For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

MEDICAL DEVICES REGULATORY UPDATES - NIGERIA

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Outline

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- Recent Updates
- Brief Overview of Medical Devices & IVDs Registration Process
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Introduction

NAFDAC ACT/MANDATE

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, 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).

FOOD, DRUG AND RELATED PRODUCTS (REGISTRATION) ACT CAP F.33

The Law was promulgated to prohibit the manufacture, sale, distribution, and advertisement of unregistered regulated products. The Law also regulates the manufacture, importation, exportation, advertisement, sale, or distribution of processed food, drugs, **medical devices**, chemicals, and bottled water.

Recent Updates in NAFDAC

Creation of the VBM-R&RA Directorate

The Vaccines, Biologics, and Medical Devices Registration and Regulatory Affairs (VBMR&RA) Directorate was created out of the Drug Registration and Regulatory Affairs (DR & R) Directorate on 13th of September 2024, and commenced operations officially on the 14th October 2024

The Directorate has the responsibility for the registration of human and veterinary vaccines, biologics, and medical devices, including in vitro diagnostics.

Key Functions

- ❑ Undertake the registration of vaccines, biologics, and medical devices, **including IVDs**.
- ❑ Develop Regulations and guidelines for the Regulation and control of vaccines, biologics, and **medical devices, including IVDs**
- ❑ Issue guidelines, grant approvals, and monitor the advertisement of vaccines, biologics, and medical devices, **including IVDs.**
- ❑ Grant market authorizations, such as permits for service medical devices and Emergency Use Authorization for vaccines and In Vitro Diagnostics, in exceptional circumstances in the interest of public health.
- ❑ Organize stakeholder engagements and training for relevant stakeholders to enable regulatory compliance.

Recent Updates in NAFDAC

WHO Global Benchmarking

WHO-GBT

NAFDAC is currently undergoing the WHO-GBT+ assessment by the WHO for towards the attainment of ML3 for medical devices & IVDs

Support for Local Production

Import Restrictions

Enhancing Local production of medical consumables through policies like import restriction of items like standard syringes

Review of Regulation

Medical Devices Regulation

NAFDAC has updated its regulations for medical devices, including IVDs and related products, to ensure alignment with the WHO GMRF and promote public trust.

Affiliate membership of IMDRF

NAFDAC joins the IMDRF

The Agency recently became an Affiliate member of the IMDRF on March 22nd, 2024

Collaboration & Harmonization

Regional & Global collaboration

Participation in the WA-RH Project, the AMDF, IMDRF meetings & WHO CRP, to harmonize regulatory processes and improve efficiency across countries.

Recent Updates in NAFDAC

Review of Technical Documentation

Migration from STED to TOC

NAFDAC is currently using the IMDRF-ToC Format for submission and assessment of Technical documents

Knowledge sharing and Capacity building

The Gambian NRA understudy visit

Ongoing effort to enhance the capacity and functionality of NRAs across the region to ensure the safety, quality, and efficacy of medical products

Establishment of Expert Committee

MDREAC

NAFDAC has established the Medical Devices Expert Advisory Committee to advise on key regulatory issues regarding medical devices.

Stakeholder Engagement

Medical Devices stakeholders meetings

As part of the efforts to educate and enlighten our stakeholders to enhance understanding and cooperation towards regulatory harmony

Regulatory Guidelines

New Reg and Renewal Guidelines

Review of Registration guidelines and development of variation guidelines and groupage guidelines

Review of Process Timelines

Process Timelines Reviewed

Review of timelines for product registration based on risk class of products

Brief Overview of Medical Devices & IVD Registration

Stepwise approach

- Application submission via NAPAMS
- Verification of risk Class & Review of Documentation.
- Laboratory evaluation/Technical Documentation assessment.
- Quality System audit/QMS review.
- Approval & Issuance of Certificate.

Conclusion

- The regulation of medical devices, including IVDs, in Nigeria is rapidly advancing, and NAFDAC is positioning itself to become a global force in the medical devices, including IVDs, regulatory space.
- Ongoing concerted efforts to strengthen its regulatory capacity to become a world-class NRA, as evident in the ongoing WHO-GBT Assessment.
- The future is indeed bright for not just NAFDAC but also for the medical devices industry and consumers alike in Nigeria and West Africa as it continues to ensure that only the right quality, safe, and well-performing medical devices are available for consumers.

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