SA Medical Device Industry Association on the Medicines and Related Substances Amendment Bill [B44-2008]

Portfolio Committee on Health

5 August 2008

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SAMED IS COMMITTED TO :

Advancing Innovation Responsibly

'The responsible and ethical advancement of the interests of the medical devices industry within the SA healthcare environment while promoting better patient outcomes'

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SAMED 's SUBMISSION :

SAMED strongly supports a legislative framework to control the manufacture, distribution and marketing of medical devices and IVD to ensure that South African patients have access to medical devices and IVD that are safe, effective and of good quality.

What is a medical device?

- **Medicines Act 101 definition is outdated and not harmonized.**

- **National Health Act speaks about health technology**

> "**health technology**" means machinery or equipment that is used in the provision of health services, but does not include medicine as defined in section 1 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);

What is a medical device?

Global Harmonization Task Force (GHTF) definition:

"…any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

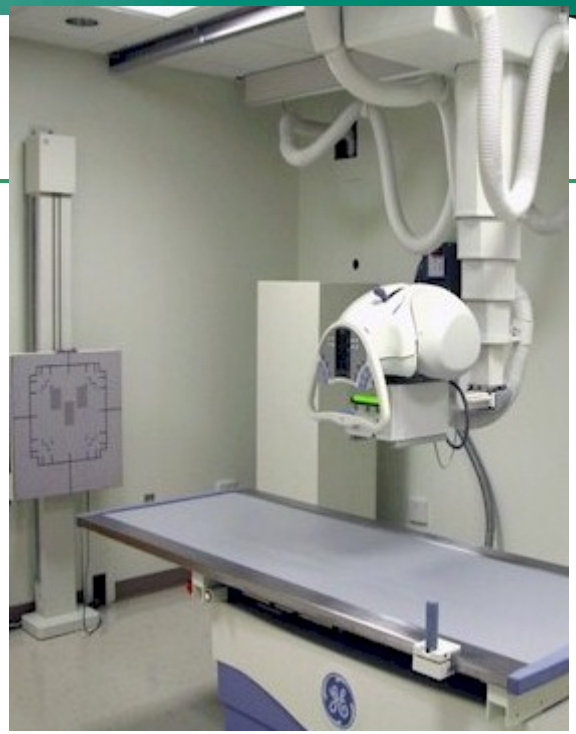
a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

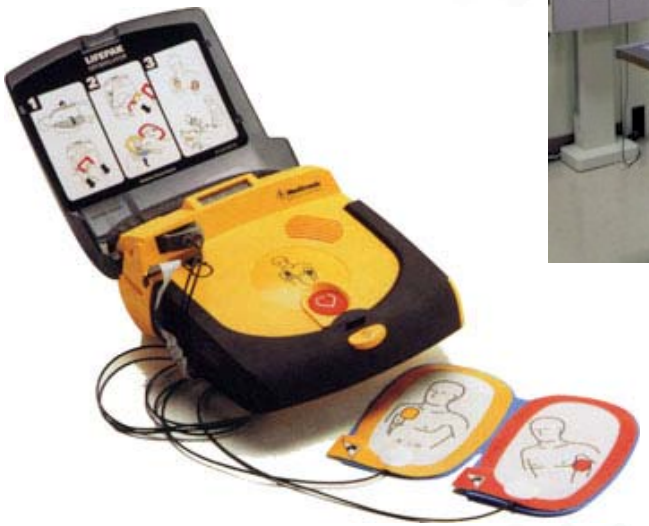
- **Diagnosis, prevention, monitoring, treatment or alleviation of disease**
- **Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,**
- **Investigation, replacement, modification, or support of the anatomy or of a physiological process…"**
- **supporting or sustaining life**
- **control of conception,**
- **disinfection of medical devices,**
- **providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body**

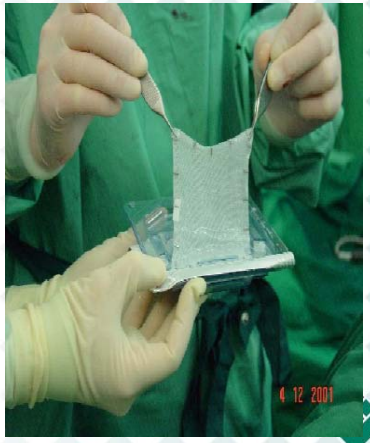
and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means"

***Source:* GHTF/SG1/N29R16:2005; Information Document Concerning the Definition of the Term "Medical Device"**







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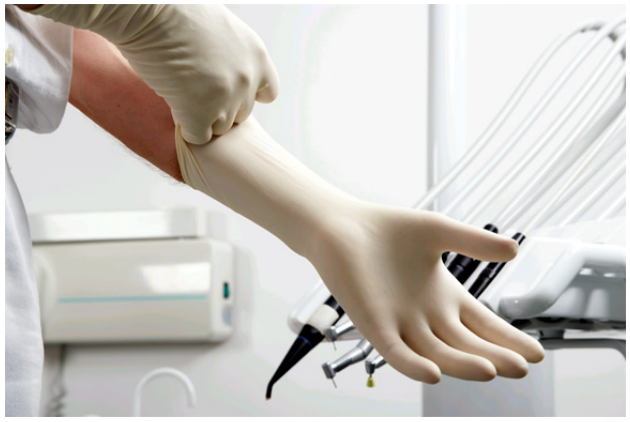

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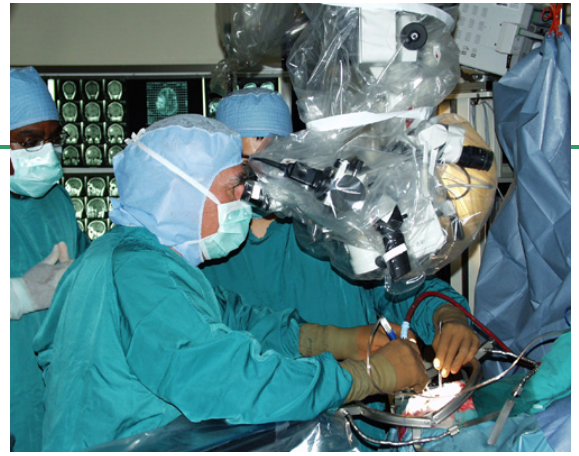

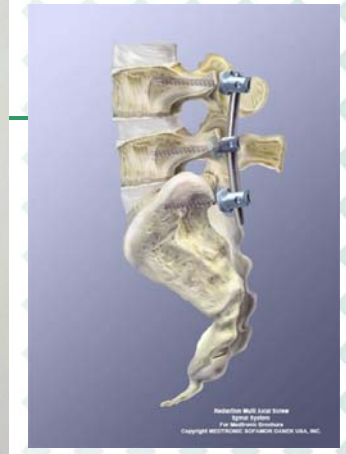

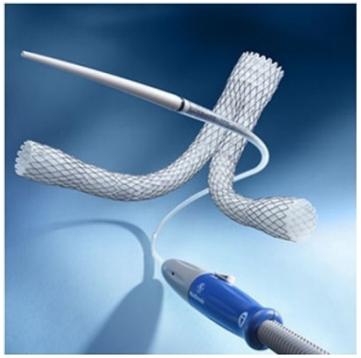

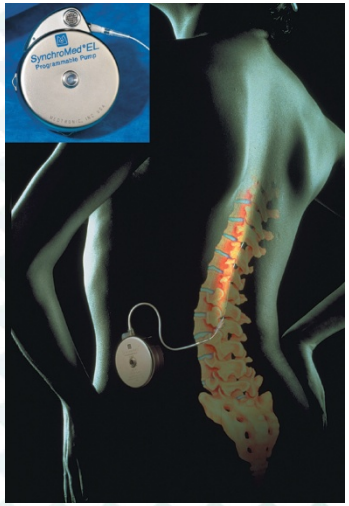

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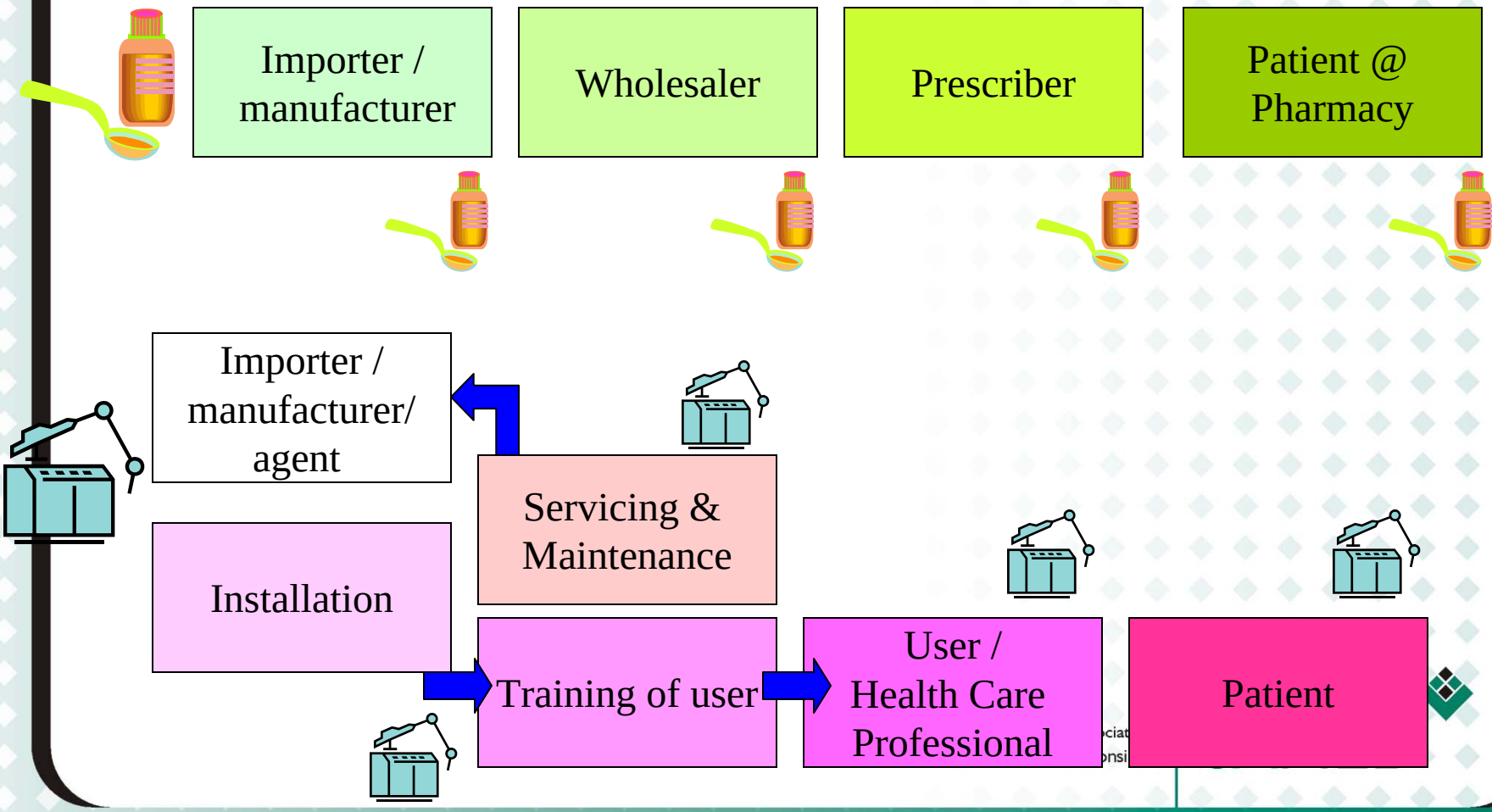
Medical Devices: Practical Considerations

- Range of Products
- Risk Classification (Class I → Class III) specific for medical devices vs scheduling of medicines
- Special Products:
  - In Vitro Diagnostics (IVD's)
  - Radiation omitting devices (X-Rays)
  - Combination Products
- Value Chain

The Act does not consider

very different supply chains –

medicines versus medical devices or IVD's



Comparative Value Chains

- The Act does not consider **very different supply chains** – medicines versus medical devices or IVD's

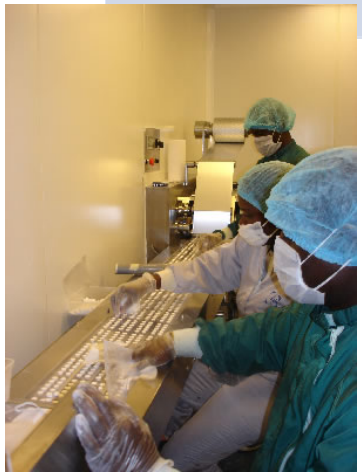
Medicines Supply Chain

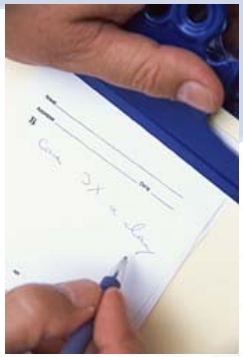
MFG/Imp

Wholesaler

Prescriber

Pharmacy/ Patient





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Medical Devices Supply Chain

MFG/Imp

Installation

Training

USER

Patient

Maintenance

Disposal/Return

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SAMED 's Submission :

1. Need for a separate chapter specifically for medical devices and Definition of Medical devices;
2. Two tiered registration and certification process;
3. Bonussing, Sampling, Discounting and Labelling;
4. Requirement for a dispenser/pharmacist; and
5. International Tendering.

The Act as amended

"(1) No person shall sell any **[medicine]** product or Scheduled substance unless the immediate container or the package in which that **[medicine]** product or Scheduled substance is sold bears a label stating the prescribed particulars."

Separate Chapter for Medical Devices

The Bill

- No specific provision for medical devices.
- Definition of medical devices requires updating

Why

- Medicines to "Products"
- Harmonization
- No empowering legislation for medical devices
- Does not take into account the complexity of medical devices

Solution

- Ideally add a chapter for medical devices and IVD's
- Alternatively make provision for specific regulations for medical devices.
- Use GHTF Definition for Medical Devices

ULTRA VIRES

The Act must make clear provision for the sets of regulations required for devices.

Not mentioning in the empowering Act that regulations would have to cover for example,

- Risk classification of devices
- Post-marketing surveillance

Could lead to someone challenging such regulations, when made in the end, as *ultra vires* (outside the scope of authority of the empowering Act)

SAMED would rather be cautious and have a comprehensive framework set by the Act, than risk non-implementation due to possible legal challenges.

Two Tiered System: Certification and Registration

The Bill

- Tier 1: Certification – Safety Efficacy and Quality
- Tier 2: Registration – 15 (4) D i – vi

Why

- For Registration:
  - Too much power to the minister
  - Non-Scientific criteria used

Solution

- This is essentially a funding issue and should be dealt with separately

CONCERNS

- Limiting access to innovative, high quality, cost-effective medical devices and IVD
- Impact on Local manufacturers
  - Insufficient resources and skill to meet registration criteria
  - Access to potential markets limited
- Possible disinvestment by multinationals
- Scientific advancement will suffer.

ADVANCEMENTS – SCIENCE & TECHNOLOGY

1989

Size: 209cc

Procedure: 2-4 hr, open chest

Hospital Days: **12**

Battery Life: <2 years

Today

Size: 36cc

Procedure: 1 hr, small incision

Hospital Days: **2**

Battery Life: >7 years

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Bonussing, Sampling, Discounts & Labelling

The Bill

- Prohibition on Discounting Sampling and Bonussing.
- Imposes labelling requirements

Why

- Inappropriate and impractical
- Medical devices are not medicines.

Solution

- Allow discounting etc under within specific parameters
- Labelling requirements should be left to regulations, appropriate to the device and risk class

Requirement for pharmacist

The Bill	• Licence conditions requiring applicant to be a pharmacist - 23 (b) (2).
Why	• Not practical or necessary • Pharmacist don't necessarily have specialised knowledge pertaining to Medical Devices. • No provision for separate sub-authorities within SAHPRA
Solution	• Exclude medical devices

International Tendering

The Bill

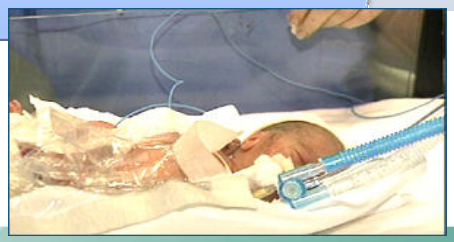
- Provides for international tendering

Why

- Training
- Calibration and Maintenance
- Warrantees

Solution

- Remove



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Conclusion

- SAMED strongly supports effective legislation.
- Serious concerns about substituting “Medicine” for “Product” and the unintended consequences.
- Proposed solutions are easy to accommodate.
- SAMED is willing to engage with government in developing workable legislation and regulations for medical devices
- In its current form there is little hope of success in creating an efficient world-class regulatory system.