**MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL**

**[B 6—2014]**

| **Clause** | **Amendments Proposed** | **Comments Department of Health** |
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| **1** | 1. On page 2, in line 14, after "pamphlet" to insert ", electronic media" | Agree |
|  | 1. On page 3, in line 2, to omit "definitions" and to substitute "definition". | Agree |
|  | 1. On page 3, from line 3, to omit the definition of "biological medicine" | Agree |
|  | 1. On page 3, from line 14, to omit paragraphs *(d)*, *(e)* and *(f)*. | Agree to omit paragraph *(d).* Do not agree to delete *(e)* and *(f).* *Need to delete reference to “which contains a schedules substance” in both instances cosmetics and foodstuff* |
|  | 1. On page 3, after line 33, to insert the following paragraph:   *(d)* 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;"; | Agree |
|  | 1. On page 3, from line 34, to omit paragraphs *(g)* and *(h)* and to substitute: | Not in agreement to omit paragraph (*g*). If omit paragraph (*g*) from Bill 6 – 2014 then the definition of product in Act 72 remains which states:  ‘**product**’ means a medicine, a Scheduled substance or a cosmetic or foodstuff which contains a scheduled substance;’  This is incorrect. If a cosmetic or foodstuff contain a Scheduled Substance it is no longer regarded either a cosmetic or a foodstuff but a medicine.  Agree to omit paragraph (*h*) |
|  | *(e)* 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 biological medicine, complementary medicine and veterinary medicine;"; | Agree to substitute definition of a medicine and to replace the word “man” with “humans” but to omit any reference to “biological medicines” and “complementary medicines” as it would imply we need to define the definitions |
|  | *(f)* 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—  *(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 body, but which may be assisted in its intended function by such means;"; an | In agreement. To type the wording ”in vitro” in italic under point (vii) |
|  | *(g)* by the deletion of the definition of "product". | In agreement. [However see point 6] |
| **3** | 1. On page 3, from line 56, to omit "medicines, clinical trials and medical devices and related matters" and to substitute:  Scheduled substances, clinical trials and medical devices, IVDs and related matters, including regulatory oversight of foodstuffs and cosmetics, | Agree, however **to ensure that the word “medicine” is included** |
|  | 2. On page 4, in line 3, after "evaluation" to insert "or assessment". | Agree |
|  | 3. On page 4, in line 5, to omit "safety and efficacy" and to substitute " safety, **[and**] efficacy and performance, where applicable". | Agree |
|  | 4. On page 4, in line 6, after "evaluating" to insert "or assessing". | Agree |
|  | 5. On page 4, in line 9, after "periodic" to insert " re-evaluation or". | Agree |
|  | 6. On page 4, in line 12, to omit "pharmacovigilance" and to substitute "post-marketing surveillance and vigilance" | Agree |
|  | 7. 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. | Agree |
|  | 8. On page 5, in line 5, to omit "board" and to substitute "Board". | Agree |
|  | 9. 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". | Agree |
| **6** | 1. On page 7, in line 8, to omit ", Scheduled substances". | Agree |
|  | 2. On page 7, in line 10, to omit ", Scheduled substances". | Agree |
|  | 3. On page 7, from line 12, to omit ", Scheduled substances". | Agree |
|  | 4. On page 7, from line 14, to omit ", Scheduled substances". | Agree |
|  | 5. On page 7, from line 17, to omit "every six months" and to substitute "when registration is obtained". | Agree |
| **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. | Agree |
| **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, Scheduled substances, 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." | Agree |
| **15** | 1. On page 9, in line 13, after "practitioner," to insert "veterinarian," | Agree |
|  | 2. On page 9, in line 19, to omit "medicine" and to substitute "a schedule 1 and higher medicine or" to read as:  (b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical devices or IVD establishment, manufacturer, wholesaler or distributor of a ~~medicine~~ schedule 1 and higher medicine or, Scheduled substance,, medical device, IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, Scheduled substance, medical devices 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. | Not in agreement. The new wording may imply that un scheduled medicines such as *“Panado”* may be manufactured in an unlicensed manufacturer. Do not have a definition of a Distributor. The comment from stakeholders i.e. PSSA that retail companies dealing in unscheduled bulk products such as “Makro” does not require a Wholesaler license. Some distributors such as ‘Makro” and “Cash and Carry” deal exclusively with unscheduled medicines. Not required that these types of distributors comply with all the SA Pharmacy requirements or obtain a license from MCC as they operate as so called retailers dealing with bulk products. [15(b), pg 9 line 18]  Need legal discussion on this matter |
|  | 3. On page 9, from line 27, to omit subsection (6) and to substitute:  "(6) No **[medical device or IVD establishment,]** manufacturer, wholesaler or **[distributer]** distributor referred to in subsection (1)*(b)* shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any **[product, medical device or IVD]** medicine, unless he or she is the holder of a licence contemplated in the said subsection. | Non in Agreement. Manufacturer, wholesaler, importer of Scheduled substances need a licence in future.  Need to discuss Section 22C |
| **22** | 1. On page 14, in line 19, to omit "section" and to substitute "**[section]** sections 18A and". | Agree |
|  | 2. On page 14, in line 20, in line 19, after "be" to insert "effected by the Minister". | Agree |
| **25** | 1. On page 16, in line 1, after "(1)" to insert "*(a)*". | Agree. However to just correct “(1)” with “(7)” |
| **26** | 1. On page 16, in line 9, to omit "2014" and to substitute "2015". | Agree |
| **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;** | Agree |
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