Medical Device Regulations: Update and SAMED's position

18 March 2011

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Chair: SAMED Regulatory Committee

south african medical device industry association
advancing innovation responsibly

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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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POSITION ON MEDICAL DEVICE REGULATION

SAMED strongly supports a legislative and regulatory framework to control the manufacture, distribution and marketing of medical devices and *in-vitro* diagnostics (IVDs) to ensure that South African patients have access to products that are safe, effective and of good quality.

SAMED Regulatory Committee

Wayne Flowers	AEC Amersham	Brian Goemans	MD2M
Madeleine Pearce (chair)	Abbott Diagnostics	Dirk Gey van Pittius	Medtronic
Alison Jeffries	Baroque Medical	Deepa Maharaj	Roche Diagnostics
Simone Rudolph-Shortt	BSN Medical & others	Tanya Vogt	SAMED
Ruwaida Shaikh	Boston Scientific	Franciska Grobler	Stryker
Ronel Allner	Covidien	Athene Saul	Smith & Nephew
Willie McLeod	Johnson & Johnson	Lauranda Breytenbach	Southern Implants
Charl Louw	KCI Medical	Yolanda Wissner	Zimmer

SALDA Regulatory Committee

Madeleine Pearce (chair)	Abbott Diagnostics
Ambigai Naidoo	Adcock Ingram
Piet Grove	Beckman Coulter
Avanthi Bester	Becton Dickinson
Kevin Ward	Bioweb SA
Deepa Maharaj	Roche Diagnostics
Doreen Howard	SALDA
Hera Stavrinos	Siemens
Greg Northfield	Separation Scientific
Debbie Moosa	Thistle

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Other role players

- Advocate Elsabe Klinck
- Department of Health
  - Ministerial project: Health Technology
- Consultants to the Minister and the Department of Health
- International regulatory expertise from industry and regulators
  - Asian Harmonization Working Party attendance December 2010

Act 72 of 2008

- Amended the Medicines and Related Substances Control Act of 1965
- Introduced SAHPRA (the South African Health Products Regulatory Authority)
- Made provisions for the registration of medical devices and *in-vitro* diagnostics

Medical Devices are not Medicines

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Scope of regulation

- Safety ✓
- Quality ✓
- Efficacy ✓

- Economic considerations ✗

"SAMED does not support the introduction of …economic criteria for registration, as this imposes a second barrier to market entry which is unprecedented in other countries, will cause delays, and limit access to healthcare choices for the SA public. Trade and investment in healthcare in SA may also be affected."

Submission to Director General of Health, 2008

Licensing and registration

- All medical devices/IVDs to be registered
- All persons importing, manufacturing and selling medical devices/IVDs to have a license

SAMED's position: ✓

Application form for registration

SAMED's position:

There are 1000’s of line items for medical devices/IVDs

- regulate products in logical groups
- minimize the need for separate applications for registration

Classification of Medical Devices

Class	Risk Level	Device examples (illustrative only)
A	Low	Simple surgical instruments/ tongue depressors
B	Low-moderate	Hypodermic needles/suction equipment
C	High-moderate	Lung ventilator/orthopaedic implants
D	High	Heart valve/implantable defibrillator

* Global Harmonization Task Force,

GHTF/SG1/N15:2006 *Principles of Medical Device Classification*

Classification of *in vitro* Diagnostics

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser , prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self testing, Anti-Nuclear Antibody, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

* Global Harmonization Task Force, GHTF/SG1/N45:2008 *Principles of IVD Medical Devices Classification*

Medical Device Categories (nomenclature)

- Appropriate internationally harmonised nomenclature (such as the Global Medical Device Nomenclature system)

01	Active implantable devices
02	Anaesthetic and respiratory devices
03	Dental devices
04	Electro mechanical medical devices
05	Hospital hardware
06	In vitro diagnostic devices
07	Non-active implantable devices
08	Ophthalmic and optical devices
09	Reusable devices
10	Single use devices
11	Assistive products for persons with disability
12	Diagnostic and therapeutic radiation devices
13	Complementary therapy devices
14	Biological-derived devices
15	Healthcare facility products and adaptations
16	Laboratory equipment

Medical Device Categories (nomenclature)

SAMED's position: GMDN

a single, global, nomenclature system by which the authorities can regulate medical devices; this also impacts upon the health care providers, the medical device manufactures, suppliers, conformity assessment bodies and other affiliated parties, so there is a single system that provides the generic product descriptors to support patient safety.

Risk Management/Quality Assurance

SAMED's draft position

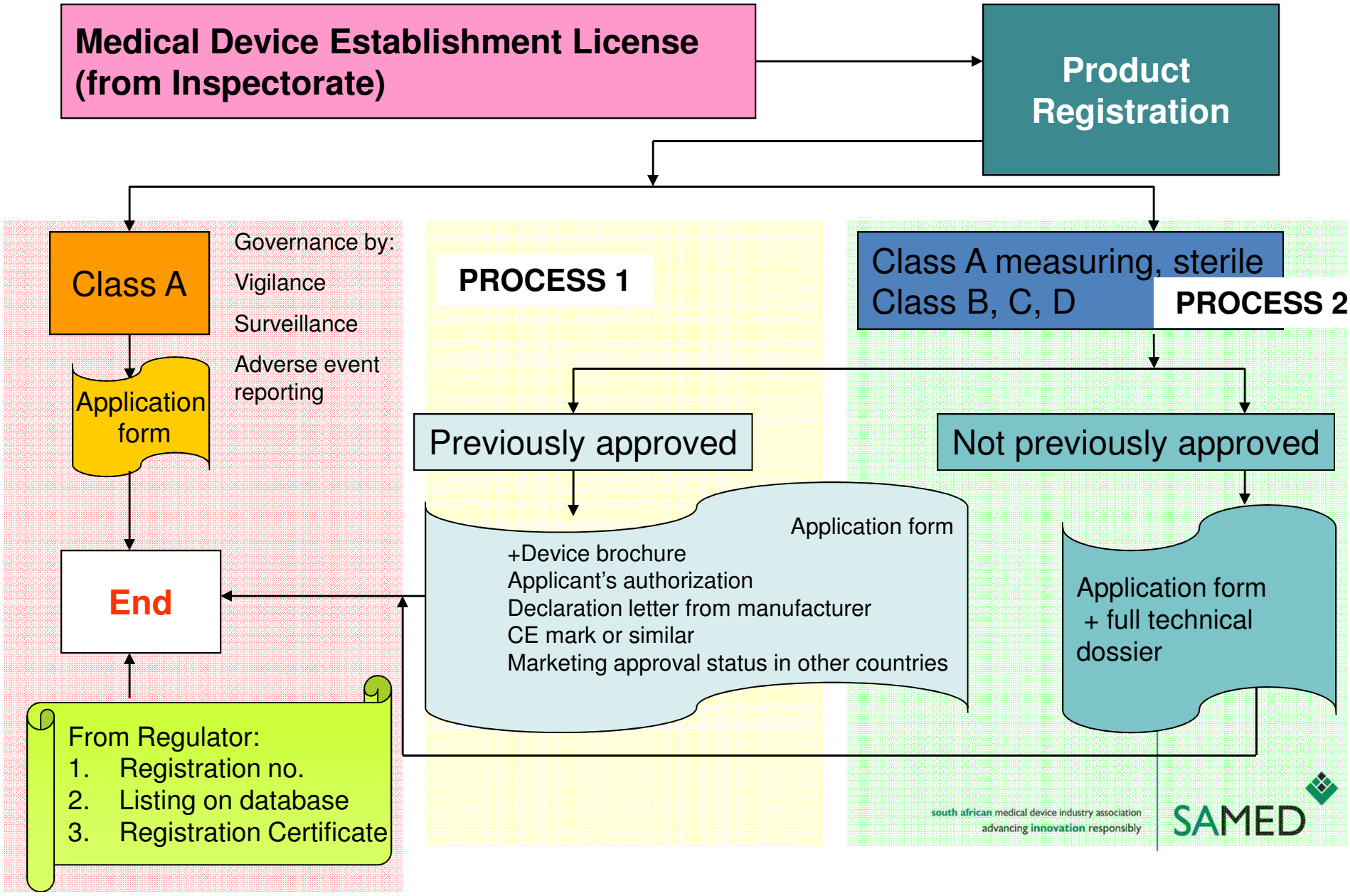
- Establishments should be certified against the quality management system for medical devices - ISO13485 certification is recommended as a pre-requisite.
- MD/IVD establishments to have 3-5 years to achieve ISO13485 accreditation from the date that regulations appear in the Government Gazette.

Registration process: SAMED's position

Principle :

The registration process must be simple and efficient, responsive to the needs of the applicant, with short lead times

Proposed Licensing & Registration Process



Conformity Assessments

SAMED's position:

- Regulators/assessors should be drawn from a pool of skilled & qualified individuals familiar with the use, technology, manufacturing methods, quality management systems and standards pertaining to the device. The credentials of the reviewer should be made available to the applicant on request.
- Conflicts of interest should be declared and managed to the satisfaction of the applicant.

Validity of a License

SAMED's position:

- Establishment renewal – every 5 years
- Registration – no re-registration
- Annual verification

Amendments to register

SAMED's position:

- The Authority should be notified of any change(s) to the original application document.
- Re-evaluation of registration documents will only be required if a change is considered major and the product is registered according to Process 2.

Information to accompany medical device/IVD

SAMED's position:

- Allow for translated IFU's for OTC retail devices to be made available in a reasonable amount of time.
- Reasonable access of information regarding the safe use of medical devices to be made available to the general public, where applicable.
- MD/IVD's used solely by HCP's to be exempt from this requirement.

Advertising

SAMED's position:

- Aligned with Code of Advertising Practice of the Advertising Standards Authority and, where applicable, to the SA Code of Practice for the Marketing of Health Products

Clinical Trials

SAMEDs position:

- Applications for clinical trials should be reviewed by an Ethics Committee and follow approved protocols.
- Patient safety and confidentiality should be a priority in any clinical trial requirements. Financial disclosures and conflicts of interest should be declared.

Please note: Randomised, double blinded clinical trials as for Pharmaceutical products are not generally conducted for medical devices/IVDs

Labelling, packaging and seals

SAMED's position:

- South African specific labelling will add cost
- Harmonised labelling conventions address safety aspects
- Labelling is most often directed to Health Care Professionals

Please note: Labelling requirements for medicines are incongruent and irrelevant in many cases for medical device and IVD labelling

Evaluation of Medical Devices/IVDs

SAMED's Position:

- Class A devices and/or appropriate OTC devices permitted to be provided FOC without restriction.
- A MD supplier may provide a limited number of registered devices FOC in order to allow a HCP to evaluate the device or for training purposes. No items supplied FOC may be subsequently charged for.
- Evaluations should be documented and adverse events reported.
- Exemption process for MD's that need to be charged for to be provided.
- Professional bodies to be consulted in terms of patient safety considerations.
- Appraisal activities must be transparent, fair value in terms of information transferred.

Evaluation of Medical Devices/IVDs

SAMED's position:

- Class A devices will have limited regulatory oversight
- Innovative devices require that the customer has the opportunity to evaluate the appropriateness of the device for ease of use, suitability for medical practice, etc.
- For exhibition purposes (displaying products or demonstrating products at conferences, etc) is allowable.

Recall

SAMED's position:

- Recall of medical devices should be a systematic process where items sold are traceable and retrievable. For retail items, the establishment conducting the recall may have to disseminate information via mass media.

Samples for investigations

SAMED's position:

- Samples to be taken for testing by the regulator -reasonable quantity at reasonable cost , accounted for, traceable and for good reason
- Samples taken should not add significantly to cost of supplying the device.

Fees, penalties

SAMED has proposed some principles on fees in particular:

Set registration fees at appropriate levels to avoid negatively impacting on the cost structures for the medical device industry

Other Regulations

- Acceptable & prohibited acts i.t.o. bonussing, rebates, and incentive schemes
- Licensing and registration fees
- Time frames for consideration of applications
  - due to the rapid innovation of medical devices, review and approval times should be reduced to a minimum. Industry has benchmarked timeframes for approvals with other regulatory authorities and expects similar service delivery from the Regulator.

Other regulations

- Transitional Measures

SAMED's Position:

the regulator should make use of grandfathering and sunset clauses. Medical devices/IVDs should be regulated in a phased approach according to risk and regulator’s capacity to process applications.

Continuity of supply of medical devices that have a track record of safety, quality and efficacy should not be interrupted. The access of patients to high quality medical devices should be unaffected by the registration process.

Questions