SAMED SUBMISSION ON AMENDMENT BILL B24-2011 OFFICE OF HEALTH STANDARDS COMPLIANCE

8 March 2012

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The Chairperson of the Portfolio Committee on Health
Dr. MB Goqwana
Private Bag x 9070
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Dear Dr. Goqwana

SAMED Submission on National Health Amendment Bill

1. Established in 1985, the South African Medical Devices Industry Association - SAMED - is recognized as a valuable participant in the healthcare industry. The Association which promote, represents and safeguards the interests of the South African medical devices and In-Vitro Diagnostics industry focuses on healthcare matters relevant to its members' interests.

2. SAMED supports all initiatives aimed at securing better health outcomes through the implementation of quality initiatives, such as the Office of Health Standards Compliance.

3. SAMED's main concern on the Amendment Bill B24-2011 ("the Amendment Bill") relates to the standards to be set on medical device manufacturers and importers through a regulatory framework still to be enacted in terms of amendments to the Medicines and Related Substances Act No 101 of 1965 and the Amendment Act No 72 of 2008, thereto. As these standards are to be set according to a different legal framework, but as medical devices are used in health establishments under the norms and standards to be enforced by the OHSC, there is a considerable risk of inadvertent overlaps or duplication.

4. Internationally, medical device manufactures and local responsible parties are responsible for the "safety and performance" of medical devices. In addition, the manufacturer / importer are responsible to ensure that the users of the medical device is sufficiently informed and/or trained to use the device successfully.

   Thereafter the responsibility shifts to the health establishment and healthcare professionals to ensure appropriate use, proper maintenance, proper processes of supply chain management, etc.

   In both systems quality management and quality assurance (as is mentioned in the proposed amendment in the form of section 79(f) in the Bill) appear, but the standards employed in each, and the responsibilities and implications are very different. Care should therefore be taken to ensure that general statements such as those containing general phrases that could have different meanings in different contexts are clarified in the law, so as to prevent application to the wrong situations.

5. The “harmonization” of possible conflicting provisions, such as those under the Health Professions Act for the professional users of devices, and standards applied by the OHSC should be better delineated, in the interest of effective enforcement, by section 79.

6. The independence of the OHSC is not guaranteed in the Bill. The OHSC seems to be strongly linked to the office of the Honorable Minister of Health, both on reporting to Parliament and in the work of the Ombud, who would have to make recommendations to be implemented by the CEO or the Minister. The fact that the Minister will prescribe standards without any mechanisms for public or expert input is of concern.

7. Judging the OHSC according to the Core Standards for Health Facilities, a document released in 2011, the OHSC will be setting norms and standards relating to patient safety and the so-called “support services” which includes various aspects implying or directly referring to medical devices / equipment / technology. It has to be very clear where the duties of manufactures end, and that of health establishments, begin. The standards that are current possibly in a grey area include, for example-

    7.1. “Sub-domain 2.4.3” that there are safety protocols in place for surgery.

    7.2. “Sub-domain 2.5” that all patient safety incidents are managed and adverse events routinely analysed.

    7.3. “Sub-domain 3.1.3” that stock levels of medical supplies are managed appropriately.

    7.4. “Sub-domain 3.2” that laboratory and X-Ray services are available and provide accurate results / quality reports;

    7.5. “Sub-domain 3.4 – Health technology” that medical equipment is safe and effective. The safety of medical equipment is a regulatory requirement that will be governed by means of medical device regulations. However, the safe use of devices would be a function of training or instructions provided by the manufacturer, but also a duty on the user and facility to ensure correct use. Par 3.4.2 does refer to training in correct use, but does not delineate responsibility in this regard. Par 3.4.3 is again within the domain of the health establishment, i.e. to ensure maintenance. However, in certain instances the duty to ensure the supply of spare parts, or repairs, may lie with the manufacturer/responsible agent.

    7.6. “Sub-domain 3.4 – Sterilisation” that decontamination and sterilization services are available and effective. In practice currently many manufacturers undertake this task in order to ensure that its equipment are not implicated in adverse events, or as a result of lack of facilities or trained staff in facilities. This duty should, rightly so, rest with the health establishment.

8. In light of the above, SAMED proposes that all standards be published in draft format prior to its finalisation, so that the practicalities in relation to compliance and responsibility, as well as conflicts with existing obligations, could be addressed timeously.

9. SAMED also proposes that the OHSC publishes the standards, and not the Honourable Minister of Health, who might be regarded as not being independent insofar as his/her oversight over, and responsibility for- all health establishments, is concerned. The OHSC cannot certify entities based on standards set by the ultimate head of such entities.

SAMED will gladly engage the Portfolio Committee on all the matters raised in the submission, and will make available any other or further information that might be helpful in the finalization of Bill 24-2011.

Yours Sincerely

Tanya Vogt

SAMED Chief Operating Officer