Medical Device Regulatory Roadmap

SAMED Conference
2 -3 December 2015

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Registrar of Medicines
Overview

• Global status on MD and IVDs
• National status on MD and IVDs
• Legislation
• Key player and Responsibilities
• Roadmap on Regulatory oversight
• Roadmap for the Regulator
• Roadmap for Applicants
• Closure
What is happening in the world

• It is apparent that while the FDA, Japan and Health Canada have reported relatively stable organizations which are moving toward more transparency with regard to decision making affecting medical devices;

• the European Union (EU) will have significant changes to their regulation of medical devices in 2016;

• Australia has recently undergone significant reforms in identifying comparative international regulatory authorities for expanded pathways to approval

• Brazil, China and Russia are actively working to implement their systems.
Why EU changes: “PIP Scandal” (2010)

• A French manufacturer (Poly Implant Prothèse) had used industrial grade silicone for the production of breast implants over 10 years.
• An estimated 500’000 women had received those implants, mainly in Europe and South America.
• Rupture rates are double compared to other implants (15-30% after 10 years vs. 10-14%).
• Criminal action, but was interpreted by media and other stakeholders as indicator of a failure of the EU-System.
• “Not enough oversight”
Lessons learnt: PIP

• The functioning of notified bodies
• Market surveillance
• Coordination as regards to vigilance
• Communication and transparency
• Stronger supervision of independent assessment bodies
Legislation: Bill 6D, 2014
• Defines MD and IVDs
• Licensing of Manufacturers, Importers, Wholesalers and Distributors
• Registration: MD, IVD
• Regulations: regulatory oversight
• Guidelines

Regulatory office
• Establish Medical Device office
• Establish MD Expert Committee on MCC
• Appoint MD staff
• Radiation officers part of office
• SANAS accreditation
A medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) —

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals for one or more of the following:
   (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
   (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
   (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process
   (iv) Supporting or sustaining life;
   (v) control of conception;
   (vi) disinfection of medical devices; or
   (vii) 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 by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means.
Definition of IVD: Act 72, 2008

**IVD (in-vitro diagnostic)**

means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes”
Medical device or IVD establishment

means a facility used by a manufacturer, wholesaler, distributor retailer, service provider or an importer of medical devices or IVDs for conducting business;
Combination Medical Devices

Combination of medical device and medicinal product

• Where a device is intended to administer a medicinal product, that device shall be governed by the Regulations on Medical Device

• Where a device is placed on the market in such way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by the Regulations on Medicines i.e. Pre-filled syringe, e.g. single-dose vaccine
What is the purpose of regulation?

- Ensure that products are safe and effective for their intended use.
- Evaluate evidence to support claims.
- Enforce the regulations.
Where we want to be...

Have devices that are:

Reliable – always work
Accurate – provide correct result
Robust – compatible with extreme working and storage conditions

Affordable – to meet budget constraints
Available – in sufficient supply to meet demand
Compatible – appropriate for the population with which it will be used
Regulation and Quality Assurance

A program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.
Key players in the MD and IVD arena

• Competent Authorities
• Notified Bodies (Conformity Assessment Bodies)
• Manufacturers
• Authorized representative
• National Regulatory Authority (MCC, SANAS)
Who is responsible for what

Shared responsibilities between:
- Manufacturers (Importer/Distributor)
- National Competent Authorities: MCC and SANAS
- Notified Bodies (NB)

• Manufacturers responsibility:
  - Quality and Risk Management
  - Liaise with Competent authority and Notified bodies
  - Design, manufacture, packaging & labelling, name and address on MD label
  - Conduct of conformity assessment procedure
  - Keep technical files/design dossier available
  - Vigilance and post-market surveillance procedures
  - Issues Declaration of Conformity
  - Appointment of Authorized Representative
Who is responsible for what ... cont

• National Competent Authorities
  o Designation of Notified Bodies
  o Perform market surveillance
  o Identify standards
  o Approve clinical studies
  o Conduct inspections

• Notified Bodies evaluate:
  o Pre-market assessment of MD (evaluate product)
  o Medical devices safety, quality and performance
  o Audit manufacturers and evaluate quality system
  o Issue conformity certificates (i.e. SABS certificate)
any natural person, resident in the Republic of South Africa,

• who has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic and

• to act on his or her behalf for specified tasks with regard to the latter's obligations and

• who has submitted an application for the registration of a medical device or IVD and

• in whose name the manufacturer licence, wholesaler licence and or certificate of registration is issued.

The authorised representative is responsible for all aspects of the medical device or IVD, including quality, safety and compliance with conditions of registration.
Roadmap on Regulatory oversight of Medical Devices & IVDs

Two key pathways:

1. License to import, manufacture, distribute or export medical devices and IVDs
   - Act 101 Section 22C (1)b

2. Registration of medical devices and IVDs
   - Act 101 Section 14 read with Section 15
   - Act 101 Regulations addressing MD and IVDs
   - Guidelines addressing regulatory oversight of MD and IVDs
First priority: License

- Implement Quality Management System for License to Import, distribute & export medical devices & IVDs;

- SANAS develop Medical Device & IVD Accreditation Programme
Requirements for License to import

• Class C & D products
  • Pre market approval / registration in one or more of following jurisdiction:
    • Australia - TGA
    • Brazil - ANVISA
    • Canada - Health Canada
    • Europe – CE
    • Japan - MAH
    • United States America CDRH - PMA or 510k

  = “Originating approval/s”

• Certificate of Free Sale
• Summary Technical Documents (STeD) for Class C and Class D medical device & IVD.
• Where relevant, certificate of conformance / analysis
• Quality Management System
Registration of NEW devices: Class C & D medical devices & IVDs

MEDICAL DEVICES AND IVDs ROAD MAP - November 2015

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Registration of New Class C & D Medical Devices

New Class C & D

Prepare

Registration of New to market Class C & D medical devices & IVDs
### MEDICAL DEVICES AND IVDs ROAD MAP - November 2015

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**Call up categories of Class D & then Class C medical devices & IVDs (currently on market)**

**Call up of Class D Medical Devices & IVDs (on the market) for registration**
- **Class D**
  - Prepare
  - CALL UP
  - APPLY

**Call up of Class C Medical Devices & IVDs (on the market) for registration**
- **Class C**
  - Prepare
  - APPLY

**Registration of Class D Medical Devices & IVDs**
Medical Device Regulatory Road Map ...cont
Class B

- License to import, manufacture, distribute & export or wholesale Class B Medical Devices & IVDs
## Medical Device Regulatory Road Map

### Summary:

**License to Import & Manufacture & Export**

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**License to Export**

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<td>Licence to Wholesale</td>
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**SANAS develop Medical Device & IVD Accreditation Programme**

- Develop accreditation programme
- Inspect, audit & certify Medical Devices & IVDs eg ISO 13485

**Registration of New Class C & D Medical Devices**

- New Class C & D
- Prepare
- Registration of New to market Class C & D medical devices & IVDs

**Call up of Class D Medical Devices & IVDs (on the market) for registration**

- Class D
- Prepare
- Registration of Class D Medical Devices & IVDs

**Call up of Class C Medical Devices & IVDs (on the market) for registration**

- Class C
- Prepare
- Registration

**Licence to Import & Manufacture & Export**

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**License to Import, Distribute & Export**

- License to Import, Distribute & Export
- License to Wholesale

**License to Wholesale**

- Prepare
- License
Roadmap for the Regulator

Four key pathways:

1. Finalise SANAS agreement / MoU
   - SANAS to develop accreditation scheme for MD and IVDs

2. Establish Regulatory office for MD and Expert Committee of MCC
   - Regulatory staff appointed
   - Guidelines finalised and implemented
   - Contact and finalise Global Medical Device Nomenclature (GMDN) access

3. Legislation
   - Enact Bill 6/2014 and Act 72 /2008
   - Act 101 Regulations addressing MD and IVDs
   - Fees published for comment and implementation

4. Personnel competency and training
   - Reviewer, External experts
   - Collaboration and leveraging
Regulatory Pendulum

Over-regulation

Political pressure?

Societal Risk Appetite?

Under-regulation

High profile case?

Smart Regulation
“test of reasonableness”

Industry lobbying?
Applicant  Road map ?
Thank you!

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