Parliamentary Portfolio Committee on Health (National Assembly)

Attention: Committee Secretary att: Ms Vuyokazi Majalamba

BY EMAIL: vmajalamba@parliament.gov.za

30 September 2014

THE HEALTH PRODUCTS ASSOCIATION OF SOUTHERN AFRICA

DEAR SIR / MADAM,

RE: Submission of comments on proposed amendments to the Medicines and Related Substances Amendment Bill [B6-2014] - public hearings and call for input

1) The HPA would like to thank the Parliamentary Portfolio Committee on Health (National Assembly) for the opportunity to submit comments and make recommendations in response to the proposed amendments to the Medicines and Related Substances Amendment Bill [B6-2014] ("the Bill").

2) The HPA is extremely concerned that when the Bill is read together with the General Regulations, as amended, ("the Regulations") to the Medicines and Related Substances Act NO. 101 OF 1965, AS AMENDED, ("THE MEDICINES ACT") and the portions of the Regulations that now deal with complementary medicines and certain additional Guidelines published by the Medicines Control Council ("the MCC") (during November 2013), inherent conflicts arise between the Bill and the Act, on the one hand and the Bill and the General Regulations, on the other hand; furthermore the HPA is of the considered view that the sequence of now publishing a definition of "complementary medicine" in the Bill when such a definition already exists in the General Regulations does not accord with the constitutional directions concerning the passing of legislation. Accordingly, in light of the current confusion that has been caused by the amendments already made to the General Regulations and the disparities between the Bill and the Amendment Regulations, we are of the view, which is supported by legal advice, that the process followed to date and that is proposed into the future by the legislative passing of the Bill in its current form are subject to constitutional challenge.

3) Without derogating from what is stated above in paragraph 2, we set out below further comments on the provisions of the Bill.

4) It is also noted that the proposed definition of "complementary medicine", as published in the Bill is now different to the one that has been amended for comment within a second set of proposed amendment regulations to the General Regulations, which amending regulations appear in Government Gazette No. 37995, published on 15 September 2014 ("the Amendment Regulations"):

    a. The key changes proposed by the Amendment Regulations relate to the definition of a complementary medicine ("CM") as detailed below;

    "complementary medicine" means any substance or mixture of substances that-

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council, **and**
(b) is used or purporting to be suitable for use or manufactured or sold for use -
(i) in maintaining, complementing, or assisting the innate healing power or physical or mental state, or
(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state , of a human being or animal, **and**
(c) is used-
(i) ***as a health supplement***, or
(ii) in accordance with those disciplines as determined by Council, or
(d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine;" (emphasis added).

5) The definition of a Medicine;
The HPA is of the view that the definition of a medicine is all-encompassing and should be retained. The regulations associated with the Bill should be amended to make provision for the various categories; classes or modalities of Medicine/s. This would enable definitions to be included for:
   i. Category A = Allopathic Medicines
   ii. Category B = Medicines which cannot normally be administered without further manipulation;
   iii. Category C = Veterinary Medicines; and
   iv. Category D = Complementary Medicines of all classes/modalities (including Health Supplements if these are not ideally to be incorporated under Food Law).

This then would empower amended regulations to deal with each category; class or modality in a risk-related and appropriate manner and bring consistency to the legislative framework.

6) Licensing
A major problem which needs to be addressed arises out of the link between the Medicines Act and the Pharmacy Act, the requirements for various licenses and a Responsible Pharmacist as applicant for product registration. These provisions were designed for allopathic medicines. Companies which purely market and sell CMs and which have outsourced their manufacturing and distribution functions to fully licensed operators are required to hold a manufacturing license, to employ a pharmacist and to register their office premises as a pharmacy. This absurdity could be addressed by empowering the Regulations to classify CM businesses according to the activities they conduct the class, category or modality of their products and define appropriate licensing requirements.

7) The HPA is also of the view that the inclusion of the term **"scheduled substances"** by the Amendment Regulations is problematic as Scheduled substances are not registered and cannot be controlled in the same manner as medicines if included in, for example, devices or foodstuffs. Furthermore, the HPA contends that the Schedules have been provided in order to control accessibility of products rather than to dictate how the product is registered, advertised or

marketed. The HPA further contends that this matter must be resolved in the wording of the Bill.

8) Many foods, for example, include Scheduled substances and there will be many unintended consequences, such as requiring yogurt containing Lactobacillus acidophilus or Lactobacillus bifidus (which are on the Schedule 1 list) to be sold behind a pharmacy counter or a margarine (with beta carotene containing vitamin A which is in Schedule 2) to be sold also from behind the counter in a pharmacy.

9) The **time periods** seem to be extremely long; a defined roll-out plan needs to be published for comment. Furthermore the absence of any transitional measures is of concern; the HPA believes that these should be provided for in order to allow stakeholders a period within which to achieve compliance.

10) The possible increased burden on our members due to the **"rationalisation"** of regulatory functions is of concern. Again, would it be possible for the publication of a detailed plan of rationalisation, for example how will the current Foodstuffs Directorate staff become integrated into South African Health Products Regulatory Authority ("SAHPRA"), how will the current laws pertaining to foodstuffs come under the authority of SAHPRA (amendments are needed), how will CMs be regulated by SAHPRA, how will cosmetics be regulated by SAHPRA - will there be sufficient staff for all these functions, will they be appropriately qualified and will the current legislation change to accommodate all of these changes?

11) **Insufficient funds** - would it be possible to provide details as to how funding shortfalls will be resolved?

12) It is noted that a **Chief Executive Officer** (CEO) will replace the current **Registrar**. It is the HPA's opinion that there may still be a need for experts who are technically conversant on the said subject-matter/s with which a registration of a medicine demands, whilst a CEO should assume a more managerial and operational responsibility.

13) The **inclusion of a Board** is welcomed. The HPA is of the view that there should, however, be clarity on the role of the Board, i.e. is it different from or similar to that of the MCC? Please would it be possible to provide clarity on the roles of each of the components of the proposed structures.

14) The **structure of the Board;** the HPA is of the view that provision should be made for the inclusion of at least 2 appropriately qualified CM persons on the Board.

15) In so far as the **staff component** of 200 is concerned; the HPA questions if this is sufficient for the tasks proposed? Furthermore, questions around training need to be considered.

16) The **recognition of work done elsewhere** is welcomed. However, the specific provision/s in the Bill concerning the scope of this must be clearly made.

CONCLUSION:

It would seem that the only course of action to remedy the current confused and unlawful state of the legislation governing Complementary Medicines is for the notice introducing the amendments to the General Regulations, dated 15 November 2013, to be withdrawn, the Bill finalised and then appropriate Regulations, consistent with the ultimate provisions in the Amendment Act be published for comment; thus superseding the further amendments to the Regulation, (published on the 15th of September 2014) which should be abandoned. Should this proposed course of action not be acceptable, the State Law Advisor should be approached for assistance.

We trust that our submission provides constructive suggestions and meaningful commentary. We are of the considered view, in light of what is stated above and in previous commentaries provided to the General Regulations and previous versions of the Bill, that unless the significant concerns stated above are addressed, along with detailed comments below are considered, the Bill will be subject to constitutional challenge.

The HPA is grateful to be afforded the opportunity to make an oral presentation to the Parliamentary Portfolio Committee on Health (National Assembly) during which time these and possibly other suggestions can be discussed.

We look forward to receiving your substantive reply to the contents of this document.

Yours Sincerely

NORMAN FELS
Chairman
Health Products Association

HPA DETAILED COMMENTS ON EACH BILL

HPA – HEALTH PRODUCTS ASSOCIATION OF SOUTH AFRICA COMMENTS COPY OF CURRENT PROPOSED AMENDMENT	**BILL NUMBER**	**JUSTIFICATION FOR CHANGE**	**PROPOSED WORDING OF CHANGE**
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 **[product]** medicine, Scheduled substance, 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 **[product]** medicine, Scheduled substance, medical device or IVD, and **'advertise'** has a corresponding meaning;'';	1(A)	*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	Remove the word scheduled substances from the wording.
1.(d)by the insertion after the definition of ''certificate of registration'' of the following definition: '' **'complementary medicine'** means any substance or mixture of substances that— *(a)* originates from a plant, mineral or animal; *(b)* is used or intended to be used for, or manufactured or sold for use, in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and	1(D)	*This definition of a complementary medicine is different to the one that has recently been amended within the regulations.* *Furthermore t*he proposed	• Below is the 2004; 2008 & 2011 definition as proposed by the Complementary and Traditional Medicine Stakeholders Committee & HPA – it was based on Canada, USA, Australia and UK definitions, and it was approved in 2004 by the Allied Health Practitioners, Educators, the CAMs Industry,

(c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);''; *1.(h)* by the substitution in the definition of ''medicine'' for the words following paragraph *(b)* of the following words: ''and includes any biological medicine, complementary medicine and veterinary medicine;''.		definition of a CAM is problematic, based on the following: The definition is currently drafted conjunctively, i.e. both (a) and (b) and (c) must be met in order for a medicine to be a CAM. This cannot be correct as not all CAMS (e.g. Energy Substances, African Traditional Medicines, Anthrophosophical Medicines, etc) are used "in accordance with the practice" of an allied health profession (although they may be used in the practice of such a professional). The definition should be drafted disjunctively, using "or", subject to our further comments. • Innate healing power is not the only aspect of CAMs, as such, it is recommended that either of the definitions listed to the right as proposed in 2004 and 2008 & 2011 respectively, be used. • In order to provide certainty and clarity, definitions should be	and Traditional Healers alike. **"Complementary and Traditional Medicine "** means any substance or mixture of substances which - ○ originate from plants, minerals or animals and include sarcodes, nosodes, allersodes or isodes, and ○ is used or intended to be used for, or manufactured or sold for use in the treatment, modification, alleviation, or prevention of disease, abnormal physical ○ or mental state or the symptoms thereof in humans or animals, and ○ is used in, but not limited to the classes so determined by the Council by notice in the Gazette. ○ They are complementary to the (innate) healing power of within a human being. • Below is the definition that was published in the 2008 Regulations) **"complementary and alternative medicine or substance (CAMS)"** means any medicine or substance or mixture of substances which- ○ originate from plants, minerals or animals and include sarcodes, nosodes,

		provided for each modality including; (African Traditional Medicine; Anthropososophical medicine, Ayurvedic medicine, Chinese medicine, Homoeopathic medicine, Sowa Rigpa medicine, Unani-Tibb medicine, etc.) and combination CAMs should also be provided for. • Ideally and in order to provide certainty and clarity, the line between a food and a CAM should be addressed/easily discernible, and in accordance with a decision tree. • Nutritional food supplements should ideally be excluded from the definition of CAMs/medicines altogether and/ or expressly stated to be foods or cosmetics, as the case may be.	allersodes or isodes; and ○ are complementary to the innate healing power of a human being or an animal; and ○ is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power in humans to mitigate, modify, alleviate, or prevent illness, abnormal physical or mental state or the symptoms thereof in humans or animals. • Below is the definitions that is accepted by the **World Health Organisation** ("WHO") ○ CAMs - the terms "Complementary Medicine" or "Alternative Medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system. ○ Traditional Medicine - is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis,

			improvement or treatment of physical and mental illness.
Composition of Board **2C.** (1) The Board of the Authority consists of not less than 10 but not more than 15 members appointed by the Minister. (2) Subject to section 2D, the Minister must appoint as members of the Board— *(a)* not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, pharmaco-vigilance, cosmetics and foodstuffs regulatory, clinical trials, good manufacturing practice, public health or epidemiology; *(b)* one person on account of his or her knowledge of the law; *(c)* one person on account of his or her knowledge of good governance; *(d)* one person on account of his or her knowledge of financial matters and accounting; *(e)* one person on account of his or her knowledge of information technology; and *(f)* one person on account of his or her knowledge of human resource management. (3) The Chief Executive Officer is by virtue of his or her office a member of the Board but with no voting rights.	2C	*We believe that provision needs to be made for at least **2** experts on complementary medicines within the Board of the Authority.*	Under point a to make provision for complementary medicines
10. Section 18 of the principal Act is hereby amended by the substitution for subsections (1) and (2) of the following subsections, respectively: ''(1) No person shall sell any **[product]**— *(a)* medicine or Scheduled substance unless the immediate container or the package in which that **[product]** medicine or Scheduled substance is sold bears a label stating the prescribed particulars; and *(b)* medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical, stating the prescribed particulars. (2) No person shall advertise any **[product]** medicine or Scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.''.	10	*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed*	Remove the word scheduled substances from the wording.

		amendment Bill.	
Amendment of section 22B of Act 101 of 1965, as substituted by section 23 of Act 72 of 2008 **14.** Section 22B of the principal Act is hereby amended— *(a)* by the substitution for the heading of the following heading: ''**Publication of information relating to [products] medicines, Scheduled substances, medical devices or IVDs**''; and *(b)* by the substitution for subsection (1) of the following subsection: ''(1) Notwithstanding the provisions of section 34 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a **[product]** medicine, Scheduled substance, medical device or IVD.''.		*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	Remove the word scheduled substances from the wording.
15. Section 22C of the principal Act is hereby amended— *(a)* by the substitution in subsection (1) for paragraphs *(a)* and *(b)* of the following paragraphs, respectively: ''*(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 (Act No. 56 of 1974), a licence to compound and dispense medicines, on the prescribed conditions; *(b)* the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a **[product]** medicine, Scheduled substance, medical device or IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such **[product]** medicine, Scheduled substance, medical device 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.''; and *(b)* by the substitution for subsection (6) of the following subsection: ''(6) No medical device or IVD establishment, manufacturer, wholesaler		*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	Remove the word scheduled substances from the wording.

or distributer referred to in subsection (1)*(b)* shall manufacture, act as a wholesaler of or distribute, as the case may be, any **[product]** medicine, Scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.''.			
Amendment of section 22H of Act 101 of 1965, as inserted by section 14 of Act 90 **of 1997 and amended by section 28 of Act 72 of 2008** **16.** Section 22H of the principal Act is hereby amended— *(a)* by the substitution for the heading of the following heading: ''**Purchase and sale of medicines, medical devices, IVDs and Scheduled substances by wholesalers**''; and *(b)* by the substitution for subsections (1) and (2) of the following subsections, respectively: ''(1) *(a)* No wholesaler shall purchase **[products]** medicines, Scheduled substances, medical devices or IVDs from any source other than from the original manufacturer or from the primary importer of the finished product. *(b)* A wholesaler shall— (i) sell **[products]** medicines, medical devices or IVDs only into the retail sector; and (ii) sell Scheduled substances to any person who may lawfully possess such substance. **[*(c)* Notwithstanding paragraphs *(a)* and *(b)*, a wholesaler may purchase from or sell to, other wholesalers or the public Schedule 0 substances.]** (2) Subsection (1) shall not be construed as preventing the return of **[products]** medicines, medical devices or IVDs for credit purposes only, to the manufacturer or wholesaler from which **[that product was]** those medicines, medical devices or IVDs were initially obtained.''.		*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	Remove the word scheduled substances from the wording.
Amendment of section 28 of Act 101 of 1965, as amended by section 26 of Act 65 of **1974, section 12 of Act 17 of 1979, section 16 of Act 90 of 1997, section 11 of**		*Scheduled substances are not registered and cannot be controlled in*	Remove the word scheduled substances from the wording.

Act 59 **of 2002 and section 35 of Act 72 of 2008** **17.** Section 28 of the principal Act is hereby amended— *(a)* by the substitution in subsection (1)*(a)* for subparagraph (i) of the following subparagraph: ''(i) any place or premises from which a person, authorized under this Act to compound **[and]** or dispense medicines or Scheduled substances, dispenses or handles **[products]** medicines, Scheduled substances, medical devices or IVDs or from which the holder of a licence as contemplated in section 22C(1)*(b)* conducts a business; or''; *(b)* by the substitution in subsection (1) for paragraphs *(b)*, *(c)* and *(d)* of the following paragraphs, respectively: ''*(b)* inspect any **[product]** medicine, Scheduled substance, medical device or IVD, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1)*(a)*; *(c)* seize any such **[product]** medicine, Scheduled substance, medical device or IVD, any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act; *(d)* take so many samples of any such **[product]** medicine or Scheduled substance, medical device or IVD as he or she may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.''; *(c)* by the substitution in subsection (2)*(a)* for subparagraph (i) of the following subparagraph: ''(i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such **[product]** medicine, Scheduled substance, medical device or IVD, or if there is no such person or if he or she is absent for any reason, in the presence of any other witness;''; *(d)* by the substitution in subsection (2)*(a)* for subparagraph (iii) of the following subparagraph: ''(iii) then be transmitted to an analyst, pharmacologist, technician,		*the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	

[or] engineer, scientist, pathologist or expert designated by the Authority together with a certificate in the prescribed form signed by such inspector.''; *(e)* by the substitution in subsection (2) for paragraph *(b)* of the following paragraph: ''*(b)* A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such **[product]** medicine, Scheduled substance, medical device or IVD or his or her agent.''; and *(f)* by the substitution for subsection (4) of the following subsection: ''(4) The owner of the **[product]** medicine, Scheduled substance, medical device or IVD from which the sample was taken may claim from **[the]** the Authority an amount equal to the market value thereof.''.			
Amendment of section 29 of Act 101 of 1965, as amended by section 27 of Act 65 of 1974, section 12 of Act 94 of 1991, section 17 of Act 90 of 1997 and section 36 of Act 72 of 2008 **18.** Section 29 of the principal Act is hereby amended— *(a)* by the substitution in paragraph *(h)* for the words preceding subparagraph (i) of the following words: ''makes any false or misleading statement in connection with any **[product]** medicine, Scheduled substance, medical device or IVD—''; and *(b)* by the substitution for paragraph (i) of the following paragraph: ''(i) sells any **[product]** medicine, Scheduled substance, medical device or IVD upon the container of which a false or misleading statement in connection with the contents is written; or''.		*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	Remove the word scheduled substances from the wording.
Amendment of section 30 of Act 101 of 1965, as amended by section 28 of Act 65 of 1974, section 13 of Act 94 of 1991, section 18 of Act 90 of 1997 and section 37 of Act 72 of 2008		*Scheduled substances are not registered and cannot be controlled in the same manner if*	Remove the word scheduled substances from the wording.

19. Section 30 of the principal Act is hereby amended— *(a)* by the substitution for subsection (2) of the following subsection: ''(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any **[product]** medicine, Scheduled substance, medical device or IVD in respect of which the offence has been committed to be forfeited to the State.''; and *(b)* by the substitution for subsection (3) of the following subsection: ''(3) Any **[product]** medicine, Scheduled substance, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with as the Chief Executive Officer may direct.''.		*included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	
Amendment of section 31 of Act 101 of 1965, as amended by section 29 of Act 65 of **1974, section 13 of Act 17 of 1979, section 19 of Act 90 of 1997 and section 38 of** **Act 72 of 2008** **20.** Section 31 of the principal Act is hereby amended— *(a)* by the substitution in subsection (1) for paragraph *(a)* of the following paragraph: ''*(a)* any quantity of a **[product]** medicine, Scheduled substance, medical device or IVD in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;''; and *(b)* by the substitution in subsection (1) for paragraph *(d)* of the following paragraph: ''*(d)* any statement or entry contained in any book, record or document kept by any owner of a **[product]** medicine, Scheduled substance, medical device or IVD or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him or her as an admission of the facts set forth in that statement or entry, unless evidence to the contrary which raises a reasonable doubt shows that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner		*Scheduled substances are not registered and cannot be controlled in the same manner if included in devices, foodstuffs, etc. than when included in medicines.* *This matter must be resolved in the wording of the proposed amendment Bill.*	Remove the word scheduled substances from the wording.

in the course of his or her work as manager, or in the course of his or her agency or employment.''.			

END.