Line 52: insert after the word "product" the words "medical device or IVD"

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Lines 9 and 17: insert after the word "product" the words "medical device or IVD"

Line 21: Substitute the following section for section 18A

"**18A** (1) No person shall supply any product, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1)."

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

Line 26: Substitute the following section for section 18B

"**18B** (1) No person shall sample any product, medical devices or IVD.

(2) For the purposes of this section 'sample' means the free supply of products, medical devices or IVDs by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act No. 56 of 1974), or any professional or person authorized to use the device.

(3) Use of products, medical devices or IVD's for exhibition purposes shall be as prescribed.

Line 38: insert after the word "product" the words "medical device or IVD"

Line 39: substitute the word "shall" for the word "may"

Line 41 : insert after the word "product" the words "medical device or IVD"

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Lines 4, 6, 7, 10, 14, 22, 27, 32 and 37: insert after the word "product" the words "medical device or IVD"

Line 47: delete the words "uncertified or"

Line 48: insert after the word "product" the words "medical device or IVD"

Line 49: delete the words "in consultation with the Minister"

Line 51: insert after the word "product" the words "medical device or IVD"

Line 52: delete the words "certified or"

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Line 1: insert after the word "product" the words "medical device or IVD"

Line 4: delete the words "in consultation with the Minister"

Line 10: insert after the word 'by" the following paragraphs:

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

"**[Director-General]** Authority to cause certain information to be furnished"

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

Line 10: delete the words "the substitution for"

Line 11: delete the words "subsection (1) of the following subsection"

Lines 15, 18 and 19 insert after the word "product" the words "medical device or IVD"

Lines 20 and 21: delete the words "certified or"

Lines 21, 24 and 25: insert after the word "product" the words "medical device or IVD"

Line 28: delete the words "certification or"

Line 29: insert after the word "product" the words "medical device or IVD"

Line 31: delete the words "certification or"

Line 32: insert after the word "product" the words "medical device or IVD"

Line 33: delete the words "certification or"

Line 44: Insert after line 44 the following paragraphs

(c) by the substitution in subsection (4) for paragraph (b) of the following paragraph:

(b) to any person apparently under the age of **[14]** 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of [14] 12 years;

(d) by the substitution in subsection (6) for paragraph (e) of the following paragraph:

(e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of **[14]** 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a

licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of **[14]** 12 years;

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Lines 3 and 8: insert after the word "product" the words "medical device and IVD"

Line 13: After line 13 insert the following paragraph:

(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"

Line 14: substitute the letter (b) for the letter (a)

Line 17: insert before the word "manufacturer" the words "medical device establishment"

Line 20: insert after the word "product" the words "medical device or IVD"

Line 24: substitute the letter (c) for the letter (b)

Line 25: substitute the following paragraph for the existing paragraph

(2) A licence referred to in subsection (1)(a) shall not be issued unless the applicant has successfully completed a supplementary course determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa, **[the Allied Health Professions Council of South Africa]** and the South African Nursing Council.

Line 30: substitute the letter (d) for the letter (c)

Line Line 36: substitute the letter (e) for the letter (d)

Line 40: substitute the letter (f) for the letter (e)

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

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Line 33: insert after the word "products" the words "other than Schedule 0 substances"

Lines 43, 45, 50 and 52: insert after the word "product" the words "medical device or IVD"

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Lines 2, 5 and 8: insert after the word "product" the words "medical device or IVD"

Line 49: insert after the word "Authority" the words "except the decision contemplated in section 15(3)(f)"

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Lines 16 and 17: delete the words "and the High Court may confirm or set aside the decision of the appeal committee"

Lines 18, 19 and 20: delete the lines

Line 45 and 47: insert after the word "pharmacologists" the word "engineers".

Line 47: insert after the word "pathologists" the words "or any other appropriately qualified person"

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Lines 7, 11, 14, 19 and 27: insert after the word "product" the words "medical device or IVD"

Line 32: insert after the word "pharmacologist" the word "technician".

Lines 36 and 39: insert after the word "product" the words "medical device or IVD"

Line 44: insert before paragraph (a) the following paragraph:

(a) by the substitution for paragraph (e) of the following paragraph:

"(e) contravenes or fails to comply with any condition imposed under section **[15(7)]** 15(6)"

Line 45: substitute (b) for (a)

Line 48: insert after the word "product" the words "medical device or IVD"

Line 49: substitute (c) for (b)

Line 50: insert after the word "product" the words "medical device or IVD".

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Lines 6, 10, 18 and 25: insert after the word "product" the words "medical device or IVD"

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Line 26: insert the following paragraph before paragraph (b) and the subsequent paragraphs renumbered accordingly:

(b) by the substitution for paragraph (xii) of the following paragraph:

(xii) prescribing the particulars which shall be published in the Gazette in respect of any application for registration referred to in section **[15(11)]** 15(10)

Line 26: substitute the following paragraph for paragraph (b). Paragraph (b) must be renumbered (c).

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

"(xiii) relating to the responsibilities of both medical device and IVD establishments and users of medical devices and IVDs, in relation to the use, training, maintenance, calibration, post-marketing surveillance, sterilisation, disinfection, recall, decomposition, decommissioning or decontamination of medical devices and IVDs"

Line 30: delete the words "certification or the"

Line 31: delete the words "certification or the"

Line 32: insert after the word "product" the words "medical device or IVD"

Line 34: delete the words "certification or the"

Line 35: insert after the word "product" the words "medical device or IVD"

Line 43: substitute the following paragraph for paragraph (xxxvii):

"(xxxvii) relating to the scientific, pharmaceutical, clinical, technical or other skills required by members of staff of the Authority to evaluate the safety, efficacy and quality of products and the safety and quality of medical devices and IVD's"

Lines 47 and 51: insert after the word "product" the words "medical device or IVD"

Line 52: substitute the number (x) for the number (xi)

Lines 54: - insert after the word "product" the words "medical device or IVD"
- substitute the word "registration" for the word "certification"

Lines 57 and 59: insert after the word "product" the words "medical devices and IVD"

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Lines 8, 13,14, 15, 16, 18, 19: insert after the word "product" the words "medical device or IVD"

Line 30: substitute the number "36(1)" for the number "36"

Line 33: insert after the word "product" the words "medical device or IVD"

Line 34: insert after line 34 the following paragraph:

> (2) Notwithstanding subsection (1), the exclusion of any product from the operation of section 22G shall be on the recommendation of the Pricing Committee.

Line 46: delete the words "certified and"

Page 21 (Memorandum on the Objects of the Bill)

Item 3 (Summary)

The following paragraphs are substituted for the second and third paragraphs:

> "The Authority replaces the Medicines Control Council and the latter will cease to exist on the commencement of the Amendment Act. The Authority will comprise full time Chief Executive Officer and staff and will be responsible for the registration of products, medical devices and IVD's.
>
> Any person may object to the registration of products, medical devices or IVD on public interest grounds."

Item 4 (clause 4.5)

The following paragraph is substituted for paragraph 4.5:

" Clause 7 provides for the registration of products, medical devices and IVD's by the Authority, that before the Authority can register a product, medical device or IVD, it must first declare its intention to register such a product, medical device or IVD and afford interested persons an opportunity to object to such intended registration. Objections can only be lodged on grounds of public interest.

Once an objection is received a three member panel, each member appointed by the Minister of Health, the Minister of Trade and Industry and the Minister of Agriculture respectively, hear the objector, the applicant or any other interested person and make recommendations to the Authority and the latter still makes a decision on whether to register the product or not."

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