- What are the main regulatory challenges that medical device manufacturers face in South Africa, and how are these challenges evolving?

  As with ALL African countries where the maturity of legalisation is centuries behind other continents e.g. EU, USA, Canada, Japan and the past Drug control methodologies under Pharmacists control is a creating a problem and hinderance to the health products supply chain in that non medicine products are being aligned to the pharmaceutical value chain, which involves manufacturing pharmacies, wholesale pharmacies and retail pharmacies.

  This is problematic in that medical devices, IVD, complimentary medicines and traditional medicines should not follow the restricted Pharmacist supervision as the value chain involves a vast variety of many other Qualified persons e.g. general engineers (metal fabrication), microbiologists, chemists, biomedical engineers as well as laypersons and diversity of trades such as healthcare practitioners, hospital establishments, retail pharmacies and out lets such as retail stores

  In addition, the cost of technical evidence with standards testing, clinical evaluation and product assessment by competent / accredited authorities, as well as the QMS (quality management system) cost of ISO13485 / MDSAP is prohibitive to commercialisation

  For many manufacturers and innovation economic operators the level of discipline to Design Control (ISO13485 C7.3) often results in retrospective collation of technical evidence, verification testing and validation conclusion. In addition, the understanding and application of the essential requirements for safety and performance of the intended use of the product is not fully understood or applied; and not always populated for the required Technical Documentation for Product assessment (registration) by the Regulatory Authorities.

- How does the MDMSA support its members in navigating the complex regulatory landscape for medical devices, both within South Africa and across the broader African continent?

  The Medical Device Manufacturers industry association of South Africa (MDMSA) is a local medical technology, not for profit, membership-based association. When a member company joins MDMSA, there are three main areas that they benefit from namely.

  engagement and representation, through engagement with many government, academic and regulatory stakeholders,

  insight & intelligence, through workshops, communications, advocacy, international meetings and participation in the South African Health products Master Plan

  networking & value proposition, with regular member meetings, workshops, Memorandum of Understanding with other associations

- Can you provide insights into the recent or upcoming changes in South African medical device regulations, and how these changes might impact manufacturers?

  Unfortunately, this information is not available, and South Africa are doing a feasibility study for product registrations end 2024 – 2025. We in South Africa are waiting for revised medical device regulations.

- How does the MDMSA collaborate with other regulatory bodies or associations in Africa to harmonize medical device regulations, and what are the key goals of these collaborations?

  As above we have:

a) stakeholder engagement and participation e.g. ITG (Industry Task Group)/ RTF (Regulatory Technical Forum) with SAHPRA, SAMRC Regulatory Forum, and USAID MDCG (medical device convergence group)

b) participation through Sector Specific Assistance or SA National Pavilions with SA government body DTiC (department of Trade and Competition) e.g. Arab Health, Africa Health, East Africa Health and with other associations e.g. ProudlySA, HASA (Hospital Association of SA), SAFHE (South African Federation of Healthcare Engineering)