Act 101 of 1965, as amended by Act 72 of 2008

1. With the exception of sections 1, 14(3)*(b)*, 18(1) and (2), 19(2), 20(1)*(b)*, 22B(1), 22C(1)*(b)*, 22C(6), 22H(1)*(a)* and *(b)*, 22H(2), 28(1)*(a)*(i), 28(1)*(b)* and *(c)*, 28(2)*(a)* and *(b)*, 28(4), 29*(h)* and *(i)*, 30(2) and (3), 31(1)*(a)* and *(d)*, 35(1)(i) to (xi), (xv), (xvii), (xviii), (xix), xxii), (xxiii), (xxiv), (xxvii), (xxviii), (xxix), (xxx), (xxxi), (xxxii), (xxxiv), (xxxviii), (xl), (xlii), 35(6) and 36(1), the word "product(s)", wherever it appears in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) hereinafter referred to as "the principal Act", is hereby deleted and replaced by the word "medicine(s)" as the case may be.

Amendment of section 1 of Act 101 of 1965, as amended by section 1 of Act 72 of 2008

2. Section 1 of the, is hereby amended—

(a) by the substitution for the definition of "advertisement" of the following definition:

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

(a) appearing in any newspaper, magazine, pamphlet or other publication;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever,

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

(b) by the substitution for the definition of "cosmetic" of the following definition:

" **'cosmetic'** means a cosmetic as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), **[which contains a Scheduled substance]**;";

(c) by the insertion after the definition of **"cosmetic"** of the following definition:

" **'Department'** means the National Department of Health or its successor in title;";

(d) by the substitution for the definition of "foodstuff" of the following definition:

" **'foodstuff'** means a foodstuff as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) **[,which contains a Scheduled substance]** ;";

(e) by the insertion after the definition of **"export"** of the following definition:

" **'health product'** means a medicine, Scheduled substance, medical device, IVD, cosmetic or foodstuff;"; and

(f) by the deletion of the definition of **"product".**

Amendment of section 2 of Act 101 of 1965, as substituted by section 2 of Act 72 of 2008

3. Section 2 of the principal Act is hereby amended:

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

"(1) The South African Health Products Regulatory Authority is hereby established as an organ of state <u>within the public administration</u> but outside the public service.;

(b) by the addition after subsection (4) of the following subsection:

<u>(5) The Authority is responsible for the regulatory oversight of cosmetics and foodstuffs as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).".</u>

Amendment of section 14 of Act 101 of 1965, as substituted by section 7 of Act 72 of 2008

4. Section 14 of the principal Act is hereby amended by the substitution for paragraph *(b)* of subsection (3) of the following paragraph:

"*(b)* if an application for the registration of such medicine **[product]**, medical device or IVD is made within the said period, on the date one month after the date on which a notice in respect of such medicine **[product]**, medical device or IVD is published in the *Gazette* in terms of section **[15(10)]** 15(9) or section 17(a).".

Amendment of section 15 of Act 101 of 1965, as substituted by section 8 of Act 72 of 2008

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

(a) the substitution for item (iii) of paragraph *(a)* of subsection (3) of the following item:

"(iii) is safe, effective and of good quality**[;and]** the Authority shall issue the applicant with a certificate of registration to that effect. ;

(b) the deletion of item (iv) of paragraph *(a)* of subsection (3); and

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

"*(c)* If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the Authority is still not satisfied as aforesaid, it shall reject the application **[not issue the certificate of registration]**.".

Amendment of section 16 of Act 101 of 1965, as substituted by section 12 of Act 72 of 2008

6. Section 16 of the principal Act is hereby amended by the insertion after paragraph *(b)* of subsection (1) of the following paragraph:

"*(c)* is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be available to the public;".

Amendment of section 18 of Act 101 of 1965, as substituted by section 14 of Act 72 of 2008

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

"**Labels and advertisements**

18. (1) No person shall sell any medicine or Scheduled substance **[product]** unless the immediate container or the package in which that medicine or Scheduled substance **[product]** is sold bears a label stating the prescribed particulars and in the case of a medical device or IVD unless the medical device or IVD bears a label, where practical, stating the prescribed particulars.

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

Amendment of section 19 of Act 101 of 1965, as substituted by section 18 of Act 72 of 2008

8. The following subsection is hereby substituted for subsection (2) of section 19 of the principal Act:

"(2) The Authority may by notice in writing require any person who manufactures or sells medicines **[products]**, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine, medical device or IVD 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 **[product]**, medical device or IVD.".

Amendment of section 20 of Act 101 of 1965, as substituted by section 19 of Act 72 of 2008

9. Section 20 of the principal Act is hereby amended by the substitution for paragraph *(b)* of subsection (1) of the following paragraph:

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

Amendment of section 22A of Act 101 of 1965, as substituted by section 22 of Act 72 of 2008

10. The following subsection is hereby substituted for subsection 22A(1) of the principal Act:

"22A Control of medicines, Scheduled substances, medical devices and IVD

(1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine, Scheduled substance, medical device or IVD except in accordance with the prescribed conditions.".

Amendment of section 22B of Act 101 of 1965, as substituted by section 23 of Act 72 of 2008

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

"Publication of information relating to medicines, Scheduled substances [products], medical devices or IVDs

22B. (1) Notwithstanding the provisions of section 34 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, Scheduled substance **[product]**, medical device or IVD.".

Amendment of section 22C of Act 101 of 1965, as substituted by section 24 of Act 72 of 2008

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

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

"(1) Subject to the provisions of this section—

(a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;

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

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

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

Amendment of section 22H of Act 101 of 1965, as substituted by section 28 of Act 72 of 2008

13. Section 22H of the principal Act is hereby amended by the substitution for subsections (1) and (2) of the following subsections:

"22H Purchase and sale of medicines, medical devices and IVD's by wholesalers

(1) (a) No wholesaler shall purchase medicines, Scheduled substances, medical devices or IVD's **[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, medical devices or IVD's **[products]** only into the retail sector.

[(c) Notwithstanding paragraphs (a) and (b), a wholesaler may purchase from or sell to, other wholesalers or the public Schedule 0 substances].

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

Amendment of section 28 of Act 101 of 1965, as substituted by section 35 of Act 72 of 2008

14. 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, authorized under this Act to compound and dispense medicines or Scheduled substances, dispenses, or handles medicines, Scheduled subsances **[products]**, medical devices or IVDs 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 medicine, Scheduled substances **[product]**, medical device or IVD, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1)*(a)*;

(c) seize any such medicine, Scheduled substances **[product]** medical device or IVD, any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act;";

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

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

(d) 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, Scheduled substance, **[product]**, medical device or IVD, or if there is no such person or if he or she is absent for any reason, in the presence of any other witness;

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

(iii) then be transmitted to an analyst, pharmacologist, technician, engineer, scientist **[or]** pathologist or expert designated by the Authority together with a certificate in the prescribed form signed by such inspector

(b) A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such medicine, Scheduled substance **[product]**, medical device or IVD or his or her agent."; and

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

"(4) The owner of the medicine, Scheduled substance **[product]**, medical device or IVD from which the sample was taken may claim from the Authority an amount equal to the market value thereof.".

Amendment of section 29 of Act 101 of 1965, as substituted by section 36 of Act 72 of 2008

15. 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, Scheduled substance **[product]**, medical device or IVD—"; and

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

"*(i)* sells any medicine, Scheduled substance **[product]** medical device or IVD 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 substituted by section 37 of Act 72 of 2008

16. 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, Scheduled substance **[product]**, medical device or IVD in respect of which the offence has been committed to be forfeited to the State."; and

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

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

Amendment of section 31 of Act 101 of 1965, as substituted by section 38 of Act 72 of 2008

17. 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, Scheduled substance **[product]**, medical device or IVD in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;"; and

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

"*(d)* any statement or entry contained in any book, record or document kept by any owner of a medicine, Scheduled substance, **[product]**, medical device or IVD or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him or her as an admission of the facts set forth in that statement or entry, unless evidence to the contrary which raises a reasonable doubt shows that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his or her work as manager, or in the course of his or her agency or employment.".

Amendment of section 35 of Act 101 of 1965, as substituted by section 41 of Act 72 of 2008

18. Section 35 of the principal Act is hereby amended:

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

"(i) prescribing the categories of persons by whom application may be made for the registration of any medicine, medical device or IVD or to whom a certificate of registration may be transferred;";

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

"(ii) prescribing the forms which shall be used for any application for the registration of any medicine, medical device or IVD the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine, medical device or IVD in question or any component of such medicine, medical device or IVD is manufactured and the premises in which such medicine medical device or IVD or any such component is manufactured);";

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

"(iii) providing for the classification of medicines, medical devices or IVD's into classes or categories for the purposes of this Act;";

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

"(iv) prescribing the samples of any medicine, medical device or IVD and the quantity thereof which shall accompany any application for the registration of a medicine, medical device or IVD's;";

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

"(v) prescribing the form in which the medicines', medical devices' or IVDs' register shall be kept and the particulars which shall be entered therein in respect of any registered medicine, medical device or IVD;";

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

"(vi) prescribing the form of any certificate of registration of any medicine, medical device, or IVD;";

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

"(vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine, Scheduled substance, medical device or IVD may be sold;";

(g) the substitution in subsection (1) for paragraph (viii) of the following paragraph:

"(viii) prescribing the manner in which any package containing any medicine, Scheduled substance, medical device or IVD shall be labelled, packed or sealed;";

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

"(ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine, Scheduled substance, medical device or IVD sold, and the manner in which such particulars shall be furnished;";

(i) the substitution in subsection (1) for paragraph (x) of the following paragraph:

"(x) prescribing the particulars which shall appear in any advertisement relating to any medicine, Scheduled substance, medical device or IVD or prohibiting the inclusion of any specified particulars in such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organization or a specified category of organizations;";

(k) the substitution in subsection (1) for paragraph (xi) of the following paragraph:

"(xi) prescribing the requirements with which any medicine or any component thereof, medical device or IVD shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;";

(l) the substitution in subsection (1) for paragraph (xv) of the following paragraph:

"(xv) prescribing the forms of licences, registers, prescription books, records and other documents which shall be kept or used in respect of medicines, Scheduled substances, medical devices or IVD's, the manner in which they shall be kept, the particulars which shall be entered therein and the place where and the period for which they shall be retained;";

(m) the substitution in subsection (1) for paragraph (xvii) of the following paragraph:

"(xvii) as to the transshipment or the exportation from or importation into the Republic of any medicine, Scheduled substance, medical devices or IVD's specifying the ports or places at which such medicine, Scheduled substances, medical devices or IVD's may be brought into the Republic;";

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

"(xviii) authorizing and regulating or restricting the transmission through the Republic of medicines, Scheduled substances, medical devices or IVD's;";

(o) the substitution in subsection (1) for paragraph (xix) of the following paragraph:

"(xix) prescribing the manner in which packages containing medicines, Scheduled substances, medical devices, IVD's shall be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they shall be kept;";

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

"(xxii) authorizing and regulating the possession by persons entering or departing from the Republic of specified quantities of medicines, Scheduled substances, medical devices or IVD's for personal medicinal use;";

(q) the substitution in subsection (1) for paragraph (xxiii) of the following paragraph:

"(xxiii) as to the disposal or destruction of a medicine, Scheduled substance, medical device or IVD and the records which shall be kept in respect thereof;";

(r) the substitution in subsection (1) for paragraph (xxiv) of the following paragraph:

"(xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines, Scheduled substances, medical devices or IVD's and the manner in which medicines, Scheduled substances medical devices or IVD's shall be kept and controlled in different categories of hospitals;";

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

"(xxvii) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device, IVD or class of medical devices, IVD's or medicines in respect of its safety, quality and efficacy;";

(t) the substitution in subsection (1) for paragraph (xxviii) of the following paragraph:

"(xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines, medical devices or IVD's;";

(u) the substitution in subsection (1) for paragraph (xxix) of the following paragraph:

"(xxix) as to the summary seizure and disposal of any medicine, Scheduled substance, medical devise or IVD found in the possession or custody of any person not entitled under this Act to keep or use it;";

(v) the substitution in subsection (1) for paragraph (xxx) of the following paragraph:

"(xxx) as to the disposal or destruction of a medicine, Scheduled substance, medical devise or IVD which has become unfit for use, and the report to be furnished in respect thereof;";

(w) the substitution in subsection (1) for paragraph (xxxi) of the following paragraph:

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

(x) the substitution in subsection (1) for paragraph (xxxii) of the following paragraph:

"(xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, medical devices or IVD's the issuing of permits and certificates under this Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the quality, safety and efficacy of medicines, Scheduled substances, medical devices or IVD's for the purpose of registration, the evaluation of technical amendments and changes to the particulars contained in registers and the testing for batch release of biological medicines;";

(y) the substitution in subsection (1) for paragraph (xxxiv) of the following paragraph:

"(xxxiv) relating to the conditions under which medicines, Scheduled substances, medical devices or IVD's may be sold;";

(z) the substitution in subsection (1) for paragraph (xxxviii) of the following paragraph:

"(xxxviii) relating to the safety, quality and efficacy of imported medicines, medical devices and IVD's;

(aa) by the insertion after paragraph (xxxix) of the following paragraphs, the existing paragraphs (xl) and (xli) becoming paragraphs (xliv) and (xlv), respectively:

"(xl) relating to medicines, Scheduled substances **[products]**, medical devices or IVDs in respect of matters contemplated in paragraphs (i) up to and including paragraph (xi) and paragraphs (xxiii), (xxiv), (xxxii), (xxxiv) and (xxxviii);

(xli) relating to the control of medicines, Scheduled substances, **[products]**, medical devices and IVD's in general;

(xlii) relating to the licensing for possessing or using certain medicines, Scheduled substances **[products]**, medical devices or IVDs;";

(bb) By the substitution for subsection (6) of the following subsection:

"(6) Regulations may be made under this section in respect of particular medicines, **[or]** Scheduled substances, medical devices or IVDs or classes or categories of medicines **[or]** Scheduled substances or medical devices or IVDs or in respect of medicines, **[or]** Scheduled substances, medical devices or IVDs other than particular classes or categories thereof **[of medicines, Scheduled substances],** and different regulations may be so made in respect of different medicines, **[or]** Scheduled substances, medical devices or IVDs or different classes or categories thereof **[of medicines or Scheduled substances]**.".

Amendment of section 36 of Act 101 of 1965, as substituted by section 42 of Act 72 of 2008

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

"Exclusion of any medicine, Scheduled substance [product], medical device or IVD from operation of Act"

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

Amendment of 101 of 1965

20. The principal Act is hereby amended by the insertion after section 37A of the following section:

"Medicine, medical devices or IVD's manufactured for export

37B. Notwithstanding anything to the contrary in this Act contained, the provisions of this Act relating to the registration of medicines shall not apply in respect of any medicine or any quantity of any medicine which is manufactured in or imported into the Republic solely for the purpose of export from the Republic and is not used or disposed of for use in the Republic and in respect of which the Authority has granted a certificate that it is satisfied in regard to its quality, purity and safety.".

Transitional measures

21.(1) *(a)* Medicines, medical devices and IVD's that are registered at the date of commencement of this act shall be deemed to be registered in terms of the principal Act, and the Chief Executive Officer shall enter them in the relevant register.

(b) The Medicines Control Council shall cease to exist the day before this Act is brought into operation and the Minister shall appoint:

(i) members of the Advisory Committee contemplated in section 4; and

(ii) the Chief Executive Officer contemplated in section 3

to assume office on the day that this Act is brought in operation

(c) 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.".

(2) *(a)* The following components of the Department must cease to exist, and together with their employees be incorporated into the Authority from the commencement date:

(i) Cluster Pharmaceutical, Trade and Product Regulation

(ii) Directorate Radiation Control

(iii) Directorate Health Technology

(iv) Directorate Food

(3) *(a)* The Minister of Health must, at least 30 days before the commencement date, designate every employee of the National Department of Health who is engaged in the provision of medicine regulatory, health technology, radiation control and food as per section 45(1) as employees to be transferred to the Authority and the Cluster: Pharmaceutical and Related Products Regulatory Management, Directorate: Radiation Control, Directorate: Health Technology and Directorate: Food shall cease to exist.

(b) An employee contemplated in paragraph *(a)* must, as soon as possible after designation, be informed in writing of such designation.

(c) The transfer of designated employees must be in accordance and subject to—

(i) the relevant labour legislation;

(ii) the Public Service Act, 1994; and

(iii) any collective agreement reached between employers and employees.

(d) Any designated employee who disputes a transfer to the Authority may refer such a dispute to the Commission for Conciliation, Mediation and Arbitration in terms of Chapter VII of the Labour Relations Act, 1995.

(e) (i) A person transferred to the Authority as contemplated in subsection (1) remains subject to any decisions, proceedings, rulings and directions applicable to that person immediately before the transfer date to the extent that they remain applicable.

(ii) Any proceedings against such person which were pending immediately before the transfer date must be disposed of as if that person had not been transferred.

(f) For the purposes of the Income Tax Act, 1962 (Act No. 58 of 1962), no change of employer must be regarded as having taken place when employment is taken up at the Authority by a person contemplated in subsection (1).

(4) *(a)* Registration of medicines, medical devices or IVD's which are pending registration on the commencement date of the Act as contemplated in section 15 of the principal Act, shall be transferred to the Authority and dealt with by the Authority as if the Act has not been passed.

(b) Decisions, guidelines and procedures made and adopted by the components referred to in Section 45 or the Medicines Control Council which are in force on the commencement date of the Act, remains in force until repealed and/or amended in so far as they deal with any matter in respect of which the Authority may make rules and guidelines.

(c) When any matter is, on the commencement date of the Act, pending before an appeal committee as contemplated in section 24 of the principal Act, it shall be dealt with as if the Act has not been passed.

(5) *(a)* (i) Movable property owned by the State, but which was used for purposes of a medicine, food, medical device, or IVD regulation are transferred and ceded by notice in the Gazette to the Authority on the commencement date.

(ii) In the event of the movable property being held under a lease and/or pledge and/or any form of security, such lease and/or pledge and/or any other security be transferred on the commencement date to the Authority by notice in the Gazette.

(b) On production of a certified register by a competent authority that movable property that constitutes part of the resources of the medicines, food, medical devices and IVD regulation service is owned by the State, the Authority shall make such entries or endorsements in or on any relevant register or other document to register that movable property in its name, and the Department shall remove the asset from its asset register.

(c) From the commencement date all contractual rights, obligations, assets and liabilities of the bodies referred to in section 45 are transferred to the Authority.

(d) Any litigation resulting from any cause of action in relation to the assets, rights, obligations or liabilities transferred to the Authority in terms of paragraph *(a)* which arose-

(i) before the commencement date, must be conducted by or against the designated institution concerned; and

(ii) on or after the commencement date must be conducted by or against the Authority.

(6) The fees to be charged by the Authority for medicine, Scheduled substance, medical device and IVD regulation services rendered to applicants shall, from the commencement date, be as contained in the regulations in force and used by the Department immediately before the commencement date until they can be determined in terms of section 33A.

(7) *(a)* All debt owing to the Department for medicines regulation immediately before the date of commencement, is payable to the Authority and must be managed under the same conditions that applied immediately prior to the commencement date.

(b) The Authority may alter the conditions under which the debt is managed after giving the debtors three months notice of the proposed changes.

(c) The Bank Account held by the Department for medicine regulation and all amounts in the account must be transferred to the Authority on the commencement date."

Repeal

22. Section 44 of Act 72 of 2008 is hereby repealed.

Short title and commencement

23. This Act is called the Medicines and Related Substances Amendment Act, 2012, and comes into operation on a date determined by the President by proclamation in the *Gazette*.