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THE PRESIDENCY

No. 434 21 April 2009

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:–

No. 72 of 2008: Medicines and Related Substances Amendment Act, 2008.

AIDS HELPLINE: 0800-123-22 Prevention is the cure

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.

(English text signed by the President.)
(Assented to 19 April 2009.)

ACT

To amend the Medicines and Related Substances Act, 1965, so as to provide for the establishment of the South African Health Products Regulatory Authority; for the Chief Executive Officer and staff of the Authority; for the registration of medicines, medical devices, certain foodstuffs and cosmetics; for transitional measures; and for matters connected therewith.

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

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

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

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

" '**advertisement**', in relation to any **[medicine or 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 or Scheduled substance]** product, medical device or IVD, and **'advertise'** has a corresponding meaning;

" '**advisory committee**' means the advisory committee established in terms of section 4;";

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

" '**Authority**' means the South African Health Products Regulatory Authority established by section 2;";

(c) by the insertion after the definition of ''certificate of registration'' of the following 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;'';

(d) by the deletion of the definition of ''**council**'';

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

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

(f) by the insertion after the definition of ''**interchangeable multi-source medicine**'' of the following definition:

'' '**IVD**' ***(in vitro diagnostic medical device)*** means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;'';

(g) by the substitution for the definition of ''medical device'' of the following definition:

'' '**medical device**' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—

(a) intended by the manufacturer to be used, alone or in combination, for human beings for—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;'';

(h) by the insertion after the definition of ''medical device'' of the following definition:

'' '**medical device or IVD establishment**' means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;'';

(i) by the substitution for the definition of medicine of the following definition:

'' '**medicine**' means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in **[man]** humans; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in **[man]** humans, and includes any veterinary medicine'';

(j) by the insertion after the definition of ''**prescribed**'' of the following definition:

'' '**product**' means a medicine, a Scheduled substance or a cosmetic or foodstuff which contains a scheduled substance;'';

(k) by the deletion of the definition of ''**registrar**''.

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

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

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

2. (1) The South African Health Products Regulatory Authority is hereby established as an organ of state but outside the public service.

(2) The Authority is—

(a) a juristic person;

(b) subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

(c) accountable to and reports to the Minister.

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

(4) In performing its functions, the Authority shall act without fear, favour or prejudice.".

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

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

"**Chief Executive Officer and other staff of Authority**

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

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

(a) is an unrehabilitated insolvent;

(b) is mentally unfit; or

(c) has been convicted of an offence committed after the Constitution of the Republic of South Africa, 1993 (Act No. 200 of 1993) took effect and sentenced to imprisonment without the option of a fine.

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

(a) serious misconduct;

(b) permanent incapacity; or

(c) engaging in any activity that is reasonably capable of undermining the integrity of the Authority.

(4) The Chief Executive Officer—

(a) is appointed for a term of five years and may be reappointed for one additional term of five years;

(b) is appointed subject to the conclusion of a performance agreement with the Minister;

(c) is accountable to and reports to the Minister;

(d) is entitled to the benefits as may be determined by the Minister in consultation with the Minister for the Public Service and Administration;

(e) is responsible for the general administration of the Authority and for the carrying out of any functions assigned to the Authority by this Act and the Minister;

(f) must manage and direct the activities of the Authority;

(g) must appoint and supervise staff of the Authority; and

(h) must compile business and financial plans and reports in terms of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

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

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

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

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

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

(9) The Chief Executive Officer shall appoint committees, as he or she may deem necessary, to investigate and report to the Authority on any matter within its purview in terms of this Act.''.

Substitution of section 4 of Act 101 of 1965

4. The following section is hereby substituted for section 4 of the principal Act:

''**Advisory committee**

4. (1) The Minister shall establish an advisory committee to advise or act as a consultative body for the Minister and the Authority on matters concerning corporate governance of the Authority.

(2) The advisory committee contemplated in subsection (1) shall consist of not more than 5 persons who shall be appointed from persons outside the Authority.

(3) The Minister shall appoint a chairperson for the advisory committee from among the members after having consulted the members.

(4) Members of the advisory committee shall—

(a) be appointed for a term not exceeding five years, which is renewable;

(b) be fit and proper persons; and

(c) have appropriate expertise, skills, knowledge or experience and the ability to perform effectively as a member.

(5) The advisory committee shall determine procedures for its meetings.

(6) An advisory committee member who has a personal or financial interest in any matter on which the advisory committee gives advice shall disclose that interest and where the advisory committee deems it necessary withdraw from the discussions.

(7) The Authority shall remunerate a member mentioned above and compensate the member for expenses, as determined by the Minister after consultation with the Minister of Finance.

(8) The advisory committee or its members shall not interfere with the powers assigned to the Chief Executive Officer or the Authority in terms of this Act in so far as those powers relate to the safety, efficacy and quality of products, medical devices or IVDs.''.

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

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

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

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

''**Registers**

13. The Chief Executive Officer shall keep separate registers for products, medical devices or IVDs; in which he or she shall record—

(a) the registration of products, medical devices or IVDs by the Authority; and