141126PCHEALTH

Bill 6 of 2014 amending the Medicines and Related Substances Act, 1965 as Amended

Bill 6 is a proposed amendment of the Medicines and Related Substances Control Act 101 of 1965, as amended, and includes amendments that were made by Act 72 of 2008.

The intention of B6 of 2014 published in Government Gazette no. 37361 on 20 February 2014 is to amend the Medicines and Related Substances Act, 1965 when read together with Act 72 of 2008 and therefore intends to:

- establish a new South African Medicines Regulatory Authority (SAHPRA)
  - to provide for the establishment of a Board the so called SAHPRA board
  - to address good governance structures for running of SAHPRA
  - to provide for certain transitional matters from the current MCC structure to SAHPRA
- to allow for the regulatory oversight of Medical Devices and IVDs
- to allow for the regulatory oversight of Scheduled Substances
- to allow for the regulatory oversight of Complementary Medicines
- to delete and insert certain words in certain definitions;
- to effect certain technical corrections

During the Portfolio Committee on Health public hearings Wednesday 29 October 2014, Friday 31 October 2014 and Wednesday, 5 November 2014 representation was received from 18 stakeholders' i.e.

- *Roche Diagnostics*
- *Prof Roy Jobson*
- *Dental Traders Association of South Africa*
- *Johnson & Johnson*
- *South African Medical Device Industry Association (SAMED)*
- *Self medication Manufacturers' Association of South Africa (SMASA)*
- *Traditional and Natural Health Alliance*
- *Pharmaceutical Society of South Africa (PSSA)*
- *Pricing Committee*
- *PHARMISA*

- *Allied Health Professions council of South Africa*
- *Innovative Pharmaceutical Association of South Africa (IPASA)*
- *Doctors without Borders*
- *Regulatory Discussion Group (RDG)*
- *Health Products Association of Southern Africa*
- *MediQ Sustainable Healthcare Solutions*
- *Southern African Laboratory Diagnostics Association (SALDA)*
- *Combined COSATU and NEHAWU*

As the comments received relates mainly to either Medical Devices and IVDs, Complementary medicines, the SAHPRA Board and governance, or Scheduled Substances a matrix had been prepared addressing comments in these areas.

	Comments from Stakeholders	National Department of Health Rationale
Establishment of SAHPRA		
Roche Products Johnson & Johnson SMASA	Unclear what is meant by the legislative phrase "within public administration but outside of public service how SAHPRA could retain income and how budget shortfalls will be dealt with. The movement of staff from the current employer to SAHPRA will have labour relations implications due to the transfer of staff to a new entity.	The governance of SAHPRA will be in accordance with the PFMA with SAHPRA accountable as per the provisions of the PFMA but will be able to retain fees collected for service delivery [2, pg 3 line 47]. It is not envisaged that SAHPRA will be 100% responsible for own income. As per the SAHPRA Business plan a 70/30 financial structure with Treasury still allocating 30% budget. The NDOH is aware of the labour relations implications to move staff to the new entity, therefore the Business case on SAHPRA address the labour implications.
Roche Products	Chairman of the Board to be appointed only for 1 year with expertise rotating between medicines, Medical Devices and IVDs	Not in agreement. Rotation of chairmanship not best practices for any organisation and not in line with international best practises [2E(1) pg 5 line 15 read together with 2D (4) pg 5 line 7]
HPA Allied Health Professions Council	To amend the composition of the Board to allow for the appointment of experts (2) on complementary medicines to serve as board member. In addition the expert appointed must hold a professional qualification with the Allied Health Professional Council of SA.	Not in agreement. The composition of the Board consists of *inter alia* members with expertise in medicine. This will include a member with expertise in orthodox and complementary and biological medicine. In addition the General Regulations to the SAHPRA Act will address the skills of the Board and its Committees (See current General Regulations that address the skills of the MCC)
Roche Products SALDA	Delete definition of foodstuffs and cosmetics from the Act. SAHPRA to refrain from having regulatory oversight foods and cosmetics as it will increase the workload at SAHPRA	Not in agreement. Policy decision by NDOH that SAHPRA will be the regulatory body that have oversight over food and cosmetics in terms of the relevant defined legislation i.e. Foodstuffs, Cosmetic and Disinfectants Act, 1972 (Act 54 of 1972) [1(e) pg 3 line 27 and 1(f) page 3 line 30, 2B (3), pg 4 line 28]
Dental Traders Association	Delete reference to the Foodstuffs, Cosmetics and Disinfectants Act and that of the Hazardous Substances Act as neither the two acts give any authority to	Not in agreement. Policy decision by NDOH that SAHPRA will be the regulatory body that have oversight over food and cosmetics as well as hazardous substances in terms of the relevant defined

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Johnson & Johnson SAMED SMASA SALDA	SAHPRA to have regulatory oversight over food, cosmetics and Group III and IV Hazardous Substances. All authority remains with the Director General of Health. The reference to these products under the Functions of the Authority [2B (3), pg 4 line 28] without amending the corresponding legislation will not give the Authority sufficient power.	legislation. Matter not included in Bill 6 of 2014. [2B (3), pg 4 line 28]
SALDA	Propose to amend the Hazardous Substances Act to avoid overlap between the Medicines Act requirements and the Hazardous Substances Act on matters governing electro-medical and radiation devices	The intention of the Medicines Act is not to regulate electro-medical radiation devices.
SMASA	Not in support of SAHPRA Committees evaluating cosmetics and foodstuffs	Not in agreement that SAHPRA will evaluate foodstuffs and cosmetics. A misunderstanding from stakeholder. This activity will remain with the Units dealing with food and cosmetics [2B (3), pg 4 line 28].
SMASA	Stakeholders to be allowed to comment on the current Regulations that address the new regulatory requirements in terms of B6 of 2014 such as General Regulations that address Medical Devises and IVDs, Labelling and Advertising of Food, General Regulations on Complementary Medicines.	Comment period on these General Regulations are open except for Medical Devices which closed on July 2014.
Johnson & Johnson Dental Traders Association SAMED SMASA	To include timelines for the process of evaluating and registering a medicine, Medical device and IVD in the General Regulations as the life cycle of medical devices is very short as long time lines for the registration could find that the medical device is obsolete by the time of registration.	Act 72 of 2008 Section 35(1)(xl iii) makes provision for time frames for the consideration of an application by the Authority. Also Section 15(2)(b) To address in General Regulations. [2B (1)(b), pg 4 line 8] In addition the General Regulations on Medical Devices and IVDs address "Fast Track" registration of medical devices and IVDs

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IPASA SALDA Doctors without Borders PHARMISA		
IPASA	To include a definition for "prescribed ethical and professional criteria and defined standards"	Not in agreement. This section relates to the evaluation of clinical trial protocols and the conduct of a clinical trial. The Guidelines on Good clinical Practises include ethical and professional criteria for the conduct of trials. [2B(1)(f), pg 4 line 17]
IPASA	Propose the following heading for Section 3 : "Appointment of Chief Executive Officer"	Not in agreement. Heading included that states "Chief Executive Officer and other staff of the Authority"
SMASA SALDA	To include an abbreviated and expedited registration process with the recognition of work done by other national regulatory authorities.	Not in agreement to add to main Act. The General Regulations (Regulation 5) makes provision for an Expedited registration process and under Functions of the Authority [2B(2)(a)] provision is made to liaise with other national authorities to allow exchange of information..
Dental Traders Association	The functions of SAHPRA and the provision to liaise with other regulatory authorities must be imperative therefore the word "may" must be changed to "must"	Not in agreement. It remains the prerogative of SAHPRA to seek assistance from other national regulatory authorities. [2B(2)pg 4 line 19]
Johnson & Johnson	Transitional arrangements for staff administering the Food Act and the Hazardous Substances Act to move to SAHPRA are not supported by any amendment to the two Acts and therefore no legal framework exists for the transition.	Not in agreement. It remains the view of NDOH that SAHPRA will have regulatory oversight over the duties and functions of staff members administering these two Acts. In addition the transitional arrangements addressed in the Act allows the Minister to transfer staff to SAHPRA Sect 25(3)(a) pg14, line 50
Johnson & Johnson	Propose that all operational functions within SAHPRA relating to the different categories of products to be dealt	In agreement. The Business plan of SAHPRA addresses the matter.

	Comments from Stakeholders	National Department of Health Rationale
	with have designated staff, technical committees etc	
Johnson & Johnson SAMED SMASA SALDA	It is questionable why the registration of a medicine or medical device or IVD can be refused if it is the opinion of SAHPRA that the registration is not in public interest.	At the time of the existence of the medicine Act the registration of a medicine will only be approved if it is in public interest. This requirement has stood the test of time With the drafting of Act 72 of 2008 this section was omitted. Bill 6 of 2014 corrects the omission [9 (c), pg 7 line 48]
SAMED SALDA	The proposed structure funding and independence of SAHPRA does not support the regulatory oversight of Medical Devices and IVDs. Propose to have separate and different regulatory processes, separate staff allocation with different skills, separate Committee structures etc.	No reference or suggestions provided. However, in agreement that regulatory pathway for Medical devices and IVDs is different from that of medicines. The proposed operational structure of SAHPRA is addressed in the SAHPRA Business Case which includes different Committees and staff. Not appropriate to address operational matters in legislation.
SAMED	Criteria for Medical Device and IVDs are as per the evaluation requirements for a medicine	No reference or reasons for comment provided. Not in agreement as the criteria for evaluation of Medical Devices and IVDs will be addressed in the Guidelines on Medical Devices
SAMED SMASA HPA SALDA	Proposes that separate Registrars be appointment with technical expertise that deals with medicines, Medical Devices and IVD, cosmetics and foodstuffs. s	The Operational structure of SAHPRA is outlined in the SAHPRA Business Plan which makes provision for the different Units to report to the CEO.
IPASA	Propose to include a definition for Registrar and Chief Executive Officer	Not in agreement. The responsibilities of the Chief Executive Officer are listed in Section 3 [3(4), pg 6 line 35-45]. The role of the Registrar is obsolete.
SMASA	Proposes that the composition of SAHPRA and the different Committees be identified. In the event that the	The composition of the Board is already defined in legislation [2C(2), pg 4 line 38-45]. Board will identify so many Committees

	Comments from Stakeholders	National Department of Health Rationale
	Board is required to register a medicine, Medical Device or IVD, non technical members on the Board may out vote the technical members.	as necessary. This allows the Board the prerogative to increase the number of Committees depending on the expertise needed. [Section 22H, pg6 line 19]
SMASA	Proposes to amend the requirements to update the medicine, Medical Device and IVD registers as soon as registration is made and not only every six months to allow for transparency.	Agree that the registers should be updated when any medicine, Medical Device ort IVD is registered.[13 (2), pg 7 line 17]
Doctors without Borders	Propose to amend Section 22 to require SAHPRA to publish on receipt of an application for registration the name of the medicine, expected price, and date of submission.	Not in agreement. Section 22 not part of Bill 6 of 2014, however many generic applications are received and will be processed by the Authority while the Innovator product is still under patent.
Doctors without Borders	To amend Section 21 to allow the Department of Health and a NGO to apply for the use of an unregistered medicine solely on price.	Not in agreement. Section 21 not part of Bill 6 of 2014, however mandate of the Authority is to protect patients against the use of substandard medicines. This is done by ensuring that medicines comply with safety, quality and efficacy. Price cannot be considered as the reason for the Authority to authorize the use of an unregistered medicine as the Authority has no information relating to safety, quality and efficacy.
Doctors without Borders	To amend Section 15C(a) of the principle act, to require SAHPRA to review and examine all new pharmaceutical patents	Not in agreement. Section 15C(a) not part of Bill 6 of 2014, however the mandate of the Medicine act is to protect patients against the use of substandard medicines. This is done by ensuring that medicines comply with safety, quality and efficacy. Challenges to patents are not part of the mandate.
Doctors without Borders	To expand mechanism where the findings of another stringent national medicines regulatory authority can be utilised	Not in agreement. Section 2B(2)(a) pg 4, line 20 that deals with Functions of the Authority addresses the recognition of other national regulatory authorities. The Authority will expand on the mechanism and operational actions in appropriate guidelines.

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Medical Devices and IVD		
Roche Products SMASA IPASA	Update the definition of Medical Device and IVDs to be in line with the international definition as adopted by the International Medical Device Regulatory Forum IMDRF	Agree to update definition. IVD definition was drafted in 2008 and included in Act 72 of 2008. During drafting it complied with the then international definition for IVDs. The International Medical Device Regulatory Forum (IMDRF) updated the definition in 2012. (ref. : GHTF/SG1/N071:2012).
SALDA	To include a definition for IVD	Definition for IVD included under Act 72 of 2008.
SMASA	Include a definition for "Borderline Medical Devices" to prevent the erroneous classification of a Medical Device as a medicine	Definition for "Borderline Medical Device" to be included in the Guidelines on Medical Devices as the intention of a guideline is to clarify matters.
Roche Products SMASA IPASA	To amend the Objectives of the Authority to include reference to IVD, Scheduled substances, disinfectants and a section stating "regulatory oversight of foodstuffs and cosmetics"	Agree to include reference to IVD, Scheduled substances as well as regulatory oversight of foodstuffs and cosmetics. [2A, pg3, line 56]. Not to agree to include reference to "disinfectants" as the SABS has been mandated to have regulatory oversight of "disinfectants". *(disinfectants is regarded a product used on dead surfaces to clean).*
Roche Products	Functions of the Authority should refer to Medical Devices and IVDs being evaluated for performance and not efficacy as in the case of a medicine	Agree to change wording to be clear that Medical Devices and IVDs should demonstrate performance [2B(1)(a), pg 4 line 5]
Roche Products	Functions of the Authority: Not to allow the Authority to re-assess any registration of a medicine, Medical Device or IVD	A number of national regulatory authorities worldwide have included the requirement to re-assess any registration with the view to ensure that the information on the product is current [2B(1)(c), pg 4, line 10]
Roche Products	Function of the Authority: to replace the word pharmacovigilance with post-marketing surveillance and vigilance	Agree to change the wording as post marketing surveillance and vigilance refer to both medicines, Medical Devices and IVDs. The term "Pharmacovigilence" could be regarded restricted to medicine

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		[2B(1)(d), pg 4, line 12
Roche Products SALDA	To note that clinical trials are not performed on IVDs but "pre-market clinical performance studies for an unregistered IVD"	The Guidelines on IVDs will clarify the reference to a clinical trial in the event of an IVD as a "pre-market clinical performance studies for an unregistered IVD" [2b(1)(f), pg 4, line 15
Roche Products	Registration of a Medical Device and IVDs the Authority need to consider performance and not efficaciousness as in the case of a medicine	Agree to change wording to be clear that Medical Devices and IVDs should demonstrate performance [8(a)(iii) pg 7 line 34]
Roche Products SAMED SMASA SALDA	Section 35 that deals with the various enabling regulations must separate requirements for medicines from Medical Devices and IVDs as not all sections is applicable to both medicines, Medical Devices or IVD.	Not in agreement to separate the requirements for medicines, Medical Devices and IVDs. It is practise that enabling Regulations applicable to medicines, Medical Devices or IVDs are prepared as per the requirements of Section 35. Separate sets of Regulations for medicines and Medical Devices and IVDs are available.
Roche Products SMASA SALDA	Requires transitional arrangements for the registration of Medical Devices and IVDs in the legislation as well as foodstuffs and cosmetics.	Not in agreement to include transitional arrangements in the main legislation. As with previous experience when medicines were called up for registration, the callup process will be handled through Government Gazette notices in a staggered approach while allowing so called grandfather medical Devices and IVDs on the market. In addition, it is not the intention of SAHPRA to register foodstuffs and cosmetics.
Dental Traders Association	To include the definition of "family of Medical Devices" in the Act	Not in agreement to include the definition in the main Act but to include in the General Regulations addressing Medical Devices
Dental Traders Association SMASA	To delete reference to the control of Medical Devices when it contains a Scheduled substances as per Section 22A.	Not in agreement. Many combination medical devices which consists of a device that incorporates a pharmaceutical product is already registered by the MCC i.e. an estragon implant which contains a Schedule 4 substance. The principle /primary use of the combination product will determine the status of the product

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		either as a medicine or Medical Device [13 (a) pg 8 line 40]
Dental Traders Association Johnson & Johnson SAMED SALDA	Request that Section 22H that deals with the sale and distribution of Medical Devices be amended to allow for keeping of a consignment of devices, importation of devices by different importers and for any importer to directly distribute Medical Devices and IVDs. Often more than one importer will import the same Medical Device or IVDs.etc.	All importers of Medical Devices or IVDs will be licensed by the Authority. The Wholesaling and distribution practise of Medical Devices and IVDs will be addressed in the Guidelines on Wholesaling and Distribution. .[16(a), pg 9 line 35]
PSSA	Amend Section 22H(1)(b) to allow for the export of medicines and medical devices or IVDs as current inscription does not allow exports.	Not in agreement. Current inscription does not prohibit export by Wholesalers provided that an export license in terms of Section 22C(1)(b) has been obtained. [15, (1)(b), pg 9 line 17]
SMASA	To clarify under which circumstances medicine and Medical Devices or IVDs may be returned to the Wholesaler.	Not in agreement. To include in Guidelines
SAMED	Proposes that an abbreviated registration process, recognition of registration by other national regulatory authorities and listing of devices according to classification risks be included in the main Act.	The Requirements are addressed in the Regulations on Medical Devices and IVDs and the corresponding Guidelines. Section 2B(2)(a) pg 4, line 20 that deals with Functions of the Authority addresses the recognition of other national regulatory authorities
MEDI-Q	Propose that the concept of remanufacturing of single use medical devices to allow the reuse of these devices be addressed in the Bill which will lead to cost reduction, infection control and environmental care.	Not in agreement to include in the main Act. Requirements for Single Use medical devices and reuse of Medical Devices are addressed in the proposed General Regulations on Medical Devices and IVDs as well as in Guidelines on Medical Devices.
Complementary medicines		
Roy Jobson	To delete the definition of a Complementary medicine from the Act and replace it with a new proposed	In agreement to delete the definition of Complementary medicine from the Act and include the definition in the Regulations to the

	Comments from Stakeholders	National Department of Health Rationale
SMASA IPASA RDG HPA Allied Health Professions Council of SA (AHPCSA)	definition as published on 15 September 2014 as an amendment to the General Regulations. Also the current definition does not mention treatment of disease, exclude certain complementary medicines i.e. Veterinary complementary medicines, disciplines not controlled by the AHPCSA such as Traditional African Medicines	Act. Complementary medicines are regarded a sub specie of a medicine. The definition of a medicine is included in the Act. As Complementary medicines can over time include more alternative therapies it would be appropriate to include the definition in the Regulations [1(d), pg 3, line 16].
SMASA	To include definition of "Food supplement" to legislation	In agreement that "Food supplement" be defined. As food supplement could be regarded as either a sub spesie of food or that of a complementary medicine it has been included in the Guidelines on Food supplements. These products contain Vitamins and or Minerals to supplement a diet in a non therapeutic dosage.
Scheduled substances		
Roche Products SAMED SMASA PSSA HPA	Scheduled substances are not registered. Only medicines, Medical Devices and IVDs would be registered. Delete the requirement to keep a register for Scheduled substances not applicable	Agree to change. Inclusion was in error. [13(1)(a), pg 7 line 8 and 9]
HPA	To delete the control of Scheduled substances from various sections of the proposed Bill.	Not in agreement. Scheduled substances form the basis of the Medicines Act. As per the definition of "Scheduled substances" in

	Comments from Stakeholders	National Department of Health Rationale
		the current act, it includes medicines and scheduled substances
Roche Products	Reference to control Medical Devices and IVDs containing Scheduled substances in terms of Section 22A and Section 18 be deleted	Not in agreement. Section 18 deals with the requirements on labelling and advertising of Medical Devices and IVDs as well as scheduled substances. Regulations in this regard are necessary to allow appropriate labelling of Medical Devices and IVDs. [10, pg 8, line 7] Section 22A deals with who may sell scheduled substances, to whom and under which circumstances. Not in agreement to delete the requirements that Medical Devices containing a Scheduled substance to be sold on the open market. Many combination medical devices may contain an antibiotic or narcotic which may not be sold on the open market. [13, pg 8, line 40]. In agreement that the reference to IVDs containing a scheduled substance be removed as the amount of the scheduled substance in an IVD will be neglectably small. [13, pg 8, line 40].
Johnson & Johnson SAMED	Reference to control Medical Devices and IVDs containing Scheduled substances under Section 22A is inappropriate. In addition, no prescription is issued by a medical practitioner for a Medical Device	Not in agreement. Combination medical devices are often prescribed by medical practitioner i.e. Asma inhalers which contain a Schedule 3 or Schedule 4 substance
SMASA	To delete reference to "Scheduled substances" in the definition of an advertisement.	Not in agreement. The definition of advertisement has always contained reference to "scheduled substances". Act 72 of 2008 replaced the wording "medicine and Scheduled substances" with "product". With Bill 6 of 2014 the legislation reverts back to the original inscription. [1(a), pg 2 line 11]
SMASA	To expand the definition of advertisement to include reference to current communication media as well such as websites and electronic platforms.	In agreement. The definition of advertisement only refers to information appearing in newspapers, magazines, pamphlets or other publications. In today's electronic environment electronic media should also be included. [1(a), pg 2 line 14]

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Pricing Committee PHARMISA	To amend the requirements for obtaining exemption of a medicines, Medical Device or IVD from bonus and pricing control from SAHPRA but provide for the obtaining of the exemption from the Pricing Committee to the Minister	In agreement. SAHPRA to consider the request for exemption. SAHPRA mandate is quality, safety and efficacy not pricing. [22 (2), pg 14, line 19]
Pricing Committee	To amend the section on Bonus to include the input from the Pricing Committee and to replace the word "product" with medicine and Scheduled substance as per the correction of Bill 6 of 2014.	In agreement. Mandate of the Pricing Committee is to pronounce on marketing, bonusing and pricing matters and advise the Minister accordingly.
Miscellaneous		
Roy Jobson	To include the definition of the Advertising Standard Authority as the current MCC approves the ASA Code of Advertising practices	Not in agreement. The MCC and in future SAHPRA is only a stakeholder that submits comments to the ASA on its ASA Code of Advertising practices.
Roy Jobson	To include a sub section under Section 18C Marketing of Medicines to state that advertising of medicines forms an integral component of marketing of medicines	This section does not form part of the Bill 6 of 2014. In addition it is the understanding that advertising of medicines includes marketing. In terms of Section 18C a Marketing Code is available that deals with various marketing practises.
Roy Jobson RDG	The definition of a biological medicine is ambiguous and should be deleted	In agreement to delete the definition of Biological medicine from the Act and include the definition in the Regulations to the Act. Biological medicines are regarded a sub specie of a medicine. Definition to be listed in the Regulations or the Guidelines on Biological medicine prepared by the MCC / Authority [1(c)pg 3, line 3]
RDG	Propose that the existing definition in the Act should remain. Delete reference to complementary medicines and biological medicines and include the definitions under the General Regulations	In agreement. [1(h)pg 3, line 37]

	Comments from Stakeholders	National Department of Health Rationale
Roy Jobson IPASA	To include a definition for "Biosimilars" in the Act as the Biosimilars is regarded so called interchangeable "generic" biological mediicnes	Not in agreement. The MCC/Authority include the definition of a Biosimilar in the Regulations or Guidelines on Biological medicine prepared by the MCC/Authority. In addition the definition of Biological medicine will be removed from the main Act and included in the General Regulations
Roy Jobson	To include various new definitions in the legislation i.e. definition for "cosmeceuticals" and functional foods" and "nutritional supplements" and "health supplements"	Not in agreement. The Medicines Act deals with the regulatory oversight of medicines. The Foodstuffs, Cosmetic and Disinfectant Act deals with the regulatory oversight of foods, cosmetics and disinfectants. Not acceptable to introduce a grey definition in legislation that intends to mix a medicine with a food. These concepts may be included in Guidelines prepared by the Authority to clarify any misunderstanding
Roy Jobson	To amend the definition of a medicinal claim and that of medicine	Not in agreement. Both the definition of a medicinal claim and that of a medicine have stood the test of time. The proposed amendment to the definitions may cause uncertainty in interpretation.
Roy Jobson	To amend Section 20 that deals with false and misleading advertisements to allow better drafting.	Not in agreement. Current drafting does not allow misinterpretation. Amendment not included in Bill 6 of 2014.
PSSA	To include the requirements that veterinarians intending to compound and dispense medicines obtain a license from the Director-General	In agreement. Veterinarians compound and dispense veterinary medicines. Experience has shown that veterinarians lack knowledge on compounding and dispensing of medicine although previously it was claimed that the pre graduate Curriculum for veterinarians include training on compounding and dispensing. [22C (1)(a), pg 9 line 11]
Allied Health Professionals Council of SA (AHPCSA)	To delete the word "supplementary" from Section 22C (2) that prescribe the requirements to obtain a dispensing and compounding license by any non pharmacist that intends to perform these functions. This will allow the SA Pharmacy Council to use discretion in	In agreement. SAPC should define the need to undergo a supplementary course for each category of professional's i.e. medical practitioner, nurse, practitioner, veterinarian etc that intends to dispense and compound a medicine, based on the

	Comments from Stakeholders	National Department of Health Rationale
	accreditation of courses aimed at practitioners that has already completed courses as part of the primary medical qualification.	courses completed as part of the primary qualification.
PSSA	To subject veterinary medicines to the regulatory requirements of the Pricing Committee	Not in agreement. NDOH policy not to subject veterinary medicines to price control. Also section 22G not part of Bill6 of 2014.
PSSA	Proposal that retail companies dealing in unscheduled bulk products such as "Makro" does not require a Wholesaler license.	In agreement. 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]
PSSA	Typographical error on the spelling of "distributer"	In agreement. Correct typographical error on the spelling of "distributer".[15(b)(6), pg 9 line 28]
Johnson & Johnson	Request that a comprehensive regulatory impact assessment be undertaken and that all related legislation be reviewed.	Noted.
SAMED SALDA	Proposed that a transitional plan be tabled at the Portfolio Committee	Business case for SAHPRA includes a transitional plan
HPA	Propose to publish a rationalision plan for SAHPRA to address the incorporation of the Food Directorate within the NDOH into SAHPRA.	Business case for SAHPRA includes a comprehensive rationalisation and transitional plan
COSATU and NEHAWU	Support the establishment of SAHPRA and the broader control of products that it provides for. Does not support political interference.	Noted.