Presentation to the Southern African Pharmaceutical Regulatory Affairs Association:

Latest Gazetted Regulations/MCC guidelines: Concerns/comments by SAMED

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SAMED
south african medical device industry association
advancing innovation responsibly

SAMED

- SAMED is a trade association that represents the interests of a large proportion of manufacturers and importers of medical devices and IVD's (> than 160)

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- SAMED strongly supports a legislative framework that ensures that South African patients have access to medical devices that are safe, effective and of good quality
- SAMED supports the promulgation of regulations that are: **appropriate** for the South African market, that leverage on **international experience**

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The variation in medical device product types is vast…..

..from simple to complex,
from low risk to high risk technologies.

Regulation must reflect the differences in medical device types.
Regulation cannot simply follow medicines regulation

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SAMED - Concerns and Comments

Legislation, regulation and guidance documents must provide a regulatory framework that is:

PRACTICAL – not burdensome to applicants

AFFORDABLE – cost of registration

EFFICIENT – does not deny patients access to medical devices due to lengthy lead times

HARMONISED – minimise special requirements for South Africa vs international norms

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April 2016: Status of medical device regulation

- **Legislation**: Act 14 of 2015 was signed and published in the Government Gazette on 8 January 2016 – amends Act 101 (Medicines and Related Substances Control Act). It has however not been proclaimed, i.e. not been brought into operation yet. It will come into effect once Act 72 of 2008 is proclaimed by the President
- **Regulation**: Draft regulations were published for comment in the Government Gazette on 31 July 2015
- **Guidelines**: Draft guidelines were published in 2014 and again in 2015 for comment. To be finalised when final regulations are published

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Act 14 of 2015: concerns

- Inclusion of Medical Devices and IVD's under clauses that previously only pertained to Medicines-**s2B (f); s16; s18; s22As22B; s22C; s22H; s28; s29; s21; s35**
- to require the Minister to consult with the Pricing Committee when prescribing acceptable and prohibited acts in relation to bonusing
- Overlap and conflicts with existing legislation not taken into account
- Grandfathering/sunsetting clauses and transitional period not provided for
- Health Economic Policy and Registration do not belong in the same Act - **s36** Pricing, tenders, procurement, essential equipment lists will fall under registration legislation – should be left to health policy

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Latest revision of regulations: positive developments

The removal of some terms, provisions, definitions that pertain only to medicines, for example:

- scheduling
- good manufacturing practice
- prescription
- dispensing
- registered pharmacist
- inspection of business premises
- package insert

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Latest revision of regulations: positive developments

- the adoption of some harmonized approaches (IMDRF/GHTF)
- acknowledgement of inputs by SAMED
- transparency on envisaged road map. SAMED regulatory conference
- the dedication of resources towards putting together the medical devices regulatory framework and department

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Latest revision of regulations: positive developments

- the acceptance that medical devices could be registered in groups or families
- the recognition that, internationally, medical devices are evaluated by conformity assessment bodies, not internally at the regulator
- the recognition of regulatory work by reputable regulators internationally
- the adoption of some approaches to regulation found in documents published by the **International Medical Device Regulators Forum** (IMDRF, previously GHTF), thus aligning South Africa with a more harmonised framework for medical device regulation.

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Industry Concerns with regulations

- **International Tendering – additional considerations**
  - Post purchase / After sales support
  - Service & Training Requirements
  - Post Market Requirements
    - Complaint Management & investigations
    - Vigilance Reporting
    - CAPA
    - Field Action Recalls
  - Product Returns – shipping costs liability
  - Industrial Development Vision

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Industry Concerns with regulations

- The regulations are issued under **Act 101 of 1965** in its current format excludes essential legislative amendments included in Act 72 of 2008
- Some regulations (2 and 3) are not empowered by Act 101 of 1965, and remain *ultra vires*, in terms of the current Act. This concern, which was previously pointed out in SAMED's submission in 2014, has not been addressed.

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Industry Concerns with regulations

- The Regulator remains the Medicines Control Council until SAHPRA organisation is implemented
  - current structure is not designed to regulate the wide variety of medical devices that may require registration
  - expertise and skills within the Regulator remain largely with the discipline of pharmacy
  - South African Health Products Regulatory Authority (SAHPRA) with its various sub-departments would be a more appropriate authority to attempt medical device regulation.

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Industry Concerns with regulations

- The section on expedited registration has been removed.
- This is a concern because of the short life cycle of medical technologies.
- SAMED wants a requirement that medical devices be registered **within 90 days**
  - to avoid obsolescence and barriers to access to technology for South African patients.
- The regulations do not commit the Regulator to a Service Level Agreement.
- SAMED wants assurances in regulations that medical device registrations
  - will be efficient and cost effective
  - will not result in lengthy backlogs as seen with medicines registrations.

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Industry Concerns with regulations

Clarification is required for the responsibilities of the:

- authorised representative
- the legal manufacturer
- the holder of the certificate of registration

Some provisions may be unworkable or ambiguous

[Refer to Regulation 6 (1) c (ii); 6(10); 9 (7); 11 (2) b; 18(1) (3) (5)].

Internationally, two possibilities exist for the function of the authorised representative:

(i) only for communication between the legal manufacturer and regulator

and

(ii) as a qualified person who takes responsibility for quality and safety of a medical device

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Industry Concerns with Regulations

- SAMED has requested a meeting with the Registrar to discuss and clarify the roles, expectations and requirements of the various positions referenced in the regulations to address any misunderstandings

  (i.e. authorised representative, legal manufacturer and holder of the certificate of registration)

- the outcome of this discussion may lead to a guidance document to define the appropriate responsibilities

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Industry Concerns with Regulations

- Risk classification is best determined by the manufacturer, not Council, as the manufacturer is best able to follow classification rules as experts in the technologies under consideration
- The requirements for clinical trials for Class A and B medical devices are overly burdensome considering that there would also be Ethics Committee oversight, and international approaches to clinical trials should be adopted

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Industry Concerns with Regulations

- Adverse event reporting regulations are not harmonised with international norms and practices – it is recommended that the regulations adopt the definitions for serious adverse events and the timelines for reporting per the IMDRF model (reference: GHTF/SG2/N54R8:2006, *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*)

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Industry Concerns with Regulations

- The restrictions on advertising of Class C and Class D medical devices are inappropriate as, unlike medicines, advertisement of medical devices does not promote self-therapy.
- There is no inclusion of provisions that permit electronic or website labelling to accommodate generally accepted global trends in labelling

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Industry Concerns with Regulations

- The Declaration of Conformity and Essential Principles are internationally recognised documents that contain prescribed requirements and standard formats - these should not be dictated by a local South African Council
- There is no clear commitment in these regulations to publish registration particulars in electronic format on a website, nor do the regulations refer to electronic labelling, which is the way of the future
- The scope of regulation of medical devices/IVDs for animal health is not clear

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Industry view on Guidelines

Guidelines are premature

- Until regulations are finalised

Two guidelines:

- General guidance
- Essential principles

Questions around:

Registration submissions- define changes vs substantial changes

Classification of medical devices- if classification of a product is different in South Africa compared with international classification

Incomplete with respect to *in-vitro* diagnostics

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Thank you

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