REPUBLIC OF SOUTH AFRICA

PORTFOLIO COMMITTEE AMENDMENTS TO

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

[B 6—2014]

(As agreed to by the Portfolio Committee on Health (National Assembly))

[B 6A—2014]

ISBN 978-1-4850-0246-8

No. of copies printed 800

AMENDMENTS AGREED TO

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL
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CLAUSE 1

1. On page 2, in line 14, after ‘‘pamphlet’’ to insert ‘‘, electronic media (including radio and television)’’.

2. On page 3, in line 2, to omit ‘‘definitions’’ and to substitute ‘‘definition’’.

3. On page 3, from line 3, to omit the definition of ‘‘biological medicine’’.

4. On page 3, from line 14, to omit paragraph *(d)*.

5. On page 3, from line 26, to omit paragraph *(e)* and to substitute:

(d) by the deletion of the definition of ‘‘cosmetic’’;

6. On page 3, from line 30, to omit paragraph *(f)* and to substitute:

(e) by the deletion of the definition of ‘‘foodstuff’’;

7. On page 3, after line 33, to insert the following paragraph:

(f) by the substitution for the definition of ‘‘IVD’’ of the following definition:

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

8. On page 3, from line 34, to omit paragraphs *(g)* and *(h)* and to substitute:

(g) by the substitution for the definition of ‘‘medicine’’ of the following definition:

‘‘ ‘**medicine**’—

(a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and

(b) includes any veterinary medicine;’’;

(h) 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]** for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)—

(a) intended by the manufacturer to be used, alone or in combination, for **[human beings]** humans or animals, for**[—]** one or more of the following:

(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, in or on the human or animal body, but which may be assisted in its intended function by such means;'';

(i) by the deletion of the definition of ''product''; and

(j) by the insertion after the definition of ''veterinary medicine'' of the following definition:

'' 'vigilance', in relation to a medicine, medical device or IVD, means the continuous monitoring and education of its safety, efficacy and performance profile and the management of any risk throughout its lifecycle.''.

CLAUSE 3

1. On page 3, from line 56, to omit ''medicines, clinical trials and medical devices and related matters'' and to substitute:

medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters

2. On page 4, in line 3, after ''evaluation'' to insert ''or assessment''.

3. On page 4, in line 5, to omit ''safety and efficacy'' and to substitute '' safety, efficacy and performance, where applicable''.

4. On page 4, in line 6, after ''evaluating'' to insert ''or assessing''.

5. On page 4, in line 9, after ''periodic'' to insert ''re-evaluation or''.

6. On page 4, in line 12, to omit ''about pharmacovigilance'' and to substitute ''with regard to post-marketing surveillance and vigilance''.

7. On page 4, from line 28, to omit subsection (3).

8. On page 4, from line 39, to omit ''pharmaco-vigilance, cosmetics and foodstuffs regulatory'' and to substitute ''vigilance''.

9. On page 5, from line 1, to omit subsection (2) and to substitute:

(2) If the Minister receives no nominations or an insufficient number of nominations within the period specified in the notice referred to in subsection (1), the Minister may either readvertise or in any other transparent manner, appoint the required number of qualified persons in terms of this Act.

10. On page 5, in line 5, to omit ''board'' and to substitute ''Board''.

11. On page 6, in line 9, to omit ‘‘entered in a book kept for that purpose’’ and to substitute ‘‘stored by such means as may be determined by the Board’’.

CLAUSE 6

1. On page 7, in line 8, to omit ‘‘, Scheduled substances’’.

2. On page 7, in line 10, to omit ‘‘, Scheduled substances’’.

3. On page 7, from line 12, to omit ‘‘, Scheduled substances’’.

4. On page 7, from line 14, to omit ‘‘, Scheduled substances’’.

5. On page 7, from line 17, to omit ‘‘every six months’’ and to substitute ‘‘when registration is obtained’’.

CLAUSE 8

1. On page 7, in line 34, to omit subparagraph (iii) and to substitute:

(iii) is safe, efficacious and of good quality**[;]** and, in the case of a medical device and IVD, performs as intended.

NEW CLAUSE

1. That the following be a new clause:

Substitution of section 18A in Act 101 of 1965, as substituted by section 15 of Act 72 of 2008

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

“Bonusing

18A. (1) No person shall supply any **[product]** medicine, 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) in consultation with the Pricing Committee referred to in section 22G.’’.

CLAUSE 15

1. On page 9, in line 13, after ‘‘practitioner,’’ to insert ‘‘veterinarian,’’.

2. On page 9, in line 28, to omit ‘‘distributer’’ and to substitute ‘‘**[distributer]** distributor’’.

CLAUSE 22

1. On page 14, in line 19, to omit ‘‘section’’ and to substitute ‘‘**[section]** sections 18A and’’.

2. On page 14, in line 19, after ‘‘be’’ to insert ‘‘effected by the Minister’’.

CLAUSE 23

1. On page 14, in line 23, to omit ‘‘22(4)*(a)*(ii),’’.

CLAUSE 25

1. On page 16, in line 1, after ‘‘(7)’’ to insert ‘‘*(a)*’’.

CLAUSE 26

1. On page 16, in line 9, to omit ‘‘2014’’ and to substitute ‘‘2015’’.

LONG TITLE

1. On page 2, in the fifth line, after ‘‘**Authority;**’’ to insert:

to require the Minister to consult with the Pricing Committee when prescribing acceptable and prohibited acts in relation to bonusing;

Printed by Creda

ISBN 978-1-4850-0246-8