Federal Republic of Nigeria
Official Gazette

No. 255 **Lagos - 6th November, 2024** **Vol. 111**

Government Notice No. 55

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

Printed and Published by The Federal Government Printer, Lagos, Nigeria
FGP 81/112024/150

Annual Subscription from 1st January, 2024 is Local : ₦100,000.00 Overseas : ₦130,000.00 [Surface Mail] ₦150,000.00 [Second Class Air Mail]. Present issue ₦3,500 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

NAFDAC (VACCINE AND OTHER BIOLOGICAL PRODUCTS (LOT RELEASE)) REGULATIONS, 2024

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 50 of 2024

NAFDAC (VACCINE AND OTHER BIOLOGICAL PRODUCTS (LOT RELEASE)) REGULATIONS, 2024

[16*th Day of October*, 2024] Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ("the Governing Council") by section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act, Cap. F33. LFN, 2004 and all other powers enabling it in that behalf, the Governing Council, with the approval of the Minister, makes the following Regulations —

PART I — OBJECTIVE AND APPLICATION

Objective

1. The objective of these Regulations is to ensure that vaccines and other biological products imported, exported, distributed, advertised, sold, displayed for sale or used in Nigeria are safe and comply with the provisions of these Regulations.

Application

2. These Regulations shall apply to the lot release of vaccines and other biological products manufactured, imported, exported, advertised, sold, displayed for sale distributed or used in Nigeria.

PART II — REGISTRATION, LABELLING, DOCUMENTATION AND LOT RELEASES OF VACCINES, AND OTHER BIOLOGICAL PRODUCTS

Registration of vaccines and other biological products

3. The registration of vaccines and other biological products shall be in accordance with the provisions of the Agency's Regulations on Drug and Related Products Registration and other relevant Guidelines.

Labelling information

4. Vaccines and other biological products shall be labelled in accordance with the provisions of the Agency's Regulations on Drug and Related Products Labelling and other relevant Guidelines.

Submission of application for lot release of vaccines and other biological products

5. An applicant for a Certificate of Registration shall —

(*a*) fill out an application form as prescribed by the Agency for the lot release of the vaccines and other biological products;

(*b*) submit the application and pay the prescribed fee to the Agency; and

(*c*) submit any other document as may be requested by the Agency.

Documentation

6.—(1) An applicant for a Certificate of Registration shall submit to the Agency the following documents with each batch subjected to independent lot release —

(*a*) notification of product release from Ports Inspection Directorate (PID), where applicable;

(*b*) summary lot protocol;

(*c*) National Regulatory Authority (NRA) lot release certificate from country of origin, where applicable;

(*d*) Plasma Pool Certificate, for plasma derived medicinal products;

(*e*) certificate of analysis of finished product;

(*f*) certificate of analysis of solvent, where applicable;

(*g*) proof of cold chain integrity; and

(*h*) any other document as be requested by the Agency.

(2) In the case of products using albumin as stabilizer, an applicant or a holder of certificate of registration shall submit —

(*a*) batch release certificate for albumin batch used from country of origin; and

(*b*) declaration on link between albumin batch used in the production and the batch of finished product.

(3) Documents to be submitted annually or when required by the Agency are —

(*a*) annual product quality report;

(*b*) Good Manufacturing Practice (GMP) certificate; and

(*c*) any other document as may be requested by the Agency.

Proof of cold chain integrity

7.—(1) A holder of Certificate of Registration shall submit to the Agency a Vaccine Arrival Report (VAR) for each lot to be released.

(2) Where a lot is imported in multiple shipments, each shipments' documentation shall be clearly distinguished.

(3) The VAR shall include —

(*a*) the product name and lot number clearly indicated on all documents;

(*b*) the date, time and location of dispatch and receipt of shipment;

(*c*) copy of the air waybill;

(*d*) the quantity per shipment;

(*e*) packing list indicating the number of containers and shipment, and the number of doses per container and shipment;

(*f*) detailed temperature monitor check sheet;

(*g*) the vaccine lot number and the number of the container, and shipment clearly indicated on the document displaying the temperature monitor data;

(*h*) supporting documentation which shall be attached showing the serial numbers of electronic monitors used in each container of the shipment;

(*i*) raw data from electronic temperature monitoring devices; and

(*j*) any other document related to VAR as may be prescribed by the Agency.

8. Vaccines and other biological products shall be subject of — Procedure for lot release of vaccines and other biological products

(*a*) inspection on arrival and sample collection at relevant point;
(*b*) review of relevant documents;
(*c*) laboratory testing; and
(*d*) any other requirement as may be prescribed by the Agency.

9. Where the Agency is satisfied that there is the need to release the lot of any vaccine and other biological products, it shall do so and issue to the applicant a Lot Release Certificate signed by the Director, Vaccines, Biological and Medical Device Laboratory Services Directorate (VBM-LSD) or the designate, subject to such conditions as it may deem fit. Issuance of Lot Release Certificate

10.—(1) Where the Agency is unsatisfied with the outcome of the review of application for lot release of any vaccine and other biological products, it shall issue to the applicant a Lot Rejection Certificate signed by the Director, Vaccines, Biological and Medical Device Laboratory Services Directorate (VBM-LSD) or the designate. Issuance of Lot Rejection Certificate

(2) The vaccines and other biological products referred to in subregulation (1) of this regulation shall be disposed in accordance with the Agency's Regulations on Recall, Handling and Disposal of Substandard and Falsified Medicinal Products and other relevant Guidelines as may be prescribed by the Agency.

11.—(1) Upon appropriate justification, the Agency may grant expedited lot release of vaccine and other biological products in exceptional cases, including — Expedited lot release

(*a*) product shortage in Nigeria;
(*b*) public health emergency;
(*c*) biological products donated from international organisations;
(*d*) urgent need as may be determined by the Agency; and
(*e*) any other case as may be determined by the Agency.

(2) Vaccines for expedited lot release shall be accompanied by —

(*a*) Lot Release Certificate issued by the responsible NRA or National Control Laboratory (NCL); and

(*b*) application for expedited lot release submitted to the Agency accompanied with the prescribed fees, where applicable.

12.—(1) Consignments with identical final labelled primary container lot, including identical expiration dates, imported after the release of the first consignments, shall be regarded as a further lot release. Further lot release

(2) The importer shall submit VAR, proof of secondary packaging and a copy of the lot summary protocol to the Agency.

(3) The importer shall, inform the Agency in writing that the shipment is a further lot release and provide evidence of first lot release certificate.

(4) The Agency may release the lot after evaluation of relevant documents.

Vaccine Vial Monitor

13. Vaccines manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria shall be accompanied with the Vaccine Vial Monitor (VVM) for the period of its use.

Lot release timelines

14. The timeline for each activity in the lot release process shall be as may be prescribed by the Agency.

Regulatory reliance

15.—(1) The requirement for routine independent lot release testing shall be based on a risk assessment or application reliance.

(2) The Agency shall consider the risk assessment of post-marketing experience related to the quality, safety and efficacy of the product.

(3) The Agency may consider reliance on some tests or reduced independent testing, subject to the availability of a Lot Release Certificate issued by a releasing NCL that is a full member of the World Health Organisation National Control Laboratory Network for Biologicals (WHO-NNB) or as detailed in the Agency's Regulatory Directives.

Prohibition

16. A person shall not manufacture, import, export, distribute, advertise, sale, display for sale or use any vaccine or other biological products except the lot release of such vaccine or other biological products is in accordance with the provisions of these Regulations.

Part III — Offences and Penalties

Offences and penalties

17.—(1) A person who contravenes any of the provisions of these Regulations commits an offence and is liable on conviction, in the case of —

(*a*) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding ₦800,000 or both; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.

(2) Where an offence under these Regulations is committed by a body corporate, firm or any other association of individuals, every —

(*a*) director, manager, secretary or other similar officer of the body corporate;

(*b*) partner or officer of the firm;

(*c*) trustee of the body concerned;

(*d*) person concerned in the management of the affairs of the association; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this regulation,

is liable to be proceeded against and punished for the offence the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction

18.—(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government —

(*a*) asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(*b*) any of the person's property or instrument used in any manner to commit or facilitate the commission of the offence.

(2) In this regulation, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

PART IV —MISCELLANEOUS

Enforcement of these Regulations

19. The Agency shall be responsible for the enforcement of these Regulations.

Interpretations

20. In these Regulations —

"*Agency*" means National Agency for Food and Drug Administration and Control;

"*Annual Product Quality Report (APQR)*" means a report submitted annually by manufacturers to the NRA or NCL containing production information on both bulk and final lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information;

"*Lot*" means a defined quantity of starting material, packaging material, or product processed in a single series of processes so that it is expected to be homogeneous;

"*Lot release*" means the process of NRA or NCL evaluation of an individual lot of a licensed vaccine before giving approval for its release into the market;

"*Lot release certificate*" means an official document that authorizes the manufacturer to release the specific lot into the market;

"*Lot Summary Protocol*" means a document summarizing all manufacturing steps and test results for each producing lot which is certified and released by the responsible person of the manufacturing company and the test results shall include the test specification and date of test conducted;

"*Minister*" means the Coordinating Minister of Health and Social Welfare;

"*Other Biological Products*" means biologicals products except human vaccines;

"*Plasma Derived Medicinal Products* (*PDMPs*)" means products prepared industrially from human plasma by pharmaceutical companies; and

"*Vaccine*" means suspension of weakened, killed, or fragmented microorganisms or toxins or other biological preparation, such as those consisting of antibodies, lymphocytes, or messenger RNA (mRNA), that is administered primarily to prevent disease.

Citation

21. This Regulations may be cited as the Vaccines and Other Biological Products (Lot Release) Regulations, 2024.

MADE at Abuja this 16th day of October, 2024.

MUHAMMAD ALI PATE, CON
Coordinating Minister of Health and Social Welfare