30th IMDRF 2026

Tanzania Updates

IMDRF Stakeholder Forum

Day 2 | 15 September 2026

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TMDA

Tanzania Updates

Regulatory progress, IMDRF alignment, reliance, and priorities for the next phase.

Regulatory framework 01

Mandate, controls and regulatory architecture

Medical device regulations 02

2025 updates and IMDRF-aligned elements

Utilizing IMDRF guidance 03

Technical documents and new guidance

Reliance Programme 04

Pre-market and QMS reliance approach

Working group involvement 05

Participation and outcomes

Strategic road map 06

Future actions and capacity-building priorities

Regulatory Mandate & Framework

Legal mandate

Executive agency under the Ministry of Health (MoH), Tanzania.

Established in 2003 under the TMDA Act, CAP 219.

Mandated to regulate medical products, including medical devices and IVDs. [section 5(1) a]

Medical devices regulatory control framework

- Regulatory controls span the product life cycle—from authorization and import/export to surveillance and testing.
- The framework supports quality, safety and performance oversight of medical devices and IVDs.

Key Updates: Medical Device Regulations

TMDA updated the regulations developed in 2015 through the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations 2026.

The updated framework is more comprehensive and specific to each regulatory function.

Essential Principles

Safety & performance

Classification

Medical devices & IVDs

Harmonization

Regulatory convergence & reliance

Emergency use

Emergency Use Authorization

Digital health

SaMD & AI

Traceability

UDI & labelling

Alignment with IMDRF technical guidance is a central feature of the updated regulatory framework.

Key Updates: Utilizing IMDRF Guidance Documents

95%

of TMDA technical documents are based on IMDRF documents

Marketing authorization guidance

A compendium of 12 Technical Guidelines covering core submission and assessment topics.

- Essential Principles of Safety & Performance
- Clinical evidence
- STED technical requirements
- Labelling
- Good Review Practices
- Emergency Use Authorization
- Classification
- Performance evaluation of IVDs
- Grouping
- Software as a Medical Device
- Regulatory Reliance
- Changes to Approved Devices

Guidance integrates TMDA processes with IMDRF approaches

Key Updates: Reliance Programme

TMDA applies an abridged pre-market assessment and desk review pathways for eligible products and facilities.

Abridged pre-market assessment

Eligible products include those approved by IMDRF member authorities (USFDA, PMDA, TGA, Health Canada and EU) and WHO CRP programmes

Desk review of manufacturing facilities

Eligible facilities include those approved by IMDRF member authorities, WHO-prequalified facilities, and facilities audited and approved by GHTF/IMDRF members.

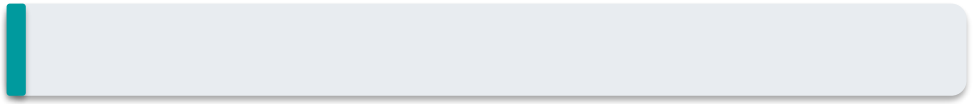
Legal basis: TMDA Act CAP 219 recognizes decisions of other international organizations.

Applications Reviewed Under Reliance

Dossier review

2%

Reliance pathway



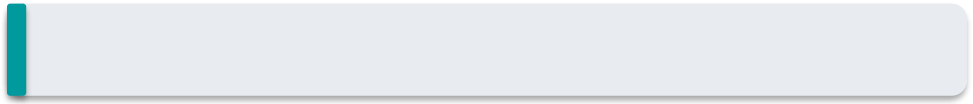
Abridged review — Normal review

98% normal review

QMS audit

2%

Reliance pathway



Desk review — On-site audit

98% on-site audit

- Reliance-based applications account for an average of 2% of total applications received per year.

IMDRF Participation & Outcomes

TMDA has actively participated in IMDRF meetings since becoming an affiliate member in 2024.

1	**Regulatory reform**	Updated regulations to improve regulatory processes
2	**Guidance & procedures**	Developed guidelines and procedures to strengthen controls
3	**Regulatory efficiency**	Improved efficiency through reliance approaches
4	**Technical capacity**	Strengthened dossier review knowledge and skills
5	**QMS audit capacity**	Built capacity through MDSAP training

Working group engagement includes review of IMDRF documents such as N52 and N9, the ongoing foundation documents review project, and meeting participation.

Strategic Road Map & Future Actions

Priority regulatory actions

Integrate ToC 01

Submission template

Structure reliance 02

Align programme with IMDRF guidance

Implement UDI 03

Strengthen device identification & traceability

Capacity-building priorities

Cybersecurity for SaMD & AI

Build capability for cybersecurity considerations in software and AI-based devices.

AI-based device regulation

Pre-market assessment, QMS audit of manufacturing plants, and PMS for AI-based devices.

Focus: strengthen convergence, reliance, digital-health oversight and regulatory capacity.

Key Challenges in Implementing IMDRF Framework

01

Cost Implications

- **Integrating ToC into our Regulatory Information Management systems (RIMS) – from STEDY**
- **Implementing UDI**

02

Limited regulatory capacity and expertise.

In sufficient number of specialities in MD regulations especially in **Cyber security, software and AI**. The IMDRF aligned regulations requires speciality in such areas.

03

Legal processes for updating Regulations and time to implement

Updating of regulations to reflect with IMDRF principles is a legal process and sometimes takes longer to be approved

04

Rapid technological changes

Keeping regulatory framework and staff updated in line with **rapid change in technology** and IMDRF principles that require to be applied to sophisticated technologies

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Thank You

Tanzania Medicines and Medical Devices Authority

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