Industry's Perspective on the Status of Medical Device Regulations

FUNDISA Workshop

09 & 10 Oct 2014

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SAMED Regulatory Committee

south african medical device industry association
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Today's Topics:

1. Medical Device Definition - Differences
2. Status of Medical Device Regulations in South Africa
3. Industry Perspective
4. Industry Concerns
5. Implementation Proposals
6. The Act and Amendments (Draft Bill 6 Overview)
7. Draft Bill 6 of 2014 Current Status
8. Draft Medical Device Regulations
9. Draft Medical Device Guidelines

Definition of a Medical Device

- **“any instrument, apparatus, appliance, material or any other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:**
- **diagnosis, prevention, monitoring, treatment or alleviation of disease, or compensation for an injury or handicap,**
- **Investigation, replacement or modification of the anatomy or of a physiological process, control of conception**
- **and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”**

*electrometrical devices are regulated by the Department of Radiation Control

Medicines and Medical Devices Differ

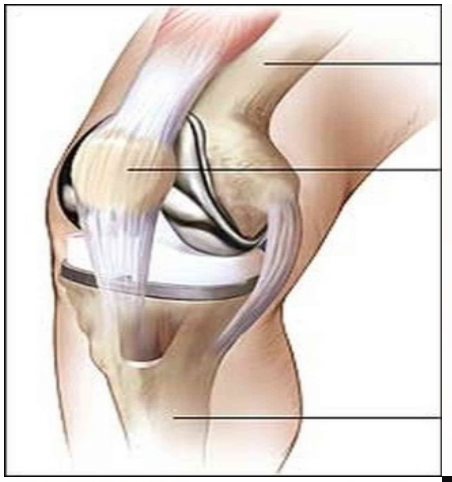
MEDICINES

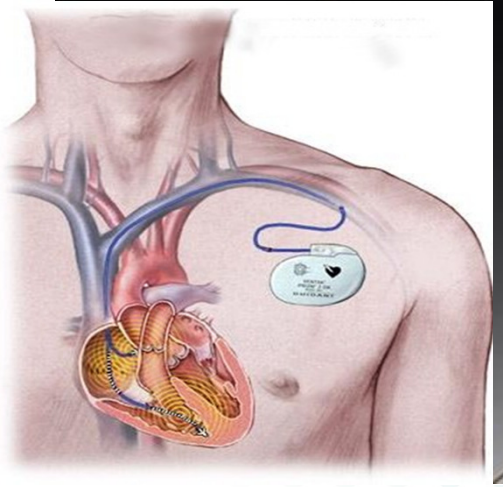
- Discovered
- Stable formulation developed
- Highly mechanised manufacture
- Consumed by use
- Systemic toxicity
- Large populations of exposure
- High % of self administration
- Patient may choose to stop use
- Use Medical Devices for administration (Needles & Syringes or Asthma pump)

MEDICAL DEVICES

- Designed
- Constant improvements or changes
- Often manufactured by hand operations
- Available for study after use
- Adverse events most often local in nature
- Relatively limited populations of exposure
- Mostly intended for professional use
- Self use mostly intended for monitoring

Medical Devices Examples





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Medical Device Regulations Status:

- As of 09 Oct 2014, medical devices and *in-vitro* diagnostics remain unregulated in South Africa*
- Bill 6 – the legislation that will empower NDoH to regulate medical devices, through the creation of the South African Health Products Regulatory Authority, required amendments
- Bill 6 of 2014 was Gazetted in February 2014 to introduce amendments.
- The NDoH issued Draft Regulations for Medical Devices for public comment on 22 April 2014
- The NDoH issued Draft Guidelines for Medical Device for public comment on September 2014

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Industry Perspective

- Industry welcomes the Department of Health's regulatory framework, drafted in the interests of safety for South African patients and users of medical devices
- SAMED appreciates the DoH's recognition of international approaches to regulating medical devices
- SAMED appreciates the DoH's recognition of other Regulatory Authorities
- SAMED appreciates other initiatives taken by the DoH in preparation for Medical Device regulation (Regulatory Institute)
- SAMED requests the DoH to recognise and engage with associations representing the Medical Devices Industry
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- SAMED recommends a phased Risk Based approach to Medical Device regulations that will not be disruptive to continued provision of MD's

Industry Concerns

- Legal Framework is Medicine focused
- Cannot Regulate by Guidelines. Contradictions Act /Regs. / Guidelines
- Transition and Capacity Building – Appropriate & Adequate Staff
- Roles of CEO, Board Members vs Registrar (Cater for Registrars)
- Inclusion of Pricing Considerations in Regulations (Stand Alone)
- Local Manufacturers – International STD's compliance costly. Quote international STD's (SANS STD's?).
- Requirements for scheduled substances in combination MD
- Record keeping for Prescriptions in Combination MD's?
- Local labelling requirements of MD's with scheduled substances- warnings, precautions, limitations, incompatibilities
- SAMED none – recognition by regulator (Lack of response)
- Implementation Road Map (Timelines)
- Consideration of other Acts Affecting Industry

Implementation Proposals

- Redraft of amendments to Enabling Act
- Amendments to Draft Regulations, must be Medical Device Specific
- Removal of Combination Medical Devices currently in Medicine register
- Stakeholder Engagement – Communication with Industry Association
- Prepare for the Regulatory / Registration Requirements
- Capacity Building Staff and IT Website

Further discussions required

Alignment & Engagement

ENABLING ACT

- **Medicine Focused**
- **Need to allow for Medical Device Specific Sections / Clauses**
- **Specific Sections for MD**
- **Further Discussions**
- **Parliamentary Portfolio**

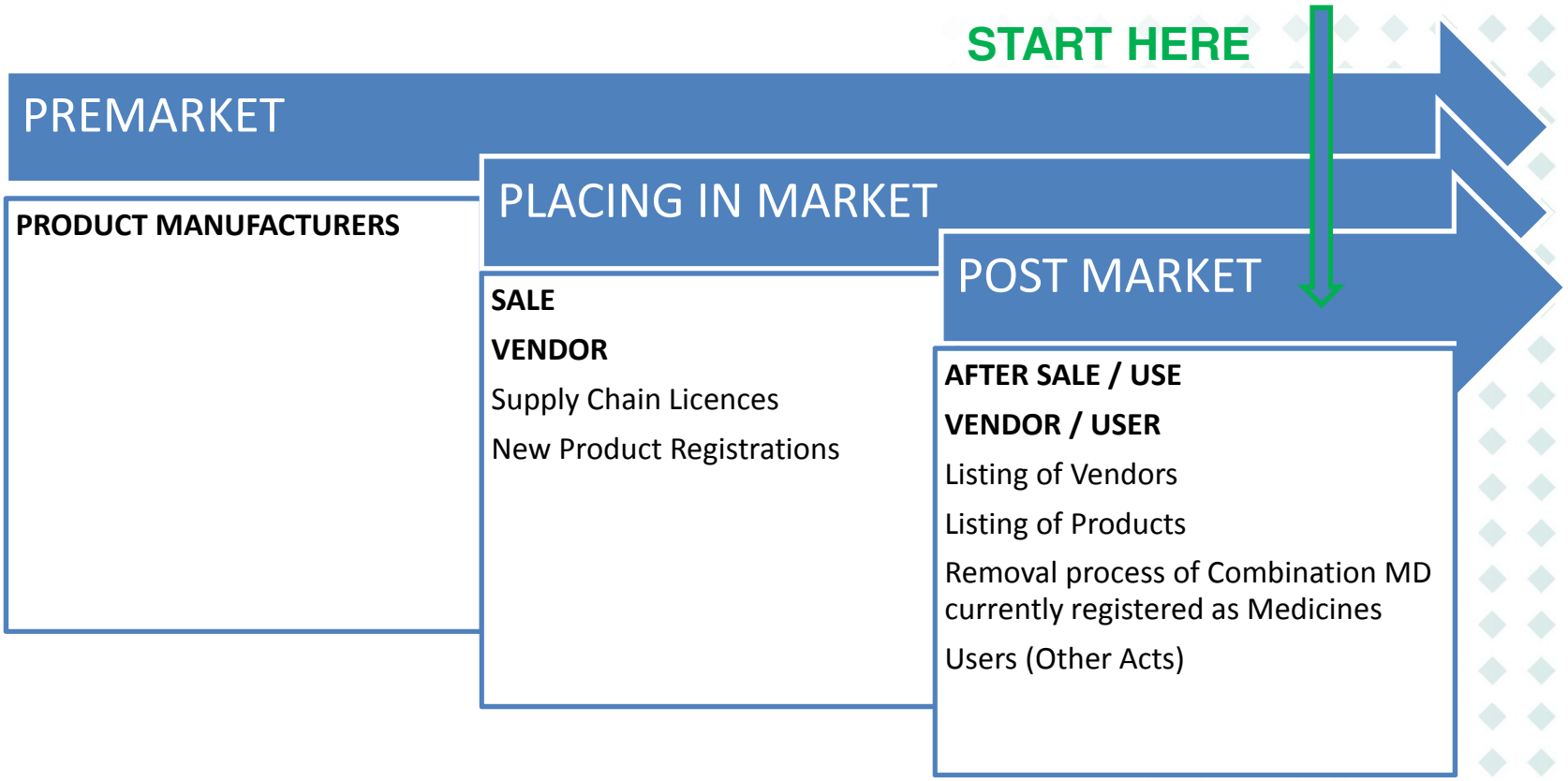
REGULATIONS

- **Not Device Specific**
- **Scheduled Substances in MD ≠ Medicines**
- **Pharmacist / Medicines Controls?**
- **Further Discussions**
- **Workshop**

GUIDELINES

- **Welcome as MD tailored & harmonised.**
- **Comments Open.**
- **Timelines Critical Global Aware e.g. Trials**
- **Further Discussions**
- **Workshop**

Phased Approach – Non Disruptive



Implementation Proposals

Estimated Timelines

START HERE

PREMARKET – Capacity Building of Various Stakeholders

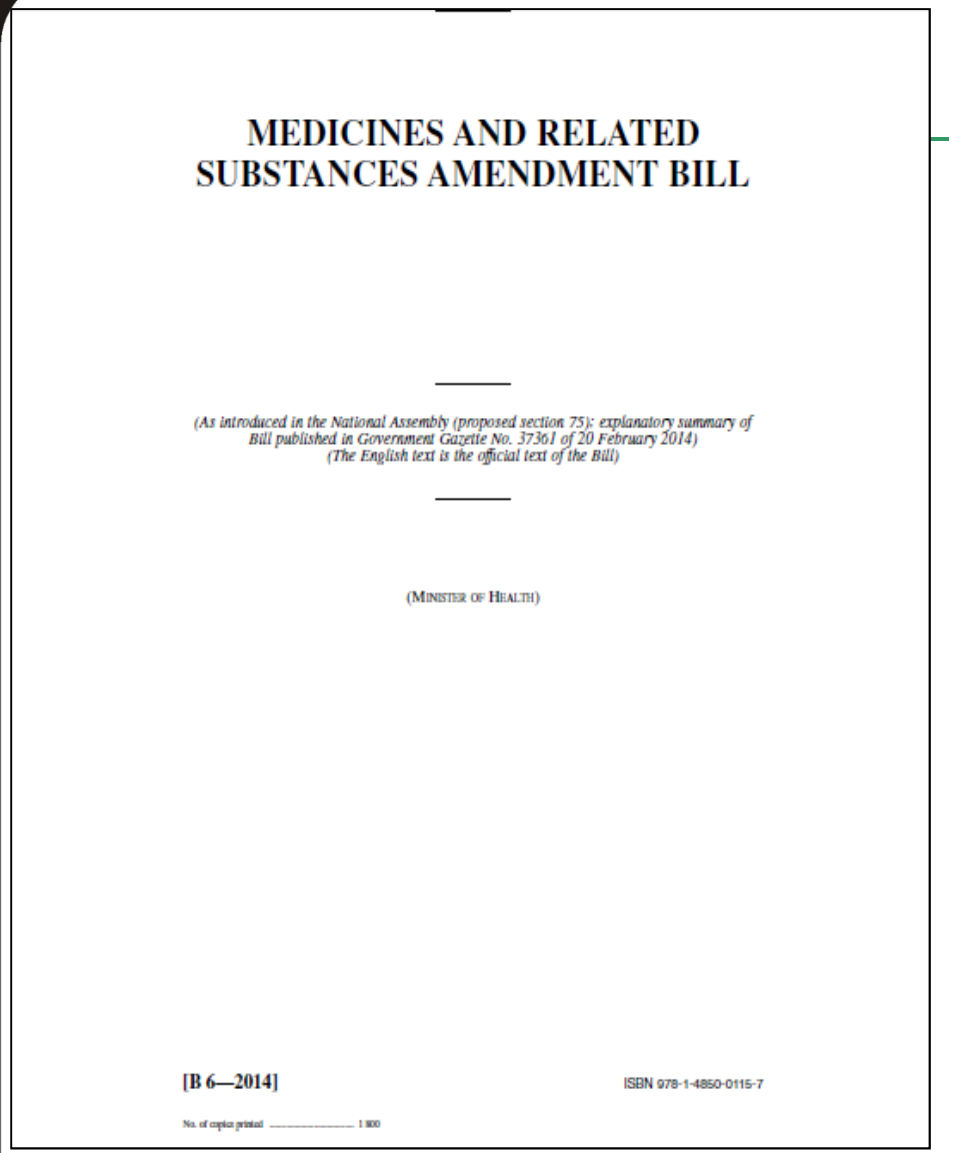
Local Manufacturers
Capacity Building SAHPRA
Conformity Assessments
Licencing of Manufacturers
Licencing of Vendors

PLACING IN MARKET
Phased Approach

Licencing of Vendors (QMS)
Listing of Exempt Class / MD
Product Listed with RA
Call Up – Risk Based
Registration of MD
- recognition of other RA

POST MARKET – ROLES OF VARIOUS STAKE HOLDERS

~ Adverse Event Reporting
~ Complaint Management
~ Vigilance Reporting -RA
~ Field Action Notifications -RA
~ Service & Maintenance
~ CAPA



MEDICINES AND RELATED
SUBSTANCES AMENDMENT BILL

(As introduced in the National Assembly (proposed section 75): explanatory summary of Bill published in Government Gazette No. 37361 of 20 February 2014)
(The English text is the official text of the Bill)

(MINISTER OF HEALTH)

[B 6—2014]

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MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

Government Gazette #37361
of 20 Feb 2014
To amend the Medicines and Related Substances Act, 1965

Draft Bill 6 of 2014: Overview

PRINCIPAL ACT 101 of 1965 Medicines & Related Substances

- MEDICINE FOCUSED
- MANY AMENDMENTS SINCE 1965
- MANY REGULATIONS UNDER THIS ACT

AMENDMENT Act 72 of 2008

- SIGNED INTO LAW
- NOT TAKEN INTO EFFECT
- MAJOR AMENDMENTS
- INCLUSION OF MEDICAL DEVICES / IVD's

DRAFT BILL

- FURTHER AMENDMENTS
- DRAFT BILL MARCH 2012
- 3 MONTHS PUBLIC COMMENT
- AMENDMENTS NOT OPERATING
- FURTHER AMENDMENTS
- DRAFT BILL PUBLISHED 2014

Draft Bill 6 of 2014: Overview

Seeks to Establish / Provides For:

- A New Regulatory Authority (‘‘SAHPRA’’)
- Operational Functioning as a Public Enterprise
- The Appointment of a Chief Executive Officer.
- Additional Definitions
- Transitional Arrangements MCC – SAHPRA

Draft Bill 6: Reasons for Amendments

1. to define certain expressions
2. to delete or amend certain definitions
3. to provide for the objects and functions of the SAHPRA
4. to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority

Draft Bill 6: Reasons for Amendments

5. to replace the word ‘‘products’’ with the word ‘‘medicines’’ and the expression ‘‘scheduled substances’’ in order to correctly reflect the subject matter of the said Act
6. to effect certain technical corrections
7. to provide for matters connected therewith

Draft Bill 6 of 2014: Current Status

Portfolio Committee on Health

BRIEFING ON THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

Date: 3 September 2014

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

20 YEARS OF FREEDOM

Portfolio Committee Public hearings set for Oct/Nov 2014

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Draft Bill 6 of 2014: SAMED Actions

- Preparing to present and to submit to the Parliamentary Portfolio Committee on health.
- Separation of Sections / Clauses not applicable to Medical Devices, where applicable.
- Propose changes for technical correctness that will allow legal enforcement.
- Harmonization (In draft guidelines, not in Draft Regulations or Bill). Proposals must align.
- Allow for Registrars, other procedures and functions
- Combination Devices

Draft Medical Device Regulations

- Define which, how Medical Devices will be regulated and includes in-vitro Diagnostics
- Requires licencing and registration of MD companies and products
- Makes provisions for combination MD's, custom-made, implantable
- Divides devices into Risk Classes A, B C, D
- Requires adverse event reporting
- Regulates labelling, IFU's, Regulates clinical trials
- Advertising
- Transitional Measures and implementation

Follows the format of medicines

Combination Medical Devices

- Requirements, where applicable:
- Registered Pharmacist?
- Approved name, schedule of therapeutic substance
- Schedule 2 and above has restricted advertising
- Schedule 5-8 registers requires reporting and record keeping
- Record keeping for Prescriptions?
- Labelling requirements - warnings, precautions, limitations, incompatibilities

Control of Scheduled substances within a Medical Device ≠ Medicines Controls. Control Supply Chain

Medical devices should not be registered as medicines
- Lack of data medicine registration, incompatible dossier
- 5 year lead time

Medical Devices are not “Free for all users”

Medical device ?

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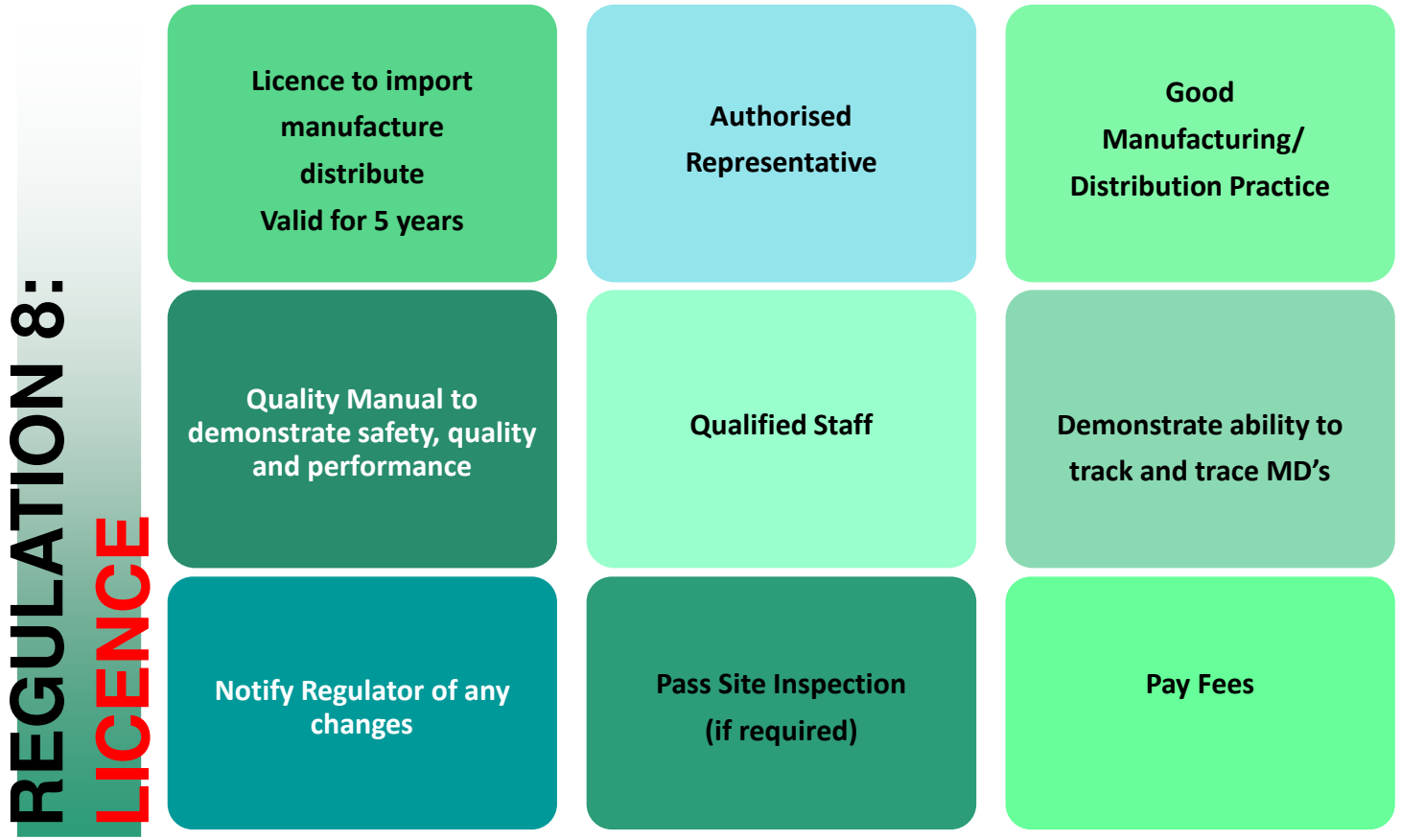
How to comply with requirements?



TAKING MEDICAL TECHNOLOGY TO THE NEXT LEVEL

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How to comply with requirements?

REGULATION 11: REGISTRATION

Details of: Applicant Holder of Certificate of Registration Responsible Person	Screening Form Manufacturer Details Site Master File Clinical Investigation Sites	Register each medical device OR group Or family
GMP certificate from Regulator of Country of Origin Conformity Assessment Certificate Site Master File	**Medical Device Details:** Name, Model Intended Purpose Country of Origin International Registrations Risk Classification GMDN Code	Evidence of conformity to the Essential Principles for Safety and Performance
International Registration Certificates Conditions of Registration	Label Package Insert Instructions for use	Pay Fees

Draft Medical Device Guidelines

- Published for comment on 26 September 2014
- Welcome by Industry – Device orientated
- Recognition of IMDRF – Harmonisation
- Recognition of other Regulatory Authorities provision
- Recognise differences between Medicines & Medical Devices
- Medical Device Specific with Local Specific Requirements
- Labelling Requirements for Combination Devices Scheduled Substance limitations and incompatibilities.
- Comment Phase open
- Errors in standards
- Timelines needed
- Grandfathering / Sun setting?
- Bill 6 – Regulations – Guidelines

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THANK YOU

Medical device ?

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