

Proposed Regulatory Requirements National Health Act, Republic of South Africa CEASA Breakfast Meeting



Presented By

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Medical Devices : Rapid Growth

- In 2000, WHO estimated half a million medical devices available on the market represented over USD145 billion. (In the same year, the US FDA estimated 10,000 new medical devices were innovated in the US alone.)
- Expected to grow to USD260 billion in 2006 (cf : Drugs USD250 billion in 2002)
- Increasingly urgent to ensure medical device safety and effectiveness. Need regulations



Differences between Drugs and Devices

	Feature	Medical Devices	Drugs
1	Use	Device-operator-patient/specimen Operator skills critical	Drug-patient No operator interface needed
2	Care	Needs proper care and maintenance	No maintenance needed
3	Recurrent cost	For consumables and maintenance	No recurrent cost

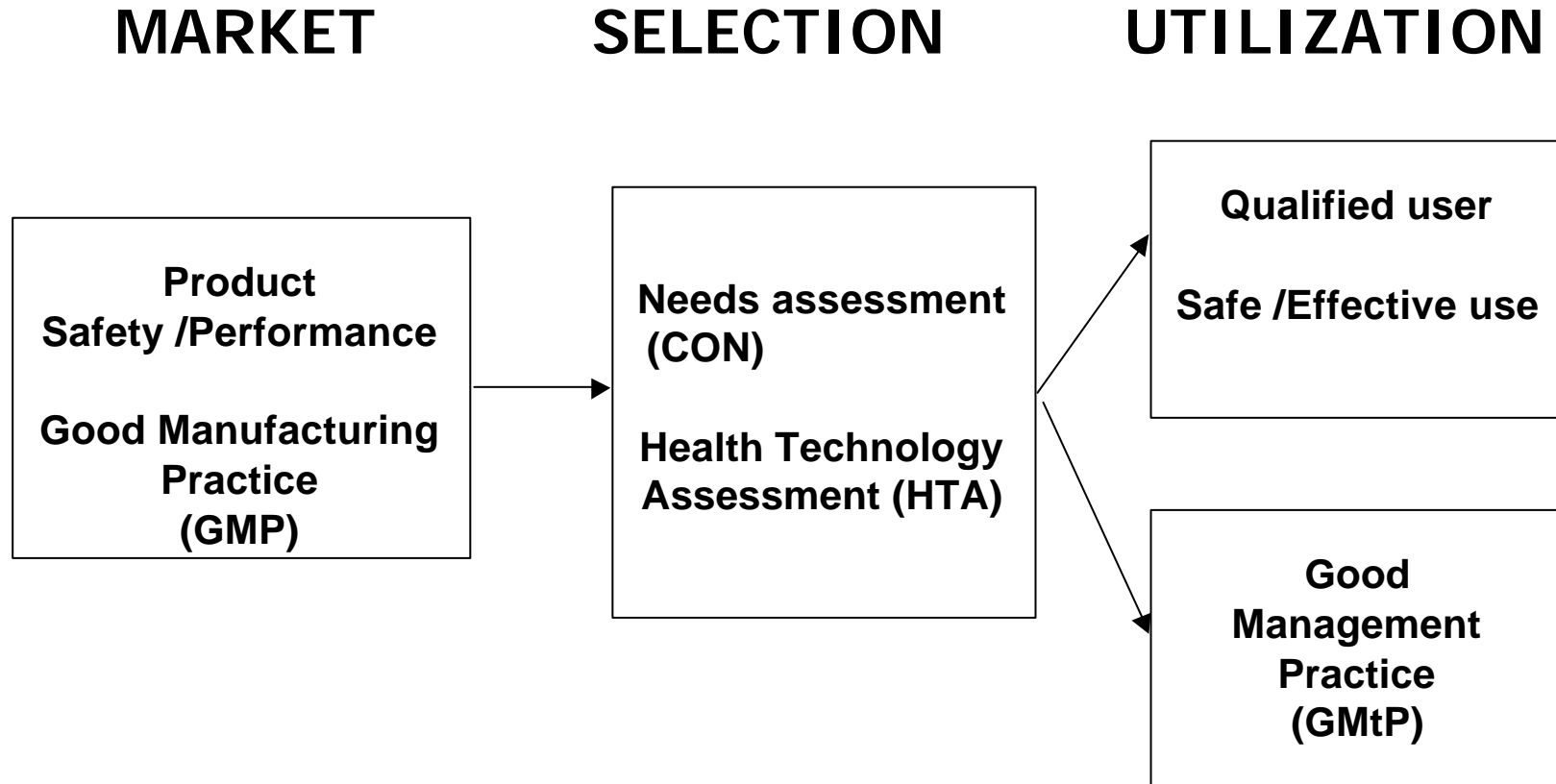


Process Thus Far...

- Analysis of existing situation and complexity thereof (various laws, stakeholders, etc.)
- Regulating in terms of the three-leveled (three “sphered”) approach
- The need for a comprehensive regulatory system with a series of supplementary guides/codes/information sheets
- Drafts of potential regulatory provisions and Guidelines



Three Levels of Medical Device Regulations



Three Levels of Medical Device Regulations

Level of regulation	Criteria	Focus	Competent Authorities
First level	Could adopt Global Harmonization Task Force criteria (GHTF)	Safety and performance Rule-based risk classification Quality systems based on ISO13485 Post-market surveillance	National
Second level	Needs assessment Health policies H.T. Assessment	Cost-effectiveness/benefit Socio, cultural, political considerations Alternative care. Other considerations	Regional Sectorial Institutional
Third level	Good Management Practice (GMtP)	Essential elements of good management of medical equipment/devices (including users training and maintenance)	National Institutional Professional



Level one

- Definition of devices
 - National Health Act, Medicines Act & Hazardous Substances Act
 - Cosmetic Devices?
 - Devices with medicinal “component”?
- Classification by means of rules
 - EU, Canada or combination
 - Based on risk + certain disease areas / types of care (critical) + SA specific issues , e.g. electricity, importance of access to specialists to maintain, etc.
- Performance:
 - Relative safety (risks & hazards)
 - If safety at risk may lead to CON withdrawn...
- Effectiveness:
 - Intended effect
 - Relative: threshold; interplay HTA e.g. *cost-effectiveness*



Level one

- Good Manufacturing Practice
 - Standards (e.g. ISO 13485)
 - Identification, elimination/addressing risks and hazards
 - Design and manufacture
- Importers
 - International Trade Administration Act – powers of Commission (SADC)
 - Require that compliance with recognised standards and SA legislative requirements
- Licensing of manufacturers, importers and (certain classes of devices)
- Standards Act: Minister may cause external standards (EC Mark, FDA, etc.) to be recognised...
- Clinical trials (to prove efficacy & safety)
 - For what categories of devices?
 - Other investigations of “lower risk” e.g. condoms



Level one

- Pricing, leases, etc.
 - Price regulations
 - Second-hand, re-used and modified devices?
 - Donations
- Incidents, adverse events
 - Definitions:
 - incidents (unusual)
 - adverse events (harmful & unintended reaction)
 - malfunction & technical/medical reaction
 - *Serious* adverse events and *unexpected* side-effects
 - Who to report what to whom?
- Liability
 - Product liability...?



Level one

- Duties to be placed on various stakeholders in chain...
- Sustained safety and performance (plays onto level 3)
 - Codes of Practice
- Marketing and advertising
 - To whom and where
 - No fraudulent or misleading adverts
- Packaging and labels
 - Not much variation, common sense
 - Take into account SA context, electricity, water, users & others that come into contact with devices – language & literacy



Level two

- Health technology assessment:
- Acquisition and CON (comparative positions)
- Essential Devices List (Essential HT Packages)
- Take into account other laws:
(Med Schemes Act & Regs - Atleast devices to be able to give effect to full PMB list (270 +25)
Sterilisation Act, ToP Act, Laboratory Services Act)

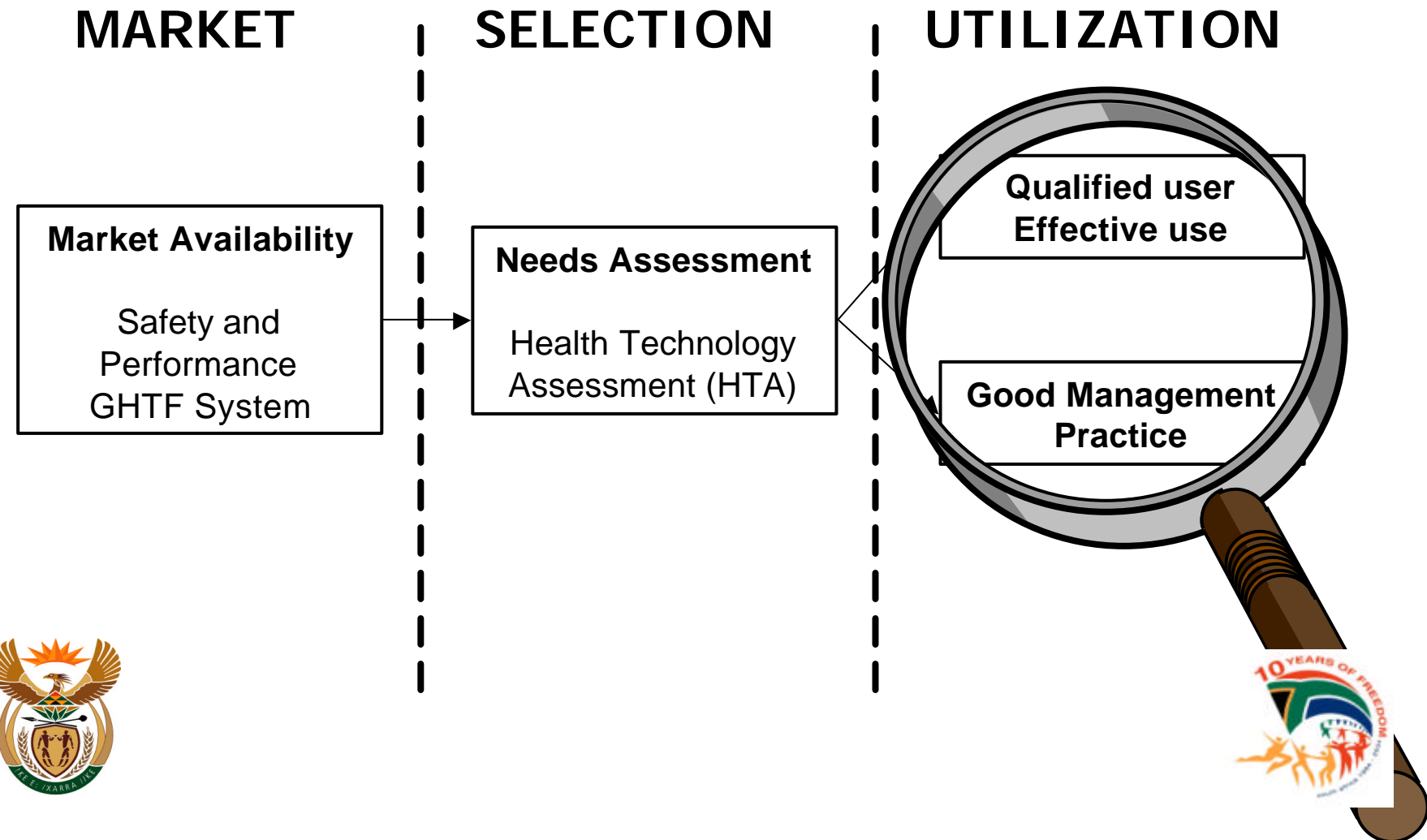


Level three

- Essential elements recognised in law:
 - Concretisation in Codes
 - Must ensure that no acquisition if cannot prove that able to fulfill minimum which includes...
 - Planning
 - Acquisition (Essential Device List, tendering, budgeting, contractual agreements (e.g. on maintenance))
 - Delivery & inspection
 - Inventory, record-keeping
 - Installation
 - Training (also HPCSA (Not Uniform Requirements In Under-grad, Training Sometimes By Manufacturers...)
Role of ECSA, SETA's – CON?)
 - Maintenance (Ultimate Responsibility With CEO Of Facility? Linked To CON?)
 - Replacement and disposal



Proposed Framework



The Third Level Regulations

- The third level regulations are of utmost importance as devices/equipment are now used on patients
- Who should be accountable (CEO/CE)
- The regulations also call for Good Management Practice for medical devices/equipment using the life cycle management approach



Essential Elements for Good Management Practice

Life cycle elements of medical equipment:

1. Planning
2. Acquisition
3. Delivery, Incoming inspection
4. Inventory and documentation
5. Installation, commissioning and acceptance
6. Training of users (**key to safe use**)
7. Monitoring of use and performance
8. Maintenance
9. Replacement or disposal (decommissioning)



Basic Planning Questions Before Acquisition

- Demonstrated clinical needs ?
- Available qualified users ?
- Approved and reassured source of recurrent operating budget (consumables, labour, parts) ?
- Confirmed maintenance services & support ?
- Adequate environment support ?
- Regulatory compliance ?



Device/Equipment Pre-acquisition Questions

- Is the device licensed in South Africa?
- Is the device subject to Certificate of Need?
- Are there Clinical Practice Guidelines issued by the HTA Agency or another competent authorities on the device?
- Is the device licence conditional upon postmarket surveillance studies?



Device/Equipment Pre-acquisition Questions (cont.)

- What are the evidence of clinical needs?
- Are there qualified users in the healthcare facility?
- Is the source of recurrent operating budget identified and approved?
- Are maintenance services confirmed?
- Are there adequate environment supports such as adequate electrical supplies, clean water, clean rooms, acceptable ambient temperature and humidity?



Device/Equipment (Used/Refurbished) Pre-acquisition Questions

- Ensure that the original manufacturer does not label the device “single use”
- Obtain a complete maintenance history of the device
- Perform all the tests prescribed by the manufacturer, as well as any tests that may be specified by the DG, in order to ensure proper functioning of the device
- Provide contractual evidence that the manufacturer/responsible agent will support the device in terms of spare parts and recalls



All Device/Equipment Use, Maintenance, Disposal

- Only qualified users use medical devices
- Policy and procedures are in place for the training of each new user for safe and effective use of medical devices
- In-house personnel and facilities, outsourced third party, or a combination of in-house and outsourced services are adequate for the maintenance of medical devices
- Policy and procedures are in place for appropriate disposal of used medical devices/equipment



Conclusion

- This initiates the public dialogue that we all ought to engage in as a nation
- Written input on all these issues would be Highly appreciated.





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THANK YOU!!

