Regulation of Medical and In-Vitro Diagnostic Devices
Roles and requirements

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Outline of the presentation

Introduction
Doctors needs discussed as follows
• Pre-marketing
• Patient-centred approach
• Unique Identification
• Risk stratification
• Post-marketing surveillance
Introduction

• SAMA welcomes the introduction of regulations
• Equitable access to quality and safe medical devices in both public and private sectors
• Development of National policy on medical devices and diagnostics, which may include but is not limited to essential medical technology
• Government must support R&D and align with international standards for economic development
Patient-centric Policy

- Good quality
- Effective
- Reliable
- Affordable
- Cost-effective
- Accurate
- Accessible
- Equitable
Pre-marketing Requirements

- Clinical evidence on safety and effectiveness.
- Rigorous trials with minimal bias ideal
- Identification and documentation of adverse events
- Potential risks associated with the device are identified and adequately addressed.
- Adequate skills are employed and utilised to assess risk in pre-marketing evaluation
Pre-marketing: Quality

• Monitoring and enforcement of a quality system in manufacturing
• Government to determine acceptable conformity standards
  – International certification enable exportation
• Ensure that standard requirements do not create barriers to entry and therefore price distortion
• Scientifically sound products
Labelling, Instructions, Packaging and Disposal

• Aimed at reducing Drs, patients, nurses etc associated risk.

• Instructions must be clear and consider all languages spoken in the country for devices intended for free market e.g. Class A&B.

• Disposal must be environmentally friendly

• Government must ensure SA is not a “dumping ground” for refurbished and reusable items
Training

• Manufacturers to take responsibility in use and training on high risk devices for their own economic (legal) benefits
• The most cost-effective model is to train the trainer.
• This will ensure wider coverage
• Due to rapid turn over in device industry, academic hospitals cannot keep up with training.
Risk Stratification

• All devices are inherently unsafe. Regulations intend to reduce the associated risk.
• The benefits of the device must always exceed the associated risks.
• Engineering design must consider possible risks and mitigation during the design phase.
• The inclusion of risk stratification is appropriate in South African
• **The doctors are in most cases knowledgeable about the likelihood of an event and impact**
Risk Stratification

The process to develop risk stratification must be:

- Clearly outlined
- Patient focused
- Transparent
- Consultative
- Take into consideration local circumstances
Risk Stratification

NDOH must publish the guidelines for risk stratification

Doctors must be involved in risk classification of devices
Identification of Devices

- Help Doctors choose safe and appropriate devices based on shared experience
- Drs needs to be educated on the
- Health care funders can assess outcomes based on claims data
- Good quality utilization of data
- Unambiguous identification
- Enable post-market surveillance
- Standardize information collection to review risk classification to test if assumption on hazard and probability of risk holds
Post-market Surveillance

• Challenging and complex
• Outcomes can be as a consequence of, patient, device or user characteristics
• Necessary as premarket evaluation data has the following limitations:
  – Small sample size
  – Lack of generalisability
  – Increased bias and confounding
Post-marketing surveillance
Types

• **Passive reporting/Vigilance**: responding after an event. The incidents may take long to detect due to underreporting.

• **Active/Registries**: pro-active collection of information on quality, safety or performance placed on the market.
Benefits of Post-marketing Surveillance: Regulator

- Recall and safety alert information
- Data to validate or revise classification status
- Feedback loop into improving premarketing safety and clinical efficacy evaluation
Benefits of Post-marketing Surveillance: Funders and NDOH

- Inform the balance of clinical and cost decisions
- Improves cost-effective allocation of resources
- Quality improvement in selection and funding decisions
- Recall processes reduce down-stream costs associated with unsafe devices
Benefits of Post-marketing Surveillance: Doctors

- Best evidence to select devices
- Focused clinician training to improve outcomes
- Quality improvement and minimisation of user errors
Benefits of Post-marketing Surveillance: Manufacturers

- Informs technology innovation, research and development
- Knowledge management
- Information sharing
- Reduces litigation costs especially if proactive surveillance is used
Pro-active Surveillance: Registries

- Critical for the identification and study of outcomes
- Commonly used for implantable high risk devices
- Comparative safety and effectiveness assessments
- Can assist with assessment on understudied populations
- Can assess effectiveness when multiple components are used.
- Take into consideration *local epidemiology, resources and skills*
- Early detection of risks and implementation of risk reduction measures
Examples of International Registries

• The Swedish Joint Registry, Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and the National Joint Registry for England and Wales (National Joint Registry) published literature on the increased failure rates of metal-on-metal hip joints compared with other materials.

• The Swedish Coronary Angiography and Angioplasty Registry (SCAAR), found that drug-eluting stents were associated with an increased risk of death as compared with bare-metal stents.

• SW.

• The AOANJRR found that many new products did not improve health outcomes compared to older devices, the newer devices were costly without any tangible added benefit.
Enablers of Post-marketing Surveillance

S. 7 c) of Medical Schemes Act

Council may make recommendations to the Minister on criteria for the measurement of quality and outcomes.

Opportunity to use claims data

Proposed E-health

Development of NDOH patient e-health strategy must consider capture of medical devices using UID.
Concerns about Proposed PMS

- Passive monitoring- allows for frequent occurrence of incidents and response based only on fatal incidences
- Missed opportunity to learn from near-misses
- Doctors, hospitals, nurses are generally poor with reporting
- The community has low health literacy
- Delayed implementation of risk mitigation strategies.
Enforcement

• Transparent, effective and efficient complaints process
• Decisive committees
• Appeals processes must prioritise the health of the patient
Unintended Consequences regulations

• Barriers to entry into the market, this may be driven by the existing international corporations
• Delays in registration making innovative technology inaccessible. Government must allocate sufficient resources
Conclusion

- Equitable access to safe, good quality and effective devices
- Rigorous pre-marketing safety and clinical evaluation to support evidence-based medicine practice
- Patient-centric national policy on devices
- Funding decisions based on safety and efficacy not price only
- Fair risk stratification
- Comprehensive post-marketing surveillance-Registries
- Enforcement and quick efficient recall processes