Extraordinary

Federal Republic of Nigeria Official Gazette

No. 123 **Lagos - 28th July, 2021** **Vol. 108**

Government Notice No. 101

The following is published as supplement to this *Gazette* :

Printed and Published by The Federal Government Printer, Lagos, Nigeria
FGP 130/072021/650

Annual Subscription from 1st January, 2021 is Local : ₦45,000.00 Overseas : ₦60,500.00 [Surface Mail] ₦75,000.00 [Second Class Air Mail]. Present issue ₦2,000 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA ACT, (CAP. M25 LFN., 2004)

IN-VITRO DIAGNOSTICS (IVDs) REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 50 of 2021

MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA ACT, (CAP. M25 LFN., 2004)

IN-VITRO DIAGNOSTICS (IVDs) REGULATIONS, 2021

[27*th Day of July*, 2021] Commencement.

In the exercise of the powers conferred on the Governing Board by Sections 4, 7 and 19 of the Medical Laboratory Science Council of Nigeria Act (Cap. M25 LFN 2004), the Board of the Council hereby makes the following regulations—

Objectives of these Regulations.

1. These Regulations is to—

(*a*) regulate In-Vitro Diagnostics activities in Nigeria ;

(*b*) create awareness, enlightenment, bring to the knowledge of the consumers and the general public their rights and privileges ;

(*c*) ensure that providers or manufacturers of In-Vitro Diagnostics equipment, reagents and consumables comply with these Regulations ;

(*d*) prescribe standards for equipment, reagents and consumables to be produced in or imported into Nigeria ;

(*e*) ensure that facilities used for IVDs are from time to time inspected so as to ensure adherence and compliance with these Regulations ;

(*f*) hold IVDs facility owners responsible for non-provisions of details of the products to be imported or manufactured to the Council before they are imported ;

(*g*) evaluate or validate equipment, reagents and consumables used in IVDs laboratory in Nigeria ;

(*h*) register manufacturers, importers, distributors and marketers of medical laboratory equipment, reagents and other consumables relating to IVDs in Nigeria ; and

(*i*) determine minimum standards for various establishments engaged in the production, importation, stocking, distribution, marketing and storage of medical laboratory equipment, reagents and associated consumables for IVDs and review such minimum standards from time to time.

Application.

2. These Regulations shall be applicable to In-Vitro Diagnostics (IVDs) activities in Nigeria and laboratories engaged in the provisions of IVDs services in Nigeria.

Registration.

3.—(1) The Council shall register facilities that manufacture, import, stock, distribute and market medical laboratory equipment, reagent and eonsumables.

(2) The owner of a facility shall be responsible for the registration of its facility.

(3) Registration is required by manufacturers, contract manufacturers and contract sterilizers, where the product is put into commercial distribution, initial importers, specification developers, re-packagers or re-labelled, re-processors of single-use devices, re-manufacturers, distributors, marketers, retailers and manufacturers of components or accessories that are ready to be used for any intended medical laboratory related purpose and are packaged or labelled for commercial distribution for such medical laboratory related purpose.

(4) All registration information, new updates or annual review, shall be submitted in appropriate form prescribed by the Council.

(5) A facility shall complete its registration with the Council within 45 days of commencement of business in Nigeria.

(6) Updates to registration information shall be submitted within 30 days after a change in the previous information submitted to the Council.

(7) Registered facilities shall renew and update its registration on an annual basis.

(8) The Council shall only register a foreign facility through a registered Nigerian agent and the Nigerian agent shall make available to the Council the telephone number, e-mail and address of such foreign manufacturers.

(9) After submission of initial registration information, the Council shall notify the registrant in writing of his new assigned registration number once the information is verified and approved.

(10) Registration information shall be submitted to the Council by an owner of a facility and payment of registration fee.

(11) A Facility shall be deemed to be registered when a letter to that effect has been issued to that effect by the Council.

(12) Facility registration is subject to renewal annually and registration information may be reviewed and updated within the first quarter of the year, January to March of every year.

Regulation of IVDs in Nigeria.

4.—(1) The Council shall be the regulatory authority for IVDs activities in Nigeria.

(2) The Council's regulatory functions shall include—

(*a*) maintenance of a register of IVDs manufacturers, importers, distributors, marketers and their respective IVDs places in the Nigeria market ;

(*b*) establishment and administration of a vigilance system for incidents attributable to IVDs ;

(*c*) examination and approval, when necessary, of applications for performance evaluation for IVDs ;

(*d*) monitoring of IVDs post market surveillance in Nigeria ;

(*e*) maintenance of market surveillance systems, which may involve inspection of IVDs manufacturers and their representatives to ensure strict compliance with relevant national and international standard ;

(*f*) ensuring compliance with relevant national and international standards, where necessary ;

(*g*) participation in international activities, including various relevant working groups and committees ;

(*h*) issuance of product certificate to manufacturers, distributors and marketers of IVDs products and services ;

(*i*) issuance of import licence or permits to importers of IVDs ;

(*j*) ensuring the withdrawals of non-certified IVDs and substandard IVDs from the market ;

(*k*) ensuring that expired reagents and consumables are properly destroyed ;

(*l*) certification of all IVDs produced or imported into the Nigerian market ;

(*m*) ensuring that all duly certified IVDs products carries the conformity mark of the Council ;

(*n*) carry out post production surveillance on the IVDs ; and

(*o*) ensuring compliance to field Safety Corrective Actions for In-vitro Diagnostics.

(3) The manufacturer of IVDs in Nigeria shall—

(*a*) register its premises, products and services with the Council ;

(*b*) register and obtain registration numbers from the Council ;

(*c*) not manufactured medical laboratory reagents and consumables of less than two years expiry dates, unless it is otherwise specified ;

(*d*) be subject to an annual registration with the Council ;

(*e*) own a brand label and be responsible for the branding of its product and ensure that conformity assessment procedures are strictly complied with by the manufacturer or his agent ;

(*f*) make available to the Council, compliance marking that is necessary for the Council to discharge its responsibilities ;

(*g*) make declaration of conformity for its products and retain them for future reference by the Council ;

(*h*) ensure that post-marketing obligations such as surveillance or vigilance are implemented in-conjunction with the Council ;

(*i*) ensure that manufacturer's responsibilities are not subcontracted to another party ;

(*j*) ensure that distributor whose name is on the packaging labels or instructions for use carries its own brand name or that of the manufacturer, where it is clear that the product is not being placed on the market under the actual manufacturer's brand name or that of his authorised representative, it shall be suspended from the market by the appropriate authority and banned ;

(*k*) include the requirement for the control of IVDs, which imposes obligations on manufacturers with respect to post-production monitoring and the reporting of adverse incidents and any malfunction or deterioration, which might lead to an adverse incident to the Council ;

(*l*) be familiar with the relevant obligations regarding the use of compliance mark of the respective originating countries ; and

(*m*) report IVDs incidents across several own brand label to the Council and failure to report attracts grave consequences.

(4) An importer or marketer of IVDs products shall—

(*a*) register its products and services with the Council ;

(*b*) be provided with registration numbers by the Council ;

(*c*) renew its registration annually ;

(*d*) not import IVDs products with less than 2 years expiry dates into Nigeria unless it is approved by the Council ;

(*e*) ensure that expired reagents and consumables are submitted to the Council for destruction ;

(*f*) ensure that appropriate conformity assessment of the Council is complied with as it relates to leaflet or branding of products as follows—

(*i*) procedures are strictly complied with by the manufacturer or sub-contractor involved,

(*ii*) ensure that manufacturer or sub-contractor make available to the Council compliance marking and necessary documentation for the Council to fulfill its responsibilities,

(*iii*) keep records of and make declaration of conformity for the IVDs products for future reference by the Council,

(*iv*) register own organisation and devices with the Council,

(*v*) properly apply compliance marking of conformity,

(*vi*) ensure that post-marketing obligations, such as surveillance and vigilance are implemented ;

(*g*) where any of the manufacturer's responsibilities are subcontracted to another party, the contract between the manufacturer and the subcontractor shall assign the subcontracted responsibilities to the subcontractors ;

(*h*) a distributor whose name appears on the package, label or instruction for use may not be considered to own a brand label or as a manufacturer, where it is clear that the product is placed on the market under the actual manufacturer's own name or that of the authorised representative ;

(*i*) where required for the control of IVDs, impose obligations on manufacturers with respect to—

(*i*) post-production monitoring, and

(*ii*) the reporting of adverse incidents, malfunction or deterioration, which might lead to an adverse incident, to the Council ;

(j) make manufacturers, including its own brand label, to be familiar with the relevant obligations regarding the use of compliance mark of the respective originating countries ;

(*k*) ensure that obligations to report IVDs incidents across the several own brand labels to the Council is mandatory and shall be taken seriously with requisite sanction for failure to report ;

(*l*) ensure that incidents or potential incidents with IVDs products in the market under a brand name is made known to the manufacturer, where the Council is of the opinion that it is the responsibility of the owner of the brand label ; and

(*m*) take responsibility for IVDs, where exists an issue with his IVDs products, so as to ensure appropriate corrective action is taken in the interest of public health.

Stocking of IVDs and sales.

5. The Council shall—

(*a*) carry out post-market surveillance on IVDs products ;

(*b*) ensure appropriate storage facility is provided for IVDs products ;

(*c*) maintain registers of organisation and their respective IVDs ;

(*d*) ensure Conformity marks is complied with as applicable ; and

(*e*) conduct periodic post-marketing surveillance or vigilance.

Withdrawal of sub-standard and fake IVDs products.

6. The Council shall—

(*a*) ensure that sub-standard and fake IVDs products are withdrawn from circulation ;

(*b*) withdraw IVDs products that are not in conformity with the standard and criteria stipulated on the manufacturer's leaflet ;

(*c*) withdraw from circulation, IVDs that are not in compliance with the safety inspection checks conducted by the Council ; and

(*d*) withdraw IVDs product that are not certified by the Council.

Conducting conformity assessment by the Council.

7. The Council shall—

(*a*) conduct conformity assessment and issue product certificates to a manufacturer, importer, marketer and distributors respectively ;

(*b*) ensure that all IVDs products in the market in Nigeria complies with these Regulations ;

(*c*) provide a declaration of conformity, product certificate is provided for IVDs ; and

(*d*) be solely responsible for issuing IVDs product certificates in Nigeria.

Listing.

8.—(1) Owners of facilities are required to register their facilities and provide product listings to the Council.

(2) Listings shall be submitted to the Council through the filling of appropriate forms.

(3) Owners of facilities shall submit their listing information at the time of initial registration, during review and during update of their product listings on an annual basis.

(4) Listing updates shall be made annually and at any time a new product is introduced into or withdrawn from the listing of the Facility's products.

(5) Owners of facilities shall submit the following listing information—

(*a*) current registration number and name of each Facility under their ownership or control that performs a regulated function of a product ;

(*b*) the proprietary or brand name under which the product is marketed ;

(*c*) information concerning any regulated activities that they perform on or to the product such as manufacturing ;

(*d*) the Council identification names for each product, which includes classification name and number and common name ;

(*e*) labelling when they are unable to identify an appropriate Council's identification name ; and

(*f*) for products under evaluation or validation, owners shall include the Council pre-market submission number.

Fees.

9. The Council shall have powers to—

(*a*) charge facility an annual business registration fees, payable at the point of submission of application for registration ;

(*b*) charge pre-market submission fees ;

(*c*) charge, such other fees as may be necessary in furtherance of the provisions of these Regulations ;

(*d*) review from time to time, such fees to be paid according to the type of business, which shall be published in the official gazette of government before it takes effect ; and

(*e*) impose sanction for failure to pay any fees required to be paid under these Regulations and such facility shall not be registered.

Labelling and leaflets of IVDs.

10. The Council shall inspect IVDs to be released into market for proper labelling, to ensure that it contains the following minimum basic information—

(*a*) label and instructions for use (IFUs) of the product ;

(*b*) the instruction or information is in English language for IVDs users ;

(*c*) user type must be considered for labels and IFUs ;

(*d*) instruction for use must accompany the IVDs ;

(*e*) shelf life of IVDs shall be stated on the package, including—

(*i*) expiry date, date of manufacture, batch number and environmental requirement like temperature and humidity, shall be visibly stated,

(*ii*) use of electronic labelling and IFUs, such as Internet, CD-ROM and other electronic device may be allowed, and

(*iii*) each IVDs is accompanied with information on usage, safety and manufacturer's identification, taking into consideration the knowledge and training limitation of the potential user.

Performance evaluation.

11. The Council shall for the purposes of performance evaluation of Public Health IVDs laboratory, register IVDs facilities to ensure the attainment of performance, monitoring of IVDs quality, security and safety of IVDs including those for performance evaluation placed in the Nigerian market.

The Council contact with the manufacturer.

12. The Council—

(*a*) reserves the right to visit any facility upon receipt of any complaints to verify such reports ;

(*b*) shall from time to time have contact with manufacturers or their authorized representatives placing products in the Nigeria market ; and

(*c*) may be in communication with the manufacturer or the authorised representative in relation to any other IVDs regulation.

Interpretations.

13. In these Regulations—

"*Conformity assessment*" means the process of review that takes place by the Manufacturer, Importer, Marketer, Distributors and the Council in order to ensure that safe and compliant products are placed in the Nigerian market ;

"*Consumable*" means materials used in the laboratory to perform certain acts at the end of which they are not available for reuse, which may include equipment, reagents but includes all other non-recoverable materials not classically defined as reagents ;

"*Council*" means Medical Laboratory Science Council of Nigeria ;

"*Equipment*" means a tool, device or machine used to perform an act in a medical laboratory at the end of which it is available in its original form and ready to perform another act ;

"*Facility*" means any place of business under one management at one general physical location, where a product is manufactured, imported, assembled, compounded, stocked, distributed and marketed in Nigeria ;

"*Import*" means to bring something or cause something to be brought from another country for commercial, industrial or medical laboratory routine and research purposes ;

"*Importer*" means a person or company that buys goods from another country to sell in Nigeria ;

"*IVDs*" means any medical laboratory diagnostic reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in-vitro use, intended by the manufacturer to be used in-vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures ;

"*Listing*" means catalogue or directory of products submitted by a Facility to the Council for purposes of commercial production, importation and marketing in Nigeria ;

"*Manufacturer*" means a person or company that produces goods in large quantities ;

"*Owner*" means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering Facility ;

"*Product*" means any equipment, reagent or consumable manufactured in or imported into and stocked or marketed in Nigeria, manufacture - fabrication and or production of goods from raw materials mostly in large quantities for commercial purposes ; and

"*Reagent*" means chemicals, compounds, mixtures and other devices employed as reactants in laboratory analysis.

14. These Regulations shall be cited as In-Vitro Diagnostics (IVDs) Regulation, 2021. Citation.

MADE at Abuja this 22nd day of July, 2021.

DR. TOSAN ERHABOR, FMLSN, FWAPCMLS
Registrar and Chief Executive Officer
Medical Laboratory Science Council of Nigeria

SCHEDULE

CLASSIFICATION OF IVDs

IVDs are categorised by risk as follows—

(*a*) those that constitute a direct risk to patients ; and

(*b*) those that could constitute a serious risk to health and are essential to control *e.g.* AIDS and hepatitis, etc.

These categories are further subdivided into four classes, dependent on risk and the level of conformity assessment required, which provides a summary of the class, perceived risk and conformity assessment requirement.

IVDs categories are as follows—

Based on intended use; expectation of users, importation information, health impact of the regulation—

A—Low Risk and D—High Risk

Rule 1 : Class D—Tests for blood, tissue, organ screening prior to transfusion or transplantation.

Rule 2 : Class C/D—Tests of immunological compatibility classified by their criticality.

Rule 3 : Class C—Moderate public health risk or high individual risk providing the critical or sole determinant for correct diagnosis.

Rule 4 : Class B/C—Self-testing devices classified by their criticality.

Rule 5 : Class B—IVD reagents, instruments and test receptacles.

Rule 6 : Class A/B—Applies to all other devices.

Rule 7 : Class A: IVD controls without an assigned value.