

REPUBLIC OF SOUTH AFRICA

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

*(As introduced in the National Assembly (proposed section 75); explanatory summary of
Bill published in Government Gazette No. 37361 of 20 February 2014)
(The English text is the official text of the Bill)*

(MINISTER OF HEALTH)

[B 6—2014]

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GENERAL EXPLANATORY NOTE:

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

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

BILL

To amend the Medicines and Related Substances Act, 1965, so as to define certain expressions and to delete or amend certain definitions; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to replace the word “products” with the word “medicines” and expression “Scheduled substances” in order to correctly reflect the subject matter of the said Act; and to effect certain technical corrections; and to provide for matters connected therewith.

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

Amendment of section 1 of Act 101 of 1965, as substituted by section 1 of Act 65 of 1974 and amended by section 1 of Act 17 of 1979, section 1 of Act 20 of 1981, section 1 of Act 94 of 1991, section 1 of Act 49 of 1996, section 1 of Act 90 of 1997, section 1 of Act 59 of 2002 and section 1 of Act 72 of 2008 5

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

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

“**‘advertisement’**, in relation to any **[product]** medicine, Scheduled substance, 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; 15

(b) distributed to members of the public; or

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

which is intended to promote the sale of that **[product]** medicine, Scheduled substance, medical device or IVD, and **‘advertise’** has a corresponding meaning;” 20

(b) by the deletion of the definition of “advisory committee”;

- (c) by the insertion after the definition of “Authority” of the following definitions:
- “**‘biological medicine’** means any substance or mixture of substances that contains a living organism, or that is derived from a living organism or biological process, including—
- (a) plasma-derived and animal products, for example clotting factors, immunosera and antivenoms;
- (b) vaccines;
- (c) biotechnology-derived medicines (rDNA products), for example rHu-antihaemophilic factors, hormones, cytokines, enzymes, monoclonal antibodies, erythropoietins and nucleic acids; and
- (d) products developed for human gene therapy;
- ‘Board’** means the Board referred to in section 2;”;
- (d) by the insertion after the definition of “certificate of registration” of the following definition:
- “**‘complementary medicine’** means any substance or mixture of substances that—
- (a) originates from a plant, mineral or animal;
- (b) is used or intended to be used for, or manufactured or sold for use, in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and
- (c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);”;
- (e) 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**];”;
- (f) 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**];”;
- (g) by the deletion of the definition of “product”; and
- (h) by the substitution in the definition of “medicine” for the words following paragraph (b) of the following words:
- “and includes any biological medicine, complementary medicine and veterinary medicine;”.

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

2. Section 2 of the principal Act is hereby amended—
- (a) by the substitution for the heading of the following heading:
- “**Establishment[, powers and functions] of South African Health Products Regulatory Authority**”;
- (b) 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 within the public administration but outside the public service.”; and
- (c) by the addition of the following subsection:
- “(5) The Authority acts through its Board.”.

Insertion of sections 2A to 2I in Act 101 of 1965

3. The following sections are hereby inserted in the principal Act after section 2:

“Objects of Authority

2A. The objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest.

Functions of Authority

- 2B.** (1) The Authority must, in order to achieve its objects—
- (a) ensure the efficient, effective and ethical evaluation and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety and efficacy; 5
 - (b) ensure that the process of evaluating and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously;
 - (c) ensure the periodic re-assessment and monitoring of medicines, medical devices and IVDs; 10
 - (d) ensure that evidence of existing and new adverse events, interactions, information about pharmacovigilance is being monitored, analysed and acted upon;
 - (e) ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and 15
 - (f) ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.
- (2) The Authority may—
- (a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of— 20
 - (i) matters of common interest; or
 - (ii) a specific investigation; and 25
 - (b) enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.
- (3) The Authority is responsible for the regulatory oversight of—
- (a) cosmetics; 30
 - (b) foodstuffs; and
 - (c) Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973).

Composition of Board

- 2C.** (1) The Board of the Authority consists of not less than 10 but not more than 15 members appointed by the Minister. 35
- (2) Subject to section 2D, the Minister must appoint as members of the Board—
- (a) not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, pharmaco-vigilance, cosmetics and foodstuffs regulatory, clinical trials, good manufacturing practice, public health or epidemiology; 40
 - (b) one person on account of his or her knowledge of the law;
 - (c) one person on account of his or her knowledge of good governance;
 - (d) one person on account of his or her knowledge of financial matters and accounting; 45
 - (e) one person on account of his or her knowledge of information technology; and
 - (f) one person on account of his or her knowledge of human resource management.
- (3) The Chief Executive Officer is by virtue of his or her office a member of the Board but with no voting rights. 50

Appointment of members of Board

- 2D.** (1) The Minister must, before appointing the members contemplated in section 2C(2), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based. 55

(2) If a suitable person or the required number of persons is not nominated in terms of subsection (1), the Minister must appoint an appropriate person or persons who qualify to be appointed in terms of this Act.

(3) Subject to section 2F, a member of the board—

- (a) holds office for a minimum period of three years, but not exceeding five years, determined by the Minister at the time of the appointment of the member; and
- (b) is eligible for re-appointment for one additional term.

(4) A member of the Board, excluding a member who is in the full-time employment of the State, must be appointed on such conditions as the Minister may, with the concurrence of the Minister of Finance, determine.

Appointment of chairperson and vice-chairperson of Board

2E. (1) The Minister must appoint a chairperson and vice-chairperson of the Board from among the members contemplated in section 2C(2).

(2) Whenever the chairperson of the Board is absent or unable to perform his or her functions as chairperson, the vice-chairperson must act as chairperson and if the vice-chairperson is absent or unable to act as chairperson the Minister must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available.

(3) Any person acting as chairperson of the Board in terms of subsection (2) has all the powers and duties of the chairperson.

Disqualification from membership of Board and vacation of office

2F. (1) A person may not be appointed as a member of the Board if that person—

- (a) is not a South African citizen and ordinarily resident in the Republic;
- (b) is an unrehabilitated insolvent;
- (c) has at any time been convicted of an offence involving dishonesty, whether in the Republic or elsewhere, and sentenced to imprisonment without the option of a fine; or
- (d) has been removed from an office of trust.

(2) A member of the Board must vacate office if—

- (a) he or she becomes disqualified in terms of subsection (1), from being appointed as a member of the Board;
- (b) he or she submits his or her resignation to the Minister in writing;
- (c) he or she is declared by the High Court to be of unsound mind or mentally disordered or is detained under the Mental Health Care Act, 2002 (Act No. 17 of 2002);
- (d) he or she has, without the leave of the Board, been absent from more than two consecutive meetings of the Board; or
- (e) the Minister, after consultation with the Board, withdraws the appointment of that member because the member is incompetent or unfit to fulfil his or her duties.

(3) If a member of the Board dies or vacates office in terms of subsection (2), the Minister may, subject to section 2D, appoint a person to fill the vacancy for the unexpired portion of the period for which that member was appointed.

Meetings of Board

2G. (1) The meetings of the Board and the conduct of business at meetings must be determined by the rules of the Board.

(2) A quorum for a meeting of the Board is the majority of its voting members.

(3) A decision of the majority of the members of the Board present at any meeting constitutes a decision of the Board and, in the event of an equality of votes, the member presiding at the meeting has a casting vote in addition to his or her deliberative vote.

(4) A decision taken by the Board or an act performed under the authority of the Board is not invalid by reason only of a vacancy on the Board, or that a person who is not entitled to sit as a member of the Board sat as a member at the time when the decision was taken or the act was authorised, if the decision was taken or the act was authorised by the requisite majority of the members of the Board who were present at the time and entitled to sit as members. 5

(5) Minutes of the proceedings of every meeting of the Board must be prepared and entered in a book kept for that purpose.

(6) Minutes of the proceedings of each meeting must be submitted at the next meeting of the Board and, if passed as correct, must be confirmed by the signature of the chairperson or other member presiding thereat and may, when so confirmed, be evidence in a court of law of the proceedings of the first-mentioned meeting. 10

(7) In the absence of the chairperson or the person acting as the chairperson from a particular meeting of the Board, the members present at that meeting may elect one of their number to preside at that meeting. 15

Committees of Board

2H. The Board may appoint one or more committees from among its members to assist it with the performance of its functions. 20

Dissolution of Board

2I. (1) The Minister may dissolve the Board if the Minister, on good cause shown, loses confidence in the ability of the Board to perform its functions effectively and efficiently.

(2) The Minister may dissolve the Board only— 25
 (a) after having given the Board a reasonable opportunity to be heard; and
 (b) after having afforded the Board a hearing on any submissions received.

(3) If the Minister dissolves the Board, the Minister— 30
 (a) may appoint an administrator to take over the functions of the Board and to do anything which the Board might otherwise be empowered or required to do by or under this Act, subject to such conditions as the Minister may determine; and
 (b) must, as soon as it is feasible but not later than three months after the dissolution of the Board, replace the members of the Board in the same manner in which they were appointed. 35

(4) The costs associated with the appointment of an administrator shall be for the account of the Authority.

(5) The appointment of the administrator terminates when the Board members have been replaced in terms of section 2C(2).” 40

Amendment of section 3 of Act 101 of 1965, as substituted by section 3 of Act 72 of 2008

4. Section 3 of the principal Act is hereby amended—

(a) by the substitution for subsection (1) of the following subsection: 45
 “(1) The [Minister] Board, after consultation with the Minister, must appoint a suitably qualified person as the Chief Executive Officer of the Authority.”;

(b) by the substitution in subsection (4) for paragraphs (b) and (c) of the following paragraphs, respectively: 50
 “(b) is appointed subject to the conclusion of a performance agreement with the [Minister] Board;

(c) is accountable to and reports to the [Minister] Board;”;

(c) by the substitution for subsection (9) of the following subsection: 55
 “(9) The Chief Executive Officer shall, in consultation with the Board, appoint committees, as he or she may deem necessary, to investigate and report to the Authority on any matter within its purview in terms of this Act.”.

Repeal of section 4 of Act 101 of 1965

5. Section 4 of the principal Act is hereby repealed.

Substitution of section 13 of Act 101 of 1965, as substituted by section 6 of Act 72 of 2008

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

“Registers

13. (1) The Chief Executive Officer shall keep separate registers for **[products]** medicines, Scheduled substances, medical devices or IVDs [;], in which he or she shall record—

- (a) the registration of **[products]** medicines, Scheduled substances, medical devices or IVDs by the Authority; and 10
- (b) such particulars in regard to the **[products]** medicines, Scheduled substances, medical devices or IVDs and the holder of certificate of registration in respect of such **[products]** medicines, Scheduled substances, medical devices or IVDs as are required by this Act. 15

(2) The Chief Executive Officer shall publish on the Authority’s website the registers referred to in subsection (1) and update those registers every six months.”.

Amendment of section 14 of Act 101 of 1965, as substituted by section 7 of Act 72 of 2008 20

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

“(b) if an application for the registration of such **[product]** medicine, 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 **[product]** medicine, 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

8. Section 15 of the principal Act is hereby amended— 30

(a) by the insertion in subsection (3)(a) of the word “and” at the end of subparagraph (ii) and the substitution for subparagraph (iii) of the following subparagraph:

“(iii) is safe, efficacious and of good quality [; and]₂.”;

(b) by the deletion in subsection (3)(a) of subparagraph (iv); and 35

(c) by the substitution in subsection (3) for paragraph (c) 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 **[not issue the certificate of registration]** reject the application.”. 40

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

9. Section 16 of the principal Act is hereby amended by the deletion in subsection (1) of the word “or” at the end of paragraph (a), the insertion of the word “or” at the end of paragraph (b) and the addition of the following paragraph: 45

“(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

10. Section 18 of the principal Act is hereby amended by the substitution for subsections (1) and (2) of the following subsections, respectively:

- “(1) No person shall sell any **[product]**— 5
- (a) medicine or Scheduled substance unless the immediate container or the package in which that **[product]** medicine or Scheduled substance is sold bears a label stating the prescribed particulars; and
- (b) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical, stating the prescribed particulars. 10
- (2) No person shall advertise any **[product]** medicine or Scheduled substance, 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 15

11. Section 19 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

- “(2) The Authority may by notice in writing require any person who manufactures or sells **[products]** medicines, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine or medical device 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 **[product]** medicine, medical device or IVD.” 20

Amendment of section 20 of Act 101 of 1965, as substituted by section 19 of Act 72 of 2008 25

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

- “(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any **[product]** medicine, 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]** section 22(1)(a)(ii) or state or suggest that any **[product]** medicine, 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 22(1)(a)(ii).” 30 35

Amendment of section 22A of Act 101 of 1965, as substituted by section 13 of Act 90 of 1997 and amended by section 5 of Act 59 of 2002 and section 22 of Act 72 of 2008

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

- (a) by the substitution for the heading of the following heading: 40
“Control of medicines [and], Scheduled substances, medical devices and IVDs”; and
- (b) by the substitution for subsection (1) of the following subsection:
 “(1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine **[or]**, Scheduled substance, medical device or IVD, except in accordance with the prescribed conditions.” 45

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

14. Section 22B of the principal Act is hereby amended—

- (a) by the substitution for the heading of the following heading: 50
“Publication of information relating to **[products] medicines, Scheduled substances, medical devices or IVDs”**; and

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

“(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 **[product]** medicine, Scheduled substance, medical device or IVD.”.

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Amendment of section 22C of Act 101 of 1965, as inserted by section 14 of Act 90 of 1997 and amended by section 6 of Act 59 of 2002 and section 24 of Act 72 of 2008

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

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

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“(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 (Act No. 56 of 1974), a licence to compound and dispense medicines, on the prescribed conditions;

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(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 **[product]** medicine, Scheduled substance, medical device or IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such [product] medicine, Scheduled substance, 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.”; and

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

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

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Amendment of section 22H of Act 101 of 1965, as inserted by section 14 of Act 90 of 1997 and amended by section 28 of Act 72 of 2008

16. Section 22H of the principal Act is hereby amended—

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

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“**Purchase and sale of medicines, medical devices, IVDs and Scheduled substances by wholesalers**”; and

(b) by the substitution for subsections (1) and (2) of the following subsections, respectively:

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

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(b) A wholesaler shall—

(i) sell **[products]** medicines, medical devices or IVDs only into the retail sector; and

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(ii) sell Scheduled substances to any person who may lawfully possess such substance.

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

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

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Amendment of section 28 of Act 101 of 1965, as amended by section 26 of Act 65 of 1974, section 12 of Act 17 of 1979, section 16 of Act 90 of 1997, section 11 of Act 59 of 2002 and section 35 of Act 72 of 2008

17. Section 28 of the principal Act is hereby amended—
- (a) by the substitution in subsection (1)(a) for subparagraph (i) of the following subparagraph: 5
- “(i) any place or premises from which a person, authorized under this Act to compound **[and]** or dispense medicines or Scheduled substances, dispenses or handles **[products]** medicines, Scheduled substances, 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), (c) and (d) of the following paragraphs, respectively: 10
- “(b) inspect any **[product]** medicine, Scheduled substance, 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 **[product]** medicine, Scheduled substance, medical device or IVD, any books, records or documents found in or upon 20
- such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act;
- (d) take so many samples of any such **[product]** medicine or Scheduled substance, medical device or IVD as he or she may consider necessary for the purpose of testing, examination or analysis in 25
- terms of the provisions of this Act.”;
- (c) by the substitution in subsection (2)(a) for subparagraph (i) of the following subparagraph:
- “(i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such **[product]** 30
- medicine, Scheduled substance, 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;”;
- (d) by the substitution in subsection (2)(a) for subparagraph (iii) of the following subparagraph: 35
- “(iii) then be transmitted to an analyst, pharmacologist, technician, **[or]** engineer, scientist, pathologist or expert designated by the Authority together with a certificate in the prescribed form signed by such inspector.”;
- (e) by the substitution in subsection (2) for paragraph (b) of the following paragraph: 40
- “(b) A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such **[product]** medicine, Scheduled substance, medical device or IVD or his or her agent.”; and
- (f) by the substitution for subsection (4) of the following subsection: 45
- “(4) The owner of the **[product]** medicine, Scheduled substance, medical device or IVD from which the sample was taken may claim from **[the]** the Authority an amount equal to the market value thereof.”.

Amendment of section 29 of Act 101 of 1965, as amended by section 27 of Act 65 of 1974, section 12 of Act 94 of 1991, section 17 of Act 90 of 1997 and section 36 of Act 72 of 2008 50

18. 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: 55
- “makes any false or misleading statement in connection with any **[product]** medicine, Scheduled substance, medical device or IVD—”;
- and

- (b) by the substitution for paragraph (i) of the following paragraph:
- “(i) sells any **[product]** medicine, Scheduled substance, 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 amended by section 28 of Act 65 of 1974, section 13 of Act 94 of 1991, section 18 of Act 90 of 1997 and section 37 of Act 72 of 2008 5

19. Section 30 of the principal Act is hereby amended—

- (a) by the substitution for subsection (2) of the following subsection: 10
- “(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any **[product]** medicine, Scheduled substance, 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: 15
- “(3) Any **[product]** medicine, Scheduled substance, 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 amended by section 29 of Act 65 of 1974, section 13 of Act 17 of 1979, section 19 of Act 90 of 1997 and section 38 of Act 72 of 2008 20

20. Section 31 of the principal Act is hereby amended—

- (a) by the substitution in subsection (1) for paragraph (a) of the following paragraph: 25
- “(a) any quantity of a **[product]** medicine, Scheduled substance, 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 in subsection (1) for paragraph (d) of the following paragraph: 30
- “(d) any statement or entry contained in any book, record or document kept by any owner of a **[product]** medicine, Scheduled substance, 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.”. 35 40

Amendment of section 35 of Act 101 of 1965, as substituted by section 23 of Act 90 of 1997 and amended by section 12 of Act 59 of 2002 and section 41 of Act 72 of 2008

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

- (a) by the substitution in subsection (1) for paragraphs (i) to (xi) of the following paragraphs, respectively: 45
- “(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; 50
- (ii) prescribing the forms which shall be used for any application for the registration of any medicine, medical device or IVD and 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 at which such medicine, medical device or IVD or any such component is manufactured); 55

- (iii) providing for the classification of medicines, medical devices or IVDs into classes or categories for the purposes of this Act;
 - (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; 5
 - (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, as the case may be;
 - (vi) prescribing the form of any certificate of registration of any medicine, medical device, or IVD; 10
 - (vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine, [or] Scheduled substance, medical device or IVD may be sold;
 - (viii) prescribing the manner in which any package containing any medicine, [or] Scheduled substance, medical device or IVD shall be labelled, packed or sealed; 15
 - (ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine, [or] Scheduled substance, medical device or IVD sold, and the manner in which such particulars shall be furnished; 20
 - (x) prescribing the particulars which shall appear in any advertisement relating to any medicine, [or] 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 organisation or a specified category of organisations; 25
 - (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;”;
- (b) by 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 IVDs, 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;”;
- (c) by the substitution in subsection (1) for paragraphs (xvii), (xviii) and (xix) of the following paragraphs, respectively:
- “(xvii) as to the transshipment or the exportation from or importation into the Republic of any medicine, Scheduled substance, medical device or IVD, specifying the ports or places at which such medicine, Scheduled substance, medical device or IVD may be brought into the Republic; 45
 - (xviii) authorising and regulating or restricting the transmission through the Republic of medicines, Scheduled substances, medical devices or IVDs; 50
 - (xix) prescribing the manner in which packages containing medicines, Scheduled substances, medical devices or IVDs 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;”;
- (d) by the substitution in subsection (1) for paragraphs (xxii), (xxiii) and (xxiv) of the following paragraphs, respectively:
- “(xxii) authorising and regulating the possession by persons entering or departing from the Republic of specified quantities of medicines, Scheduled substances, medical devices or IVDs for personal medicinal use; 60

- (xxiii) as to the disposal or destruction of a medicine, **[or a]** Scheduled substance, medical device or IVD, and the records which shall be kept in respect thereof;
- (xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines, **[and]** Scheduled substances, medical devices or IVDs, and the manner in which medicines, **[and]** Scheduled substances, medical devices or IVDs shall be kept and controlled in different categories of hospitals;”;
- (e) by the substitution in subsection (1) for paragraphs (xxvii) to (xxxii) of the following paragraphs, respectively:
- “(xxvii) authorising, 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, IVDs or medicines in respect of its safety, quality and efficacy;
- (xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines, **[and]** medical devices or IVDs;
- (xxix) as to the summary seizure and disposal of any medicine, Scheduled substance, medical device or IVD found in the possession or custody of any person not entitled under this Act to keep or use it;
- (xxx) as to the disposal or destruction of a medicine, Scheduled substance, medical device or IVD which has become unfit for use, and the report to be furnished in respect thereof;
- (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 **[product]** medicine, Scheduled substance, 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 **[product]** medicine, Scheduled substance, medical device or IVD and the date on which such annual fee shall be paid;
- (xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, medical devices or IVDs, 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 safety, quality and efficacy of medicines, Scheduled substances, **[or]** medical devices or IVDs for the purpose of registration, **[and]** the evaluation of technical amendments and changes to the particulars contained in registers and the testing for batch release of biological medicines;”;
- (f) by the substitution in subsection (1) for paragraph (xxxiv) of the following paragraph:
- “(xxxiv) relating to the conditions under which medicines, **[or]** Scheduled substances, medical devices or IVDs may be sold;”;
- (g) by 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 IVDs;”;
- (h) by the substitution in subsection (1) for paragraphs (xl), (xli) and (xlii) of the following paragraphs, respectively:
- “(xl) relating to **[products]** medicines, Scheduled substances, 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 **[products]** medicines, Scheduled substances, medical devices and IVDs in general;
- (xlii) relating to the licensing for possessing or using certain **[products]** medicines, Scheduled substances, medical devices or IVDs;”;
- (i) by the substitution for subsection (6) of the following subsection:
- “(6) Regulations may be made under this section in respect of particular **[products]** medicines, Scheduled substances, medical devices or IVDs or classes or categories **[in respect thereof]** of medicines,

Scheduled substances or medical devices or IVDs or in respect of medicines, Scheduled substances, medical devices or IVDs other than particular classes or categories **[of products, medical devices or IVDs]** thereof, and different regulations may be so made in respect of different **[products]** medicines, Scheduled substances, medical devices or IVDs or different classes or categories **[of products, medical devices or IVDs]** thereof.”. 5

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

22. The following section is hereby substituted for section 36 of the principal Act: 10

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

36. (1) The Minister may, on the recommendation of the Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any **[product] medicine, Schedule substance, 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. 15

(2) Notwithstanding subsection (1), the exclusion of any **[product] medicine or Scheduled substance** from the operation of section 22G shall be on the recommendation of the Pricing Committee.”. 20

Substitution of certain words in Act 101 of 1965

23. The principal Act is hereby amended by the substitution for the words “product” and “products”, wherever they occur except in sections 2, 22(4)(a)(ii), 22A, 22F(4)(c) and 22H(1)(a) and Schedules 0 up to and including 6, of the words “medicine” and “medicines”, respectively. 25

Repeal of law

24. Section 44 of the Medicines and Related Substances Amendment Act, 2008 (Act No. 72 of 2008), is hereby repealed.

Transitional provisions

25. (1) For the purposes of this section— 30

(a) “Authority” means the South African Health Products Regulatory Authority established by section 2 of the principal Act as amended by this Act;

(b) “commencement date” means the date on which this Act takes effect;

(c) “Council” means the Medicines Control Council established by section 2 of the principal Act; and 35

(d) “Department” means the national Department of Health.

(2) (a) The Council continues to perform the functions which it performed before the commencement date but ceases to exist the day immediately before the date of the first meeting of the Board appointed by the Minister of Health in terms of section 2C of the principal Act as amended by this Act. 40

(b) The date of the first meeting of the Board referred to paragraph (a) must be determined by the Minister.

(c) Anything done by the Council that could have been done by the Authority in terms of the principal Act as amended by this Act must be regarded as having been done by the Authority. 45

(2) Medicines, medical devices and IVDs that are registered on the commencement date must be regarded as having been registered in terms of the principal Act as amended by this Act and the Chief Executive Officer must enter them in the relevant register.

(3) (a) The Minister of Health must, at least 30 days before the commencement date, designate all the employees of the Department who are engaged in the regulation of medicines and health technologies and in radiation control and food control as employees to be transferred to the Authority. 50

- (b) An employee contemplated in paragraph (a) must be informed in writing of the designation as soon as possible after designation.
- (c) The transfer of the designated employees must be in accordance and subject to—
- (i) the relevant labour legislation;
 - (ii) the Public Service Act, 1994 (Proclamation No. 103 of 1994); and
 - (iii) any collective agreement reached between employers and employees.
- (d) 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 this subsection.
- (e) Any person transferred to the Authority in terms of this subsection remains subject to any decision, proceeding, ruling and direction applicable to that person immediately before the transfer date to the extent that such decision, proceeding, ruling and direction remain applicable.
- (f) Any proceedings against a person transferred to the Authority that were pending immediately before the transfer date must be disposed of as if that person had not been transferred.
- (4) (a) Registration of any medicine, medical device or IVD which was pending registration before the commencement date, must be dealt with by the Authority as if this Act has not been passed.
- (b) Any appeal in terms of section 24 of the principal Act that is pending on the commencement date must be dealt with as if this Act had not been passed.
- (c) Decisions, guidelines and procedures made and adopted by the Department that are in force on the commencement date and that deals with matters in respect of which the Authority may make rules and guidelines in terms of the principal Act as amended by this Act, remain in force until amended or repealed by the Authority.
- (5) (a) The ownership and control of all movable property of which the ownership and control vested in the State immediately before the commencement date and which has been used for the purposes or in connection with the exercise or performance of the powers and duties of the employees transferred to the Authority in terms of this section must be transferred to the Authority.
- (b) In the event of the movable property being held under a lease or pledge or any form of security, such lease or pledge or other security are transferred on the commencement date to the Authority.
- (c) On production of a certified register by the Director-General of the Department that movable property that constitutes part of the resources of the employees contemplated in subsection (3)(a) is owned by the State, the Authority must make such entries or endorsements in or on any relevant register or other document to register that movable property in its name, and the Director-General must remove that removable property from its asset register.
- (d) From the commencement date all contractual rights, obligations, assets and liabilities of the Department in respect of that part of the Department under which the employees contemplated in subsection (3)(a) fall vest in and must be transferred to the Authority.
- (e) 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 Department; and
 - (ii) on or after the commencement date must be conducted by or against the Authority.
- (f) If there is any uncertainty about which movable property must be transferred to the Authority, the matter must be finally determined by the Minister, in consultation with the Minister of Finance.
- (6) The fees to be charged by the Authority for services rendered to any applicant in respect of any medicine, Scheduled substance, medical device and IVD must, from the commencement date, be as contained in the regulations in force and used by the Department immediately before the commencement date until the relevant regulations have been amended or substituted by the Minister in terms of the principal Act as amended by this Act.

(7) All debt owing to the Department for medicines regulation immediately before the date of commencement of this Act is payable to the Authority and must be managed under the same conditions that applied immediately prior to that 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. 5

(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.

Short title and commencement

26. This Act is called the Medicines and Related Substances Amendment Act, 2014, and comes into operation immediately after the commencement of the Medicines and Related Substances Amendment Act, 2008 (Act No. 72 of 2008). 10

MEMORANDUM ON THE OBJECTS OF THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2014

1. BACKGROUND

- 1.1 The Medicines and Related Substances Amendment Bill (“Bill”), seeks to amend the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (“principal Act”), that has been recently amended by Medicines and Related Substances Amendment Act, 2008 (Act 72 of 2008) (“amendment Act”), so as to define certain expressions and to delete or amend certain definitions; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to replace the word “products” with the word “medicines” and expression “Scheduled substances” in order to correctly reflect the subject matter of the said Act; and to effect certain technical corrections; and to provide for matters connected therewith.
- 1.2 The amendment Act established a new regulatory authority for all medicines, medical devices and food stuffs called the South African Health Product Regulatory Authority (“SAHPRA”). The amendment Act provided for the appointment of a Chief Executive Officer to carry out, amongst other things, the functions assigned to SAHPRA under the principal Act as amended by the amendment Act.
- 1.3 The amendment Act has not been put into operation because some issues relating to the envisaged functioning of SAHPRA were identified. This in turn necessitated certain consequential amendments to the principal Act as amended by the amendment Act where certain definitions needed to be amended and some new definitions inserted. The transitional arrangements also needed to be more elaborate so as to create a smooth transition from the current Medicines Control Council (“MCC”) to SAHPRA.
- 1.4 During December 2011 Cabinet approved that the Bill be published for public comments. On 15 March 2012, the Bill was published for public comments as per Government *Gazette* number 35151 for a period of three months. Public comments were received and considered.

2. OBJECTS OF BILL

Clause 1: Amendment of section 1 of principal Act, as amended by section 1 of Amendment Act

- 2.1 Clause 1 seeks to amend section 1 of the principal Act by—
 - (a) the substitution in the definition of “advertisement” for the word “product” of the words “medicine, Scheduled substance”;
 - (b) the deletion of the words “which contains a Scheduled substance” in the definitions of “cosmetic” and “foodstuff”;
 - (c) the extension of the definition of “medicine”;
 - (d) the insertion of definition for “Board”; and
 - (e) the deletion of the definitions of “advisory committee” and “product”.

Clause 2: Amendment of section 2 of principal Act, as substituted by section 2 of Amendment Act

- 2.2 Clause 2 seeks to amend section 2 of the principal Act (that establishes SAHPRA), so as to clarify that SAHPRA is an organ of state within the public administration but outside the public service.

Clause 3: Insertion of sections 2A to 2I in principal Act

- 2.3 The new sections 2A to 2I seek to provide for—
- (a) the objects of SAHPRA;
 - (b) the functions of SAHPRA;
 - (c) the composition of the Board of SAHPRA (“Board”);
 - (d) the appointment of members to the Board;
 - (e) the appointment of a chairperson and vice-chairperson of the Board;
 - (f) disqualification from membership of the Board and vacation of office;
 - (g) meetings of the Board;
 - (h) committees of the Board; and
 - (i) the dissolution of the Board.

Clause 4: Amendment of section 3 of principal Act, as substituted by section 3 of Amendment Act

- 2.4 Clause 4 seeks to empower the Board to appoint a Chief Executive Officer after consultation with the Minister. It is also proposed that the Chief Executive Officer conclude a performance agreement with the Board and that the Chief Executive Officer is accountable to the Board. Lastly it seeks to empower the Chief Executive Officer to appoint committees in consultation with the Board.

Clause 5: Repeal of section 4 of principal Act

- 2.5 Clause 5 seeks to repeal section 4 which provided for the establishment of the Advisory Committee. The need for an Advisory Committee has fallen away as a result of the appointment of the Board.

Clause 6: Amendment of section 13 of principal Act, as substituted by section 6 of Amendment Act

- 2.6 Clause 6 seeks to amend section 13 so as to empower the Chief Executive Officer to publish the registers for medicines, Scheduled substances, medical devices or IVDs on the Website of SAHPRA.

Clause 7: Amendment of section 14 of principal Act, as substituted by section 7 of Amendment Act

- 2.7 Clause 7 seeks to replace the word “product” with the word “medicine” and to remove reference to section 15(10) which was erroneously referred to in the Amendment Act.

Clause 8: Amendment of section 15 of principal Act, as substituted by section 8 of Amendment Act

- 2.8 Clause 8 seeks to empower SAHPRA to issue registration certificates and reject applications for registration of medicines under certain circumstances.

Clause 9: Amendment of section 16 of principal Act, as substituted by section 12 of Amendment Act

- 2.9 Clause 9 seeks to empower SAHPRA to cancel registration of any medicine, medical device or IVD if SAHPRA is of the opinion that it is not in the public interest that such medicine, medical device or IVD is made available to the public.

Clause 10: Amendment of section 18 of principal Act, as substituted by section 14 of Amendment Act

- 2.10 Clause 10 seeks to amend section 18 by replacing the word “product” with the words “medicine or Scheduled substance”. It also seeks to prohibit the sale of

medical devices or IVDs unless they bear a label, where practical, stating the prescribed (by regulation) particulars.

Clauses 11 to 23:

2.11 Clauses 11 to 23 seek to replace the word “product” with the words “medicine”, “medicines, Scheduled substances” and “medical device or IVD” or by inserting the words “medical device or IVD” and “medicines, Scheduled substances, medical devices or IVD’s”.

Clause 24

2.12 Clause 24 seeks to repeal section 44 of the amendment Act.

Clause 25

2.13 Clause 25 seeks to provide for transitional arrangements so as to create a smooth transition from the MCC to SAHPRA.

3. PERSONS OR BODIES CONSULTED

The Bill was published on 15 March 2012 for public comments. Comments were received from the following institutions and persons:

NO	COMPANY	PARTICIPANT	CONTACT
1.	UNIVERSITY OF STELLENBOSCH	PROF B VAN DE WAL	bwvdewal@sun.ac.za
2.	NTP RADIOISOTOPES PTY LTD	MR DG ROBERTSON (MD)	(012) 305 5472 082 806 9704
3.	INNOVATIVE MEDICINES S.A.	VAL BEAUMONT	C +27 (0) 82 828 3256 T: +27 (0)11 880 4644
4.	SALDA (SOUTH AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION)	DOREEN HOWARD	082 901 8715
5.	SAMED (SOUTH AFRICAN MEDICAL DEVICE INDUSTRY ASSOCIATION)	TANYA VOGT	011 777 7500
6.	SMASA (SELF-MEDICATION MANUFACTURERS ASSOCIATION OF SA)	ALLISON VIENINGS	012 803 5995 / 6223
7.	IMSA (INNOVATIVE MEDICINES SA)	VAL BEAUMONT	011 8804644
8.	PIASA (PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA)	KIRSTI NARSAI	011 805 5100 / 011 265 2107
9.	PRIVATE	PROF ROY JOBSON	046 603 8070 / 8381
10.	ROCHE DIAGNOSTICS	KNUT SEIFERT	011 502 5000
11.	SAPC (SA PHARMACY COUNCIL)	TA MASANGO	012 319 8501/2
12.	PHARMACEUTICAL SOCIETY OF SA	PHARMACEUTICAL SOCIETY OF SA	(012) 301 0833

4. FINANCIAL IMPLICATIONS FOR THE STATE

The current budget of the national Department of Health in respect of the MCC will be transferred to SAHPRA. Medicine regulation fees amendments have already been prepared in consultation with the Minister of Finance and are ready for gazetting and implementation. The revenue from fees will double current revenue from about R30m to about R65m in the first year and fees will be increased as SAHPRA will provide a more efficient service. Fees will also be phased in for medical device, foodstuff and cosmetic regulation.

5. PARLIAMENTARY PROCEDURE

- 5.1 The State Law Advisers and the Department of Health are of the opinion that this Bill must be dealt with in accordance with the procedure established by section 75 of the Constitution since it contains no provision to which the procedure set out in section 74 or 76 of the Constitution applies.
- 5.2 The State Law Advisers are of the opinion that it is not necessary to refer this Bill to the National House of Traditional Leaders in terms of section 18(1)(a) of the Traditional Leadership and Governance Framework Act, 2003 (Act No. 41 of 2003), since it does not contain provisions pertaining to customary law or customs of traditional communities.