IMDRF International Medical Device Regulators Forum | 26th Session

# PUBLICATION OF LAW, DEFINITION AND REGULATIONS

## - NAFDAC EXPERIENCE ON SECTION 4.2.1 OF WHO'S GLOBAL MEDICAL DEVICES REGULATORY FRAMEWORK (GMRF) & INTERNATIONAL MEDICAL DEVICES REGULATORY FORUM (IMDRF) DOCUMENTS

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- NAFDAC –Vision, Mission and Core values
- Introduction
- Synopsis of WHO's GMRF section 4.2.1
- NAFDAC Enabling law & Mandate
- Medical Devices Regulations & Guidelines
  - Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024;
  - Medical Devices, In vitro Diagnostics and Related Products Advertisement Regulations 2024;
  - Medical Devices, In vitro Diagnostics and Related Products labelling Regulations 2024
  - NAFDAC guideline for registration of medical devices in Nigeria;
  - NAFDAC guideline for renewal of registration of medical devices in Nigeria;
- IMDRF Documents
- NAFDAC Experience
- Conclusion

## 01. OUR VISION

To be a world class regulator that ensures availability of quality and safe food, drugs, and other regulated Products

## 02. MISSION

To protect and promote the public health by instituting an effective and efficient regulatory system that ensures only the right quality Food, Drugs and other regulated products are manufactured, exported, imported, advertised, distributed, sold, and used.

## 03. CORE VALUES

1. Professionalism
2. Resilience
3. Integrity (Transparency & Good Governance)
4. Dedication & Commitment
5. Excellence

# INTRODUCTION

- NAFDAC regulatory framework for medical devices is sustainable, expandable and able to accommodate advances in clinical practices, public health needs and advancing technology.
- NAFDAC, guided by the WHO GMRF, integrated the recommendation on **basic regulatory control** into the Agency's regulation and guidelines . These documents do not only define the responsibility of NAFDAC , but also stipulates conditions under which medical devices can be placed in the market.
- Section 4.2.1 of the WHO GMRF is a premarket basic level control and enforcement mechanism that recommends establishment of a national law for medical devices that sets out principles and broad requirements for medical devices and delegate authority to the regulatory authority .

# BASIC REGULATORY CONTROL

| PREMARKET | PLACING IN THE MARKET | POST MARKET |
|---|---|---|
| **NAFDAC Enabling law Act Cap N1, LFN, 2004 establishing the Agency's mandate and functions** | E-registration platform for processing applications for registration: https://www.napams.org | Established Directorate for post market surveillance and another for pharmacovigilance with relevant guidelines |
| **Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024;** | Products considered for presentation at the FDRC meeting for approval must have satisfactory GMP audit report, operational performance evaluation report and satisfactory documentation | Established system to issue safety alerts to the public |
| **Medical Devices, In vitro Diagnostics and Related Products Advertisement Regulations 2024; Medical Devices, In vitro Diagnostics and Related Products labelling Regulations 2024;** | Establishing of NAFDAC Green Book ( phase updating of products unto the green book) – present phase for medicine s , next phase will include medical devices | Undertakes market surveillance of all NAFDAC approved products |
| **NAFDAC guideline for registration of medical devices in Nigeria; NAFDAC guideline for renewal of registration of medical devices in** | Import controls for registered products | Establish system to withdraw all unsafe NAFDAC regulated products including medical devices form the market |

# SYNOPSIS OF SECTION 4.2.1 OF WHO GMRF

- **PUBLISHED LAW, INCLUDING DEFINITION AND REGULATIONS WITH TRANSITION PERIODS:**
  - **This section recommends a legal framework that delegates authority to the NRA and outlines guidelines and prerequisites that:**
  - **Defines the scope of the law,  and MD & IVD terms in line with harmonized definition;**
  - **Allows NRA to adapt to New technologies;**
  - **Designate enforcement power and market oversight to NRA when the health of patient or users is compromised;**
  - **Specify market entry conditions for medical devices;**
  - **Provides NRA with administrative discretion and reliance on works of regulatory authorities  from other jurisdiction;**
  - **Establish record keeping, registration and reporting requirement for all parties within the scope of the law;**
  - **Requires that only safe medical devices that perform as intended by manufacturer be placed in the market**

# ENABLING LAW

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).

# Medical Devices Regulation & Guidelines

The following NAFDAC Regulations and guidelines alongside the Agency's enabling law aligns with the recommendations of section 4.2.1 of the WHO GMRF:

- **NAFDAC Act Cap N1 , LFN 2004;**
- **Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024;**
- **Medical Devices, In vitro Diagnostics and Related Products Advertisement Regulations 2024;**
- **Medical Devices, In vitro Diagnostics and Related Products Labelling Regulations 2024;**
- **NAFDAC guideline for registration of medical devices in Nigeria;**
- **NAFDAC guideline for renewal of registration of medical devices in Nigeria.**

# Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024

- The scope of the regulation is clearly defined for registration of all medical devices and invitro diagnostic medical devices manufactured , imported, exported , advertised , distributed and use in Nigeria. It has twenty-two (22)chapters
- Some of the chapters in the regulation that speak to GMRF section 4.2.1 are:
  - **Classification of Medical Devices and Related Products**
  - **Classification of In vitro diagnostics**
  - **Application for Registration**
  - Registration of novel devices
  - Post-registration changes
  - Suspension or cancellation of Certificate of Registration
  - Labelling
  - Advertisement
  - **Regulatory reliance**
  - **Enforcement of these Regulations**
  - **Interpretation**

# Medical Devices, In vitro Diagnostics and Related Products labelling Regulations 2024

- The scope of the regulation is clearly defined for labelling of all medical devices and Invitro diagnostic medical devices manufactured , imported, exported , advertised , distributed and use in Nigeria. It has twenty (20) chapters including those highlighted below:
  - Application
  - Prohibition
  - Labelling Information
  - Product identification
  - Instruction for use
  - Enforcement of the Regulations
  - Interpretation.

# Medical Devices, In vitro Diagnostics and Related Products advertisement Regulations 2024

- The scope of the regulation is clearly defined for advertisement or promotion of medical devices and Invitro diagnostic medical devices manufactured , imported, exported , advertised , distributed and use in Nigeria. It has twenty- six (26) chapters including those highlighted below:
  - Application
  - Prohibition
  - Application for the Approval of Advertisement
  - Labelling Information
  - Restrictions
  - Prohibition of misleading comparison
  - Validity of approval
  - Enforcement of the Regulations
  - Interpretation

# NAFDAC GUIDELINES FOR REGISTRATION OF MEDICAL DEVICES IN NIGERIA

- NAFDAC has two guidelines that speaks to registration of medical devices in Nigeria: Guideline for registration of medical devices in Nigeria, and Guideline for renewal of registration of medical devices in Nigeria. They both have fourteen (14) chapters. The guidelines specify in detail requirement for product registration, including those highlighted below:

**Market entry conditions:**

- Administrative documents for product registration;
- Technical documents for product registration ;
  - **Including Declaration of conformity with the ESP**
  - Product dossier
  - Clinical Evaluation Report with Statistical Data for Novel Medical Devices including Invitro diagnostics.
- Steps for product licencing;
- Labelling guidelines;
- Conditions for rejecting an application.

# NAFDAC REGULATIONS AND GUIDELINES WITH IMDRF ELEMENTS

- **Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024;**
  - GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic
  - (IVD) Medical Device;
  - IMDRF/GRRP WG/N52FINAL:2019 Principles of Labelling for Medical Devices and IVD Medical Devices
  - IMDRF/IVD WG/N64FINAL:2021: Principles of Invitro diagnostics (IVD) medical devices classification
- **Medical Devices, In vitro Diagnostics and Related Products labelling Regulations 2024;**
  - GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device;
  - IMDRF/GRRP WG/N52FINAL:2019 Principles of Labelling for Medical Devices and IVD Medical Devices
  - GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical Devices

# NAFDAC REGULATIONS AND GUIDELINES WITH IMDRF ELEMENTS

- **NAFDAC guideline for registration of medical devices in Nigeria;**
- The guideline has a caveat to be read along side relevant IMDRF documents including:
  - GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical Devices
  - GHTF/SG1/N71:2012 "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device
  - (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019 "In Vitro Diagnostic Medical Device Market Authorization Table of Contents
  - (nIVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL:2019 Non-In Vitro Diagnostic Device Market Authorization Table of Contents
- **NAFDAC guideline for renewal of registration of medical devices in Nigeria**
- The guideline has a caveat to be read along side relevant IMDRF documents including:
  - GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical Devices

# NAFDAC REGULATIONS AND GUIDELINES WITH IMDRF ELEMENTS

- GHTF/SG1/N71:2012 "Definition of the Terms 'Medical Device' and 'In Vitro
- Diagnostic (IVD) Medical Device
- (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019 "In Vitro Diagnostic Medical Device Market Authorization Table of Contents
- (nIVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL:2019 Non-In Vitro Diagnostic Device Market Authorization Table of Contents

## NAFDAC guidelines for registration of software as a medical device in Nigeria

- The guideline has a caveat to be read along side relevant IMDRF documents including:
  - IMDRF SaMD WG N10 / Software as a Medical Device: Key Definitions
  - GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical Devices"
  - GHTF/SG1/N71:2012 "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device
  - IEC 62304:2006 - Medical device software -- Software life cycle processes
  - ISO/IEC/IEEE 14764:2022 Software Engineering– Software Life Cycle Processes Maintenance

# NAFDAC EXPERIENCE WITH IMDRF DOCUMENT AND SECTION 4.21 OF WHO GMRF

- Following NAFDAC acceptance as an affiliate member of IMDRF, the Agency has taken steps to review and update its requirements to align with the IMDRF technical documents and this has aligned the Agency's processes and requirements with harmonized standards.
- IMDRF has a lot of technical guidance documents which the Agency critically considers alongside NAFDAC processes before adopting or adapting existing documents.
- Recommendations in Section 4.2.1of WHO GMRF have served as a guide for the Agency in adopting internationally harmonised technical guidance.
- The IMDRF documents have broadened the technical knowledge of the Agency's staff involved in the regulation of medical devices.

# CONCLUSION

- In implementing the recommended WHO  GMRF, NAFDAC has consciously made provisions that will accommodate implementation of the expanded regulatory control.
- NAFDAC strives to attain the status of a world-class regulator that ensures the availability of quality ,safe , efficient and high performing medical products and technology
- The Agency is open to guidance and support to further strengthen its regulatory framework for medical devices.

# GLOSSARY OF TERMS

- **FDRC** - Food and Drug Registration Committee
- **NAFDAC** - National Agency for Food and Drug Administration and Control
- **WHO GMRF**– WHO Global Medical Devices Regulatory framework
- **MD** – Medical Devices
- **IVD** – In vitro diagnostics medical device
- **ESP –** Essential Principle for Safety and Perfomance

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION & CONTROL

UNITY & FAITH, PEACE & PROGRESS

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# THANK YOU

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