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South African Health Products Regulatory Authority

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Workshop on International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Health References & Recommendations

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Background

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Medical devices play a major role in health systems, they are needed to address the burden of disease, economic challenges, and infrastructure of African nations rather than just using medical devices that were designed for the needs and resources of high-income countries.

The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.

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WHO Key documents

Global Model Regulatory Framework for Medical Devices and IVDs

- Provides guidance and support on how to develop and implement regulatory controls relating to medical devices, as well as to jurisdictions that are continuing to improve their regulatory frameworks as they take steps to ensure the quality and safety of medical devices available in their countries

Good Regulatory Practices

- Legality
- Consistency
- Independence
- Impartiality
- Proportionality
- Clarity
- Flexibility
- Efficiency
- Transparency

Good Reliance Practices

- reliance on the work of other authorities to eliminates or reduce inefficient duplication of regulatory evaluations of medical products and inspection or audit of facilities.

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Pillars of Reliance

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Medical device regulatory approval gaps within Africa

Gaps within African Regulatory authorities

- Lack of resources
- Lack of legislation to regulatory skills.
- Lack of political will
- Lack trust amongst African countries
- Lack of accessible information and confidentiality of information
- lack of regulatory alignment of product risk-classifications and inconsistent practices regarding product modifications in the area of medical devices
- Difference in the level of detail in regulatory reports, different levels of competencies

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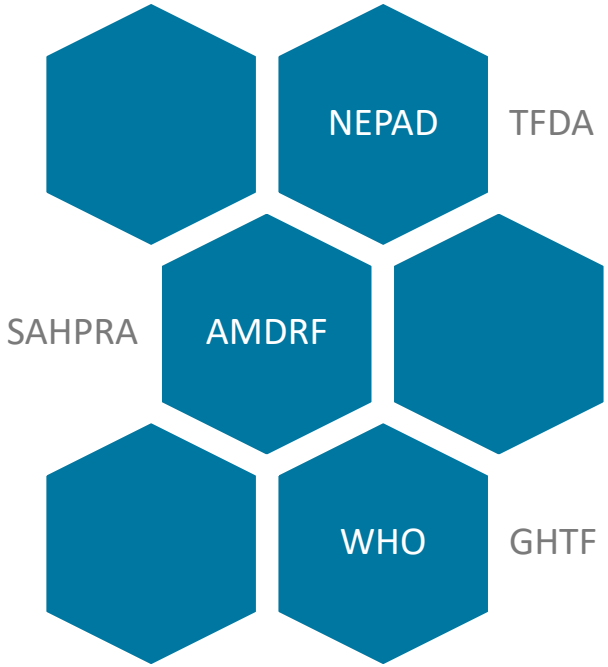
Regulatory harmonization of medical devices in Africa

Harmonisation amongst African countries



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Many researched papers have reflected the need and advantages for African regulatory authorities to convergence in order to ensure timely availability of affordable, safe and quality medical devices .

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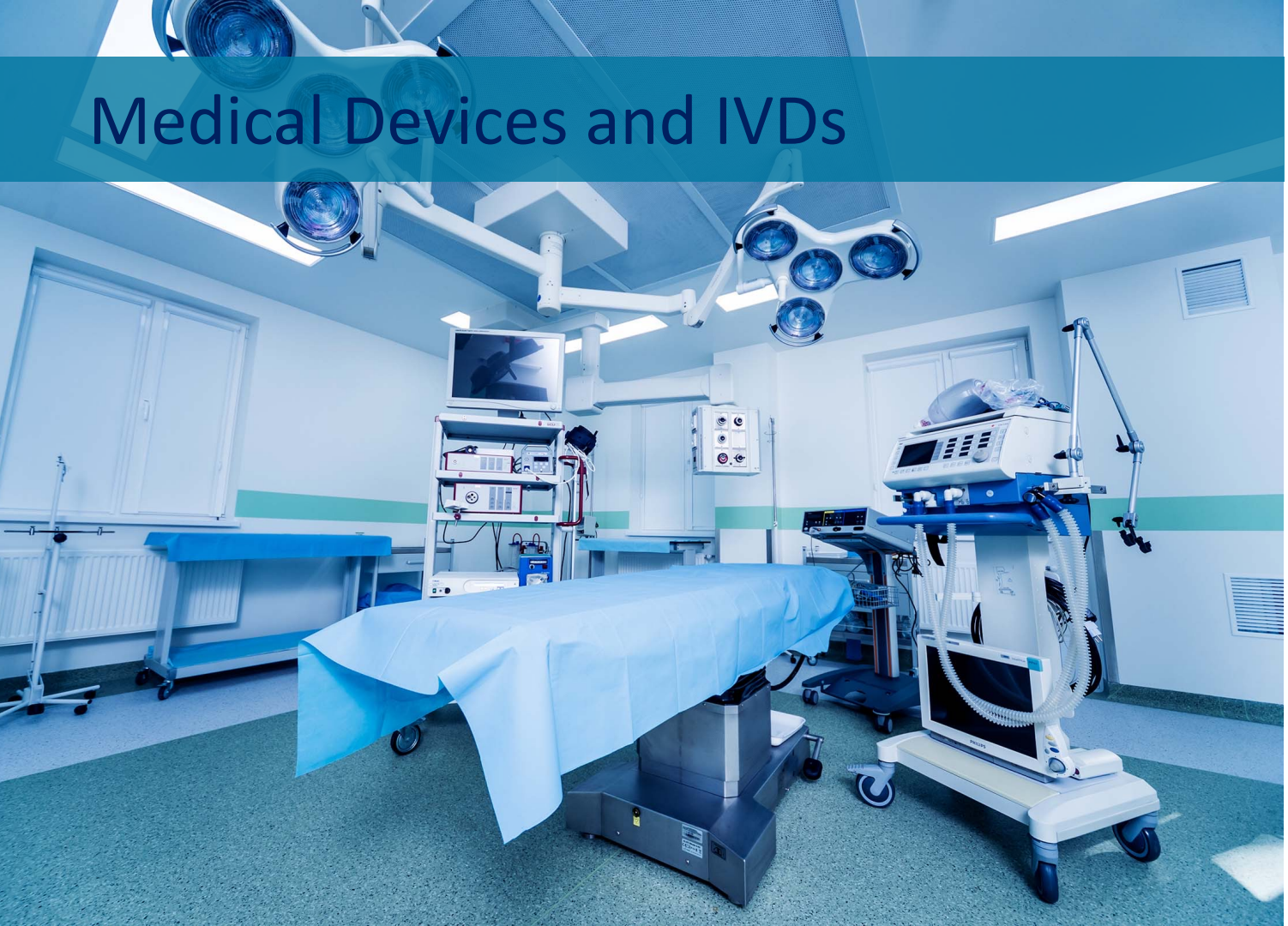
Medical Devices and IVDs



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Challenges and Advantages of Regulatory harmonization of medical devices in Africa

Challenges and Advantages of regulatory harmonisation

Challenges

- Lack of accessible information and confidentiality of information
- Lack of regulations
- Lack of resources
- lack of regulatory alignment of product risk-classifications
- different levels of competencies

Advantages

- decreased regulatory burden
- decreased workload on regulatory Authorities
- Increase the quality of regulatory decisions
- timely access to safe, efficacious and quality-assured medical products

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Way forward for Medical Devices regulation in Africa

Way forward

- Reliance does not represent a less stringent form of regulatory oversight nor an outsourcing of regulatory mandates or a compromise to independence.
- Agencies should implement quality measures and monitoring e.g. by updating IT infrastructure, this will enable sharing of data amongst regulatory authorities .
- The proactive engagement of different stakeholders from the medical device industry as partners in the implementation of the regulations will be beneficial.
- The inclusion of reliance-related provisions by NRAs as part of their flexible regulatory pathways is encouraged and should be considered for all regulatory functions over the medical product life cycle, as appropriate

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Overview of SAHPRA's role with regulation of medical devices

Status of medical devices

- Licensing Medical device establishment according to ISO 13485
- Total Establishment License issued: 2413
- Reliance with 6 Stringent NRA (US FDA, TGA, EU etc. & WHO (IVD's)

- Registration of medical device has not commenced
- Updated medical device regulations
- Call up plan in draft

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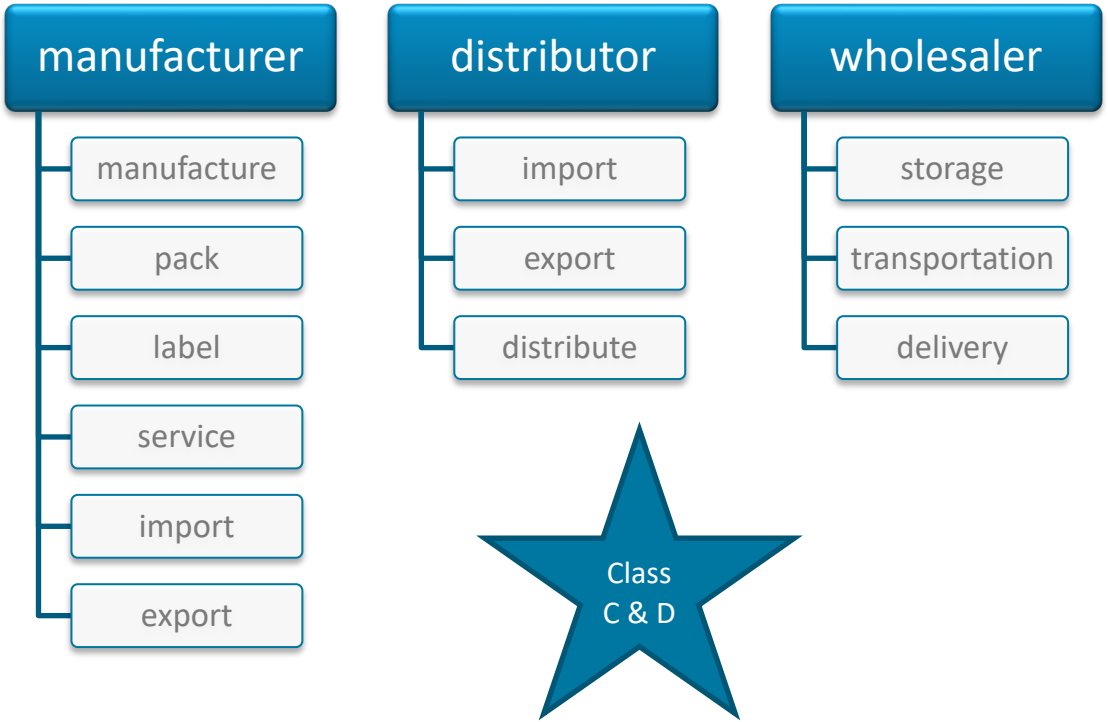
Medical Devices and IVDs

An applicant may apply for one of three types of licences for medical device establishments:



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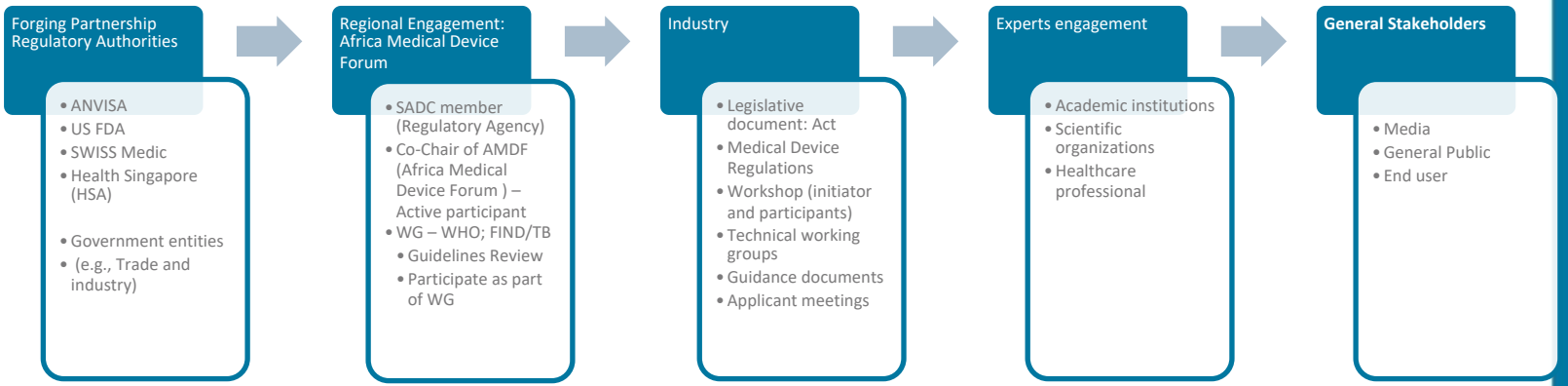
SAHPRA Engagements



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WHY Reliance?

- Well established regulatory authorities should collaborate with authorities to expedite IVDs and medical devices legislation and policy framework where it does not exist; and to identify refinement areas to existing ones where it is already in place.
- African agencies do not need to implement policies from scratch however they can adopt from organizations such as IMDRF and WHO.

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THANK YOU