SAMED Position Paper and Recommended Principles of Medical Device Regulation for South Africa

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Background information: Medical devices and IVDs (collectively termed medical technology) used in the diagnosis and treatment of disease and disability, as well as offering improvements in quality of life in humans, are regulated in many countries or regions around the world. In an increasing number of countries, legislators and policy-makers are developing or revising national systems for the regulation of medical technology.

SAMED recognizes that regulations have an impact on the medical technology market and determine the access of patients and clinicians to medical technology. Regulations also determine the level of investment in research and development in innovative technologies, local manufacturing and the attractiveness of a market.[1]

Regulators have a duty of care to the South African health system to ensure a fair and efficient regulatory environment that supports access to innovative and needed technologies by patients. SAMED acknowledges the right of the South African government to implement measures regulating medical technology including measures governing those who design, manufacture, market, use and/or distribute medical technology in South Africa.

SAMED supports reasonable, appropriate and proportionate government policies intended to ensure the safety, performance, and quality of medical technology so that they may contribute to protecting and improving public health.

With this in mind SAMED advocates for and supports the following principles of good regulatory practice for medical technology:

1. Building a strong partnership between the regulator and industry through:

1.1 Good governance

Regulators and industry engagements need to be conducted with good governance, without conflict of interest. Decisions need to be taken in the public interest and with minimised bias.

[1] https://www.uschamber.com/sites/default/files/good_regulatory_design_paper_-_4-24-2017_-_final.pdf, *pgs 5 and 6*

1.2 Ethical and transparent interaction

Regulators and industry interactions must be ethical and transparent. It is recommended that meetings are recorded, minuted and that generic email addresses be used.

1.3 Formal engagement platforms

Regular ongoing formal platforms of engagement with the regulator and industry with agreed action plans. This ensures accountability, efficient collaboration and best practice outcomes.

1.4 Digital / online platforms to support efficiencies

Use of digital and online platforms to support efficiencies, track and trace application systems that are time bound and supportive of a consistent and transparent framework that mitigates against corrupt practices or preferential treatment.

1.5 Joint training

Joint training and workshops between the industry and the regulator will ensure common understanding, alignment to guidelines by regulatory evaluators/reviewers and reduce the number of non-compliant applications from industry.

1.6 Shared responsibility / co-creation

Consultation and collaboration between industry and the regulator is key. So too allowing for sufficient time and opportunity for industry, both local and international, along with other interested parties, to carefully consider and give their views, both in written and face to face format on proposed requirements, and take these into account prior to publication of any changes in legislation, regulation and guidelines.

2. Supporting sustainability by:

2.1 Adopting a step wise approach

Consider a step wise / staged approach to implementation of medical device regulation, consistent with local public health priorities, resources and industrial development goals.

2.2 Forward planning

Forward planning will allow for appropriate resource management and capacity building.

2.3 Supporting transformation

Support the transformation and building of the local industry and be cognisant of the constraints of SMME's. The majority of medical technology companies in South Africa are small to medium companies.

2.4 Capacity building

Capacity building in both the regulatory authority and industry will ensure that adequate and appropriately qualified government and private resources are available to effectively implement new requirements before they enter into force, thus ensuring no delay in access of medical technologies to patients.

2.5 Transitional arrangements and flexibility

Provide reasonable transition timeframes for industry to comply with, and medical technology procurers to understand and implement new requirements before they enter into force.

2.6 Work toward full compliance

A regulatory impact assessment should be conducted and documented prior to the adoption of any substantial new regulation. The practicalities and cost/benefit balance should be evaluated before implementation.

2.7 Appropriate oversight and flexibility

Appropriate regulatory oversight whilst minimising regulatory burden on industry. The regulator needs to be flexible, agile and respond fast in times of need or emergency.

2.8 Communication and collaboration to establish consistent policies/implementation

Inter-ministerial and cross-functional communication and collaboration between different government authorities is needed to establish consistent policies and implementation without undue delay. Examples of key entities include: Port health; the dtic, DSTI; ITAC, NT, OECD; NDOH, NRCS, Provincial Departments of Health etc.

3. Ensuring harmonisation by:

3.1 Following international principles of good regulatory practice

Good regulatory practices aren't about more regulation or less regulation, they are about facilitating better regulatory outcomes. The OECD Report on Regulatory Reform;

Organization for Economic Cooperation and Development, Paris; 1997[2] recommends as a key principle that regulations should "produce benefits that justify costs, considering the distribution of effects across society". This principle is also known as the "proportionality principle".

See also: The bridge to cooperation: Good regulatory Design, US Chamber of Commerce, 2017, The bridge to co-operation: Good regulatory Design, US Chamber of Commerce, 2017 and WHO Good regulatory practices for regulatory oversight of medical products

3.2 Market openness

Respect the legitimate interest of manufacturers in protecting intellectual property. Government officials developing new, and/or revising existing regulatory systems are urged to adhere to the Organization for Economic Cooperation and Development's efficient regulation principles for market openness i.e.:

- Transparency and openness of decision-making
- Non-discrimination
- Avoidance of unnecessary trade restrictiveness
- Use of internationally harmonized measures
- Recognition of equivalence of other countries' (or regions) regulatory measures
- Application of competition principles

3.3 Medicines vs Medical Technology

The characteristics and mode of action of most medical technology is different to those of medicinal products. The regulatory system should be designed with this principle in mind.

3.4 Peer alignment

Wherever possible, regulators should pursue regional harmonisation and align with international regulatory approaches and technical requirements and adopt guidance documents prepared by the Global Harmonization Working Party (GHWP) [3], the

[2] *The OECD Report on Regulatory Reform*; Organization for Economic Cooperation and Development, Paris; 1997. OECD recommends as a key principle that regulations should "produce benefits that justify costs, considering the distribution of effects across society". This principle is also known as the "proportionality principle". https://www.oecd.org/gov/regulatory-policy/2391768.pdf

[3] Global Harmonization Working Party (AHWP) is a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards. See www.ahwp.info.

International Medical Device Regulatory Forum (IMDRF)[4], the World Health Organisation[5] and the Pan African Health Working Party. This would include, amongst others, the definition and risk classification for medical technology, use of internationally recognised standards i.e., those developed and adopted by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU) and conformity assessment as the basis for a medical technology regulatory framework.

3.5 Reliance models

Take into account, and give substantial weight to, marketing approvals and certifications issued by regulatory authorities and/or conformity assessment bodies in other countries or regions as evidence of substantial compliance with national requirements, thus avoiding unnecessary, costly and duplicative product testing and/or factory audits.

Adopt the GMDN (Global Medical Device Nomenclature) as the preferred nomenclature system for medical technology.

[4] The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF). The Forum will accelerate international medical device regulatory harmonization and convergence. See www.imdrf.org

[5]Without necessarily endorsing all of its recommendations, SAMED also notes the general guidance, including its references to GHTF guidance, of the World Health Organization in *Medical Device Regulations: Global Overview and Guiding Principles,* WHO, Geneva, 2003. See: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf