HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026

PARTICIPATION IN IMDRF - UPDATE ON NAFDAC (NIGERIA)

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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Background

- The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004
- **Mandate:** To regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Food, Drugs, Cosmetics, **Medical Devices,** Packaged Water, Chemicals and Detergents (collectively known as regulated products). The Agency was officially established in October 1992.

- The National Agency for Food and Drug Administration and Control (NAFDAC) became an **affiliate Member of the International Medical Device Regulators Forum (IMDRF) on March 22, 2024** as part of its strategic commitment to strengthening Nigeria's regulatory framework for medical devices including in vitro diagnostics

- IMDRF Membership has provided a structured pathway for regulatory convergence, global alignment , and adoption of internationally recognised best practices in medical devices regulation.

Strategic Reforms undertaken

Following its affiliation with IMDRF, NAFDAC initiated key regulatory and institutional reforms:

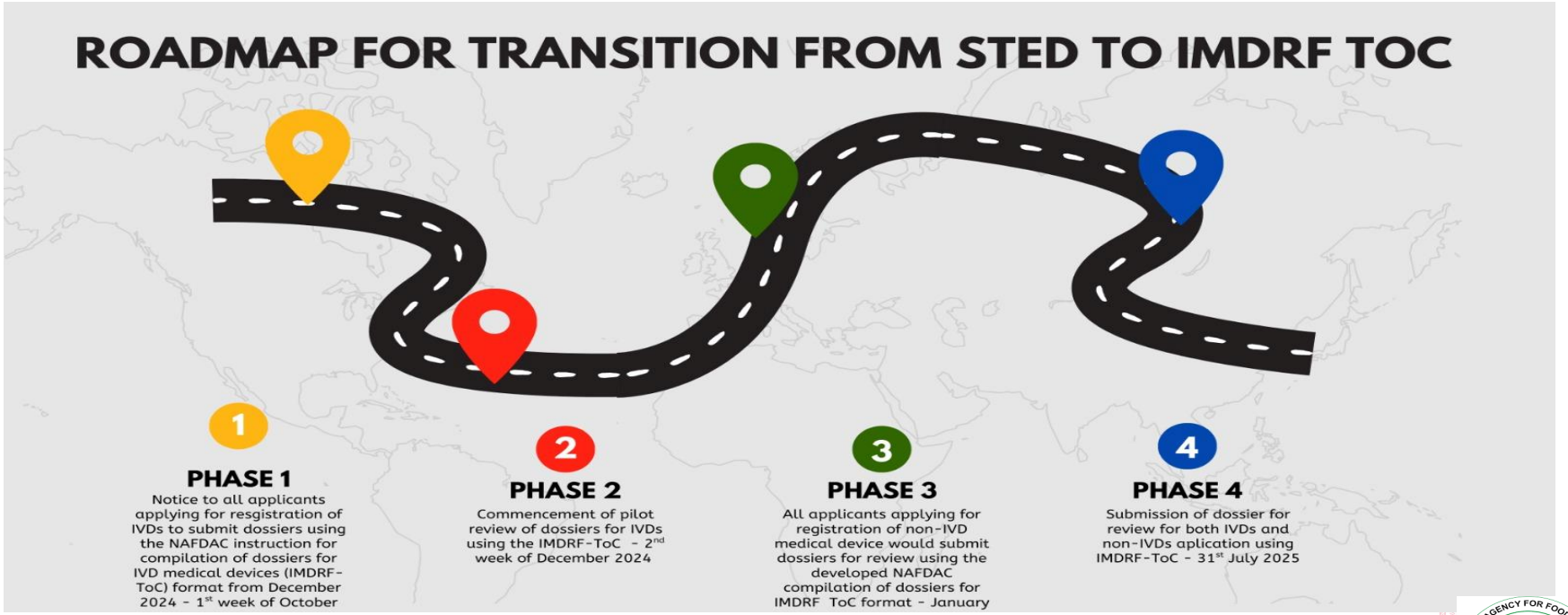
- **Development of Medical Devices Regulations (2024):** A dedicated regulatory framework for medical devices was developed and published. The regulation is currently under review to ensure full alignment with IMDRF foundational principles and global best practices.
- **Transition from STED to IMDRF Table of Contents (ToC):** Migration from the Summary Technical Document(STED) to the IMDRF ToC format for submission of technical documentation, ensuring harmonized product dossiers.
- **Guideline Harmonization: Updated** NAFDAC guidelines now require stakeholders to consult relevant IMDRF guidance documents alongside national requirements.
- **Adoption and Adaptation of IMDRF Guidance: Progressive** domestication of IMDRF foundational documents to strengthen regulatory consistency and predictability.

Strategic Reforms undertaken

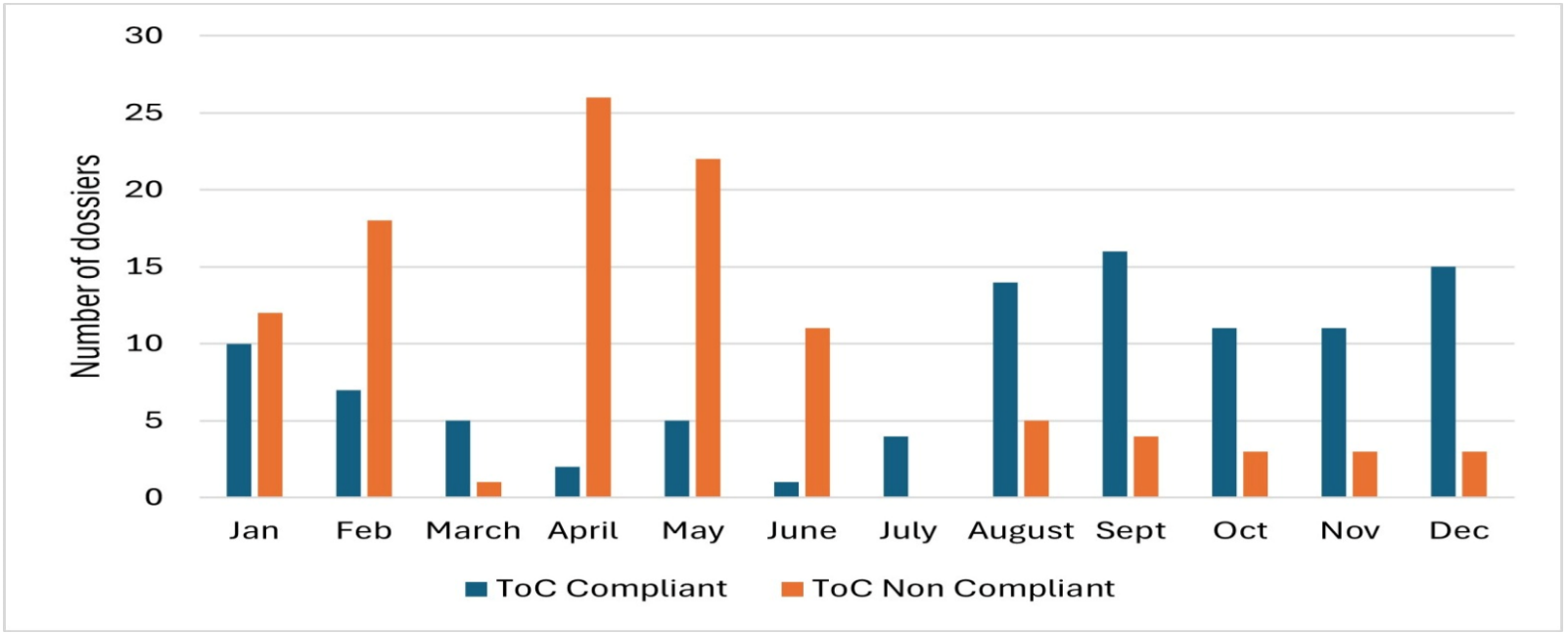
- **WHO Benchmarking Process: NAFDAC** subjected its medical devices regulatory framework to benchmarking under the Global Benchmarking Tool (GBT) of the World Health Organization (WHO), with the objective of attaining Maturity Level 3 (ML3) status.

- **Participation in IMDRF Working Groups:** Active engagement in Open Working Groups, particularly:
  - Regulatory Product Submission (RPS)
  - Quality Management System (QMS)

Transition to IMDRF Table of Contents (ToC):illustration



Transition to IMDRF Table of Contents (ToC): illustration (2025)



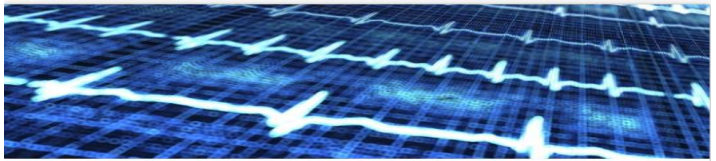
WHO BENCHMARKING

Control of Suppliers document.

IMDRF WORKING GROUP

Regulated Product Submission

Harmonize the format and content of regulatory submissions.



Quality Management Systems

Ensure alignment of IMDRF QMS and risk management documents with current international standards

REGULATED PRODUCT SUBMISSION(RPS) - Participated in work items on updating of the N9 &N 13 templates and also the development exploration of the dynamic template (e-STAR) that leverages the updated requirements from N9 & N13.

QUALITY MANAGEMENT SYSTEM(QMS)-Participated in a series of consecutive meetings to review the Control of Suppliers document to ensure alignment of critical terminologies with relevant ISO standards

REQUEST TO JOIN THE GOOD REGULATORY REVIEW PRACTICES WORKING GROUP:: The Agency has requested to join the Good Regulatory Review Practices Working Group and awaits confirmation of acceptance from th co-chair of the working group.

Key Gains Achieved on joining IMDRF

NAFDAC's affiliation with IMDRF has resulted in:

i. **Alignment with Global Best Practices:**

a. Access to internationally harmonized regulatory guidelines and technical documents
b. Adoption of globally recognized approaches to medical device and IVD regulation
c. Strengthening of regulatory consistency with mature regulatory authorities

ii. **Improved regulatory transparency and predictability by**:

a. Promoting the use of clear, internationally harmonized regulatory guidelines and terminology
b. Enhancing consistency in regulatory decisions through risk-based frameworks
c. Providing structured pathways for product classification, conformity assessment, and post-market oversight improving stakeholder confidence through transparent regulatory processes
d. Creating predictable timelines and requirements for manufacturers and importers

Key Gains Achieved on joining IMDRF (contd.)

iii. **International Recognition & Credibility**

a. Increased global confidence in Nigeria's regulatory system

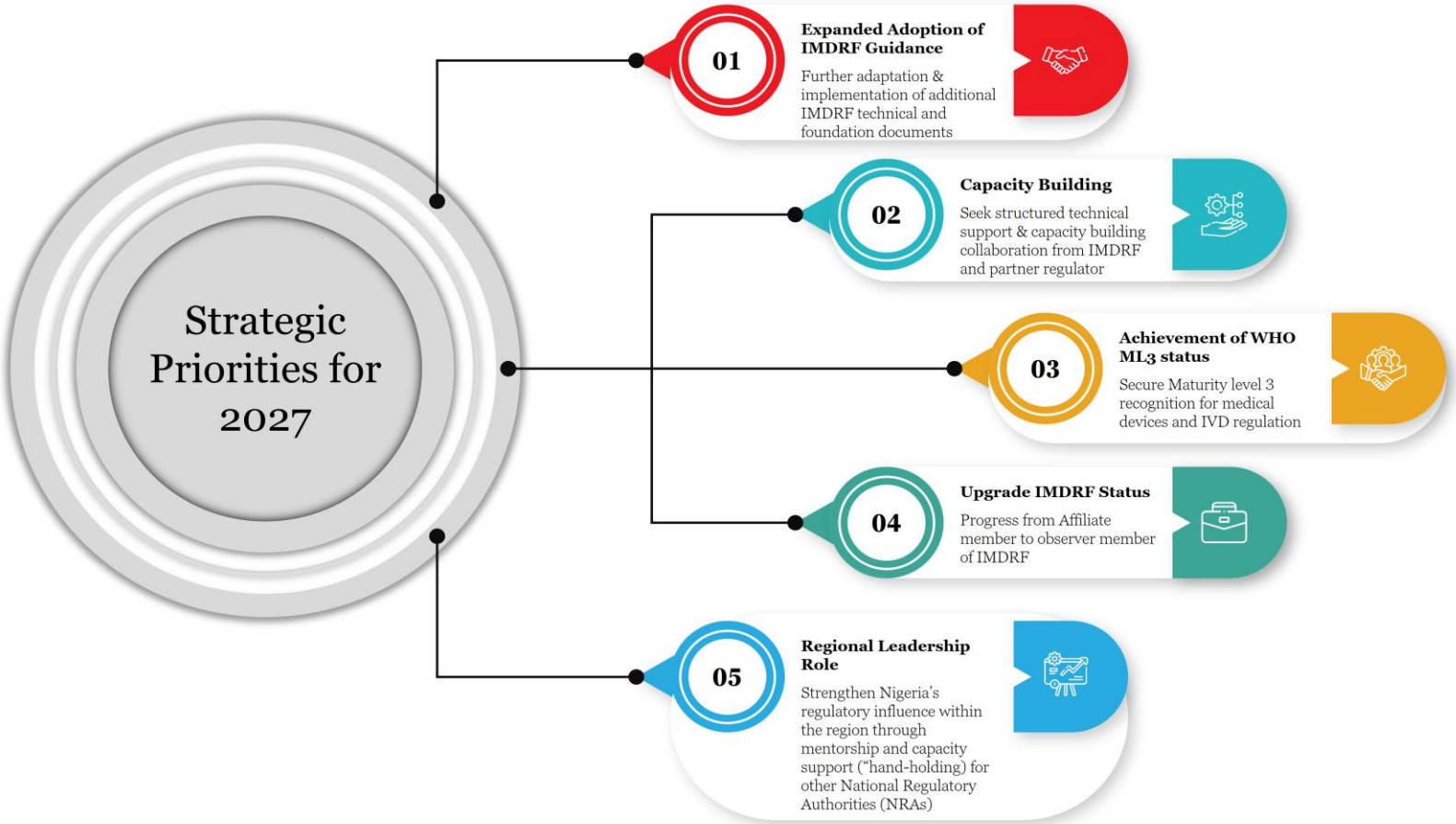
b. Improved trust from international manufacturers and stakeholders

c. Greater visibility of NAFDAC within the global regulatory community

iv. Capacity Building & Technical Expertise

- Participation in IMDRF working groups and technical discussions
- Exposure to evolving regulatory science and innovative technologies
- Knowledge exchange with leading regulatory authorities

v. **Increased readiness for reliance and collaborative regulatory pathways**


Strategic Priorities for 2027
01
Expanded Adoption of IMDRF Guidance
Further adaptation & implementation of additional IMDRF technical and foundation documents
02
Capacity Building
Seek structured technical support & capacity building collaboration from IMDRF and partner regulator
03
Achievement of WHO ML3 status
Secure Maturity level 3 recognition for medical devices and IVD regulation
04
Upgrade IMDRF Status
Progress from Affiliate member to observer member of IMDRF
05
Regional Leadership Role
Strengthen Nigeria's regulatory influence within the region through mentorship and capacity support ("hand-holding) for other National Regulatory Authorities (NRAs)

Conclusions

NAFDAC's affiliation with IMDRF represents a strategic milestone in advancing Nigeria's medical device regulatory system toward global convergence.

The reforms undertaken position the Agency for stronger regulatory performance, international recognition, and enhanced protection of public health.

The next phase will focus on institutional consolidation, maturity advancement, and expanded international engagement.

Thank You!

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