AMENDMENTS TO THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2008

Page 2

Long title: line 3: - delete the words "certification and"
- delete the words "products which include"

Lines 11 and 19: insert after the word "product" the words: "medical device or IVD"

Lines 27 and 28: delete both lines 27 and 28

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Lines 1 and 2: delete both lines 1 and 2.

Lines 4 and 5: substitute the words "which contains a Scheduled substance" for the words "in respect of which medicinal claims are made"

Line 9: substitute the words "which contains a Scheduled substance" for the words "in respect of which medicinal claims are made"

Line 11: insert the following paragraphs before paragraph (f) and the existing paragraphs (f), (g) and (h) becoming paragraphs (i), (j) and (k) respectively:

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

"'***In vitro*** **diagnostic medical device'** ('**IVD**') 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 following definition of the definition of "medical device"

"`**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 IVD's for conducting business"

Line 13: delete the words "or medical device"

Line 14: delete the words "in respect of which medicinal claims are made".

Line 17: delete lines 17, 18 and 19.

Line 38: insert the following subsections after line 38:

(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 10993) 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.

Line 39: substitute (4) for (2)

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Line 1: substitute (5) for (3)

Line 4: substitute (6) for (4)

Line 9: substitute (7) for (5)

Line 12: substitute (8) for (6)

Line 16: - substitute (9) for (7)
- substitute the word "shall" for the word "may"
- delete the words "subject to the approval of the Minister"

Line 17: substitute the words "he or she" for the word "it"

Lines 26: insert after the word "product" the words "medical device or IVD"

Line 28: substitute the following paragraph for paragraph (a):

"(a) the registration of products, medical devices or IVD's by the Authority"

Line 29: delete line 29

Line 30: delete the word "certification or"

Line 31: substitute the word "the" for the word "or"

Lines 31 and 36: inset after the word "product" the words "medical device or IVD"

Line 37: delete the words "certification or" and "certified or"

Line 39: - insert after the word "product" the words "medical device or IVD"
- delete the words "certification and"

Line 41: delete the words "certified and"

Line 43: delete the words "with the approval of the Minister"

Line 44: substitute the words "product, medical device or IVD" for the word "medicine"

Line 45: substitute the words "products, medical devices or IVDs" for the words "medicines, a cosmetic, a medical device or a foodstuff"

Line 46: delete the words "certification and"

Lines 49 and 51: insert after the word "product" the words "medical device or IVD"

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Lines 4: insert after the word "product" the words "medical device or IVD"

Line 6: delete the words "certification and"

Line 9: delete the words "certification and"

Line 10: insert after the word "product" the words "medical device or IVD'

Line 12: delete the words "certification and"

Lines 13 and 14: insert after the word "product" the words "medical device or IVD"

Line 33: delete the words "certification and"

Line 35: delete the words "certified and"

Lines 39: delete the word "certification and"

Lines 39: substitute the following section for section 15

Registration of products, medical devices or IVD's

15 (1) Every application for the registration of a product, medical device or IVD shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by-

(a) the prescribed particulars;

(b) samples of the relevant products;

(c) where practicable, samples of medical devices or IVD's; and

(d) the prescribed registration fee.

(2) As soon as possible after receipt by the Chief Executive Officer of an application contemplated in subsection (1), he or she shall inform the applicant in writing that the application is being considered;"

(3) (a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the product, medical device or IVD in question-

(i) is suitable for the purpose for which it is intended;

(ii) complies with the prescribed requirements;

(iii) is safe and of good quality; and

(iv) in the case of products, also efficacious,

it shall issue a notice in the Gazette of its intention to register the product, medical device or IVD and invite, within 30 days from the date of publication of such notice, any objection based on public interest to the intended registration.

(b) if no objection is received within the 30 days period contemplated in paragraph (a), the Authority shall register the product, medical device or IVD.

(c) If an objection is received, the Chief Executive Officer shall inform the Minister within 14 days of receipt of such objection by the Chief Executive Officer.

(d) The Minister shall, within 30 days of being informed of an objection as contemplated in paragraph (c), convene a panel comprising three persons.

(e) The panel contemplated in paragraph (d) shall-

(i) within 30 days of being convened; and
(ii) after hearing both the applicant and the objector and any other interested persons,

decide on the objection and make recommendations to the Authority.

(f) The Authority shall after receipt of the panel's recommendations, decide on whether to register the product, medical device or IVD or not and inform the applicant and the objector, if any, accordingly.

(g) An objection is based on public interest if it is based on one or more of the following grounds:

(i) public health interest including national epidemiological trends;

(ii) economic interests in relation to health policies; and

(iii) the likelihood or otherwise of registration significantly improving access to health care for vulnerable groups within society.

(h) If the Authority is not satisfied as contemplated in paragraph (a), it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may within a period of 30 days after the date of the notification furnish the Chief Executive Officer with his or her comments on the Authority's reasons for not being so satisfied.

(i) 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.

(4) Every product, medical device or IVD shall be registered under such name as the Authority may approve.

(5) The Chief Executive Officer shall allocate to every product, medical device or IVD registered under this Act a registration number which shall be recorded in the register opposite the name of such product, medical device or IVD and which shall be stated in the certificate of registration issued in respect of such product, medical device or IVD.

(6) Any registration under this section-

(a) may be made subject to such conditions as may be determined by the Authority; and

(b) shall in the case of medicines, be valid for a period of five years.

(7) No condition shall be imposed under subsection (6)-

(a) whereby the sale of the medicine in question by any person other than a pharmacist is prohibited; or

(b) until after the applicant has in writing been notified by the Chief Executive Officer that the imposition of such condition is contemplated and invited to submit written representations to the Authority in regard to the matter.

(8) If no such representations are lodged by the applicant concerned within a period of 30 days after the receipt by him or her of any notification referred to in subsection (7), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall register the product, medical device or IVD concerned subject to the said condition.

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

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

(11) The Authority shall by way of rules determine the time frames for the consideration of applications"

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Lines 1 - 4: delete lines 1 – 4.

Line 8: insert after the word "product" the word "medical device or IVD"

Line 9: delete the words "certification or"

Lines 10 and 11: insert after the word "product" the words "medical device or IVD"

Line 22: delete the words "certification or"

Line 23: - delete the words "certification or"
- substitute the word "in" for the word "on"

- insert after the word "product" the words "medical device or IVD"

Line 27: delete the words "certification or"

Line 28: delete the words "certification or"

Line 31: delete the words "certification or"

Line 33: delete the words "certification or"

Line 40: delete the words "certification or"

Line 41: delete the words "certification or"

Line 43: insert after the word "product" the words "medical device or IVD"

Line 51: delete the words "certification or"

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Line 6: delete the words "certification and"

Line 8: delete the words "certification or"

Line 10: - delete the words "certified or"
- insert after the word "registered" the word "or"

Lines 10 and 11: insert after the word "product" the words "medical device or IVD"

Lines 13 and 14: delete lines 13 and 14

Line 16: delete the words "certification or"

Line 17: insert after the word "product" the words "medical device or IVD"

Line 24: delete the words "certification"

Line 25: - delete the word "or"
- insert after the word "product" the words "medical device or IVD"

Line 27: delete line 27

Line 28: delete the words "(b) in consultation with the Minister"

Line 29: delete the words "certification or"

Line 30: insert after the word "product" the words "medical device or IVD"

Line 31: delete the words "certification or"

Lines 32 and 34: insert after the word "product" the words "medical device or IVD"

Line 38: delete the words "certification or"

Line 40: delete the words "certification or" where ever they appear

Lines 41 and 43: insert after the word "product" the words "medical device or IVD"

Line 43: delete the words "certification or"

Line 44: - insert after the word "product" the words "medical device or IVD"
- delete the words "certified or"

Line 45: insert after the word "product" the words "medical device or IVD"

Line 46: - delete the words "certification or"
- insert after the word "product" the words "medical device or IVD"

Line 49: delete the words "certification or"

Line 50: - insert after the word "product" the words "medical device or IVD"
- delete the words "certified or"

Line 51: delete the words "certification or"