NATIONAL Dept of Health Responses to ISO9 22SC SOCIAL (Feb)

NEGOTIATING MANDATES MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B6B-2014] COMMENTS AND QUESTIONS FROM THE MEMBERS OF COMMUNITIES DURING THE PUBLIC HEARINGS		
Provincial legislator	**Comments from Stakeholders**	**National Department of Health Rationale**
GAUTENG	The consequences put in place for cases wherein there is resistance to be licensed whilst selling medication. What measures are in place to ensure that there is compliance?	The Medicines Act provides for Offences (Section 29) and Penalties (Section 30). A person not willing to be licensed will be liable in terms of Section 29 and section 30
	The integration of traditional medication into the current process, as well as intensive research on the matter	Medicines containing African traditional ingredients being sold for commercial purposes will be subjected to the medicines act for registration. ATM prescribed by the African Traditional Healer will be controlled in terms of the proposed Traditional Health Practitioners Act, Act 22 of 2007 which intends to regulate the product, the practitioner and the practise of the Traditional Healers.
	The regulation of addictive medication since it is not covered by the proposed amendments to the Bill.	All narcotic medication that may be regarded addictive medicines are already controlled as Schedule 6 or Specified Schedule 5 medicine in terms of the Act. Access to these medicines and healthcare oversight is controlled in terms of Section 22A of the Act.
	The purpose of cheaper medication is common in society due to the economic factors surrounding the communities. Thus regulation of cheap acne or pimple medication sold on the streets should be taken into consideration by the Bill.	The Medicine act prohibits the sale of any medicines on the streets. Acne and pimple creams are sometimes regarded by the communities as cosmetics. The Cosmetic Act prohibits certain substances to be included in any cosmetic such as mercury or hydroquinone with the Medicines Act classifying hydroquinone containing medicines in certain Schedules.
	The lack of implementation of all relevant Medical Acts is a serious concern within the society since there is still shortage of medication being experienced in most health establishments.	Shortage of medicines is not addressed by the Medicines Act. Shortage has various reasons which may include the inability of the medicine manufacturer not being able to deliver medicines due to certain quality problems, financial problems etc.
	What is the intention of the Department to look deeper into the issue of side effects, through extensive research, especially side effects caused by HIV/AIDS Medication?	The Medicine Act requires all manufacturers to report any side effects to the MCC. MCC collects all these reports and send it to the WHO in Upsala, Sweden. By collecting all the data on side effects caused by a certain medicine, the MCC may cancel the registration of these medicines, or may add additional warnings to the medicine labelling or may limit the use of the medicine to certain patients. This is happening continuously such as in the case of some slimming agents containing "*Sibutramine*" where MCC cancelled the registration of these products due to side effects out weighing the benefit to patients.

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WESTERN CAPE	To substitute the wording on pg 2, line 7 of the long title of the Bill with the wording: "to replace the words "product" and "products" wherever they occur with the words "medicine" and "medicines" respectively, or to replace the word "product" with the expression "medicine, Scheduled substance" as the case may be, in order to correctly reflect the subject matter of the said Act	Proposed technical corrections to the wording in the title of the Act Bill is noted
	On page 5 line 25 after "or" to insert ","	Proposed technical correction is noted
	To correct the numbering of the sub clauses throughout the clause in that sub clause (2) is duplicated on pg 15 in line 12 and 21e	Proposed technical correction is noted
	The Bill was initially published in 2012, whereupon comments were submitted and substantial changes were made to the Bill. The substantially changed Bill was not published for comment, and the Committee is concerned that there may have been inadequate opportunity for the public to comment on that version of the Bill.	The intention of B6 of 2014 was published in Government Gazette no. 37361 on 20 February 2014. 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. It is the view of the Department that the hearings gave sufficient opportunity for the public to comment on the Bill. In addition the amendments made to the Bill were not substantial but related to technical corrections and clarification.
	Medical devices and in vitro diagnostics are not registered in South Africa. The Committee is of the view that registration of these devices is of great importance to patient safety and that registration and control of these items are necessary. The Committee is concerned that the Medicines Control Council may not have the capacity to review these items for registration.	Regulation to the Medicines Act on the control of Medical Devices and IVDs was published in 2014 with a second set of Regulation published on 14 July 2015 for public comment together with various Guidelines (5 sets of Guidelines) on the proposed regulatory oversight of Medical Devices and *IVD*s. This will allow for a staggered review of Medical Devices and *IVD*s based on a risk approach.
	The draft MRSA 101 General Regulations of 1965, relating to medical devices and in vitro diagnostic medical devices, makes provision for transitional arrangements with a phased-in approach to registration. It is *imperative* that adequate time and resources be allocated to implementation.	The Department accepts that the implementation of the regulatory oversight of Medical Devices and *IVD*s can only be done in a staged approach ensuring adequate financial and human resources.

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	Careful *consideration* must be given to the implications of these provisions, and cognisance must be given to existing medical devices that cannot be readily replaced in the event that they are not registered within the required time frames.	The proposed Regulations and Guidelines that will address the regulatory oversight of Medical Devices and IVDs address the availability of existing Medical Devices and the sale of new Medical Devices that will come onto the market.
	The Committee is concerned about the budgeting and staffing of the new entity (SAHPRA) and about the potential financial impact on the Provincial Budget Allocation. The Province recommends thorough consultation with provincial governments on the budget and resources of the South African Health Products Regulatory Authority (SAHPRA).	The Department has been receiving budget from National Treasuruy for the work of the MCC. In addition, the Department has been collecting fees for the registration and regulatory oversight of medicines since 2003. These fees are being transferred to National Treasury. The proposed budget of SAHPRA will call for the ring fence of these fees together with the annual budget process. No impact on the provincial Budget allocation is foreseen.
KWAZULU NATAL	Definition of **Inspector** be amended to be specific on qualification of the inspector as the Medicines Act only provides that the Director-General may authorize persons as inspectors	The qualification of an inspector is as per the Departmental HR policy and requires a person with a natural science degree and experience in a specific area of either medicine manufacturing, wholesaling, conduct of clinical trials, or alternative a law enforcement inspector with qualification as an environmental officer (importation), law, etc.
	It is proposed that as the deletion of "cosmetic" and "foodstuff" indicates that these will be regulated under the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972, this Act must be amended to make it more robust to cater for the regulatory shift	Cosmetics and Foodstuffs have always been regulated in terms of the Foodstuffs, Cosmetics and Disinfectants Act 54, 1972.
	It is proposed that clause 1(g) which defines "medicine" must include traditional medicine, supplementary medicine, complementary medicine and alternative medicines	African traditional medicines will be regulated in terms of the African Traditional Health Practitioners Act, 2007 with complementary and alternative medicine to be regulated in terms of the Medicines Act. The definition of complementary medicine is included in the Regulations to the Medicines Act.
	Clause 2 C: the composition of the Board must include a person who has expertise in traditional healing	The African Traditional Health Practitioners Act, 2007 will regulate the Traditional healer, the practice of the traditional healer, the product/medicine that the Traditional healer will prescribe and the conduct of the Traditional Healer.

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	Clause 21: The Minister must be given powers to dismiss a member of the Board without dissolving the Board	Section 2F of the Bill deals with disqualification of a member from membership of Board and vacation of office. This section allows the Minister to dismiss a member without dissolving the Board.
	Clause 26(3) the transfer of various employees into a "central agency" which is SAHPRA must exclude the transfer of the Food Safety Directorate staff to the Agency as these functions have been deleted in the Bill.	Noted and agreed. Omission to delete the Food Directorate. To correct the inscription.
	The KZN local government proposed that the local authorities' role be considered in the Bill as they consider themselves to be well resourced and are the sphere of government closest to the people and more attuned to local development.	Noted
NORTH WEST PROVINCE	Section 2C that representation of Religious groups and Traditional Healers to form part of the Board	Religious Groups and Traditional Healers will be addressed in the African Traditional Health Practitioners Act, 2007
	Section (D) appointment of Board members to include representation from all Provinces	The Board will be responsible exclusively for governance of SAHPRA which will include oversight of financial statements, performances etc. Regulations of medicines and Medical Devices / *IVDs* is of national importance
	Proposal that Traditional medicines to be regulated, controlled and tested by the Department of Health	Medicines containing African traditional ingredients being sold for commercial purposes will be subjected to the medicines act for registration. ATM prescribed by the African Traditional Healer will be controlled in terms of the proposed Traditional Health Practitioners Act, 2007 which intends to regulate the product, the practitioner and the practise of the Traditional Healers.
	A portion of licensing fees to be retained by SAHPRA to ensure self-sustainability	Fees collected by SAHPRA will be retained as per the proposed business model of SAHPRA with additional funding from National Treasury for purposes of addressing the deficit to run the regulatory authority.
	The North West Provincial Legislature votes in favour of the Bill with proposed amendments.	