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

Vaccine and Other Biological Products (Lot Release) Regulations 2022

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 5th December, 2022).

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ARRANGEMENT OF REGULATIONS

Regulation:

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Commencement:

[ ]

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Minister of Health hereby makes the following Regulations: -

1. **Scope**
   These Regulations shall apply to the lot release of vaccines and other biological products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria.

2. **Prohibition**
   No person shall manufacture, import, export, distribute, advertise, display for sale or use any vaccines and other biological products unless the lot release of such product is in accordance with the provisions of these Regulations.

3. **Registration of Vaccine and other biological products**
   The registration of Vaccines and other biological products shall be in accordance with the provisions of the extant Drug and Drug Products Registration Regulations and as may be prescribed by the Agency.

4. **Labelling Information**
   Vaccines and other biological products shall be labelled in accordance with the provisions of the extant Drug and Drug Products Labelling Regulations and as may be prescribed by the Agency.

5. **Submission of application for Lot release of Vaccine and other biological products**
   The Certificate of Registration Holder 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;
   c. Submit any other document as may be prescribed by the Agency.

6. **Documentation**
   The Certificate of Registration Holder shall submit the following documents with each batch subjected to independent lot release.
   a. Documents to be submitted with each batch**:**

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i. Notification of product release from Ports Inspection Directorate (where applicable)
ii. Summary lot protocol
iii. National Regulatory Authority (NRA) lot release certificate from country of origin (where applicable)
iv. Plasma Pool Certificate (For Plasma Derived Medicinal Products only)
v. Certificate of analysis of finished product
vi. Certificate of analysis of solvent (if applicable)
vii. Proof of cold chain integrity

b. In case of products using albumin as stabilizer, the Certificate of Registration Holder shall submit:
    1. Batch release certificate for albumin batch used from country of origin
    2. Declaration on link between albumin batch used in the production and the batch of finished product.

Documents to be submitted annually or when required:

i. Annual product quality report
ii. Good Manufacturing Practice (GMP) certificates.

c. any other document as may be prescribed by the Agency.

7. **Proof of cold chain integrity**
    a. A Certificate of Registration Holder shall submit to the Agency a Vaccine Arrival Report (VAR) for each lot to be released.
    b. In cases where a lot is imported in multiple shipments, each shipments' documentation should be clearly distinguished.
    c. The VAR should include the following:
        i. The product name and lot number clearly indicated on all documents.
        ii. The date, time and location of dispatch and receipt of shipment.
        iii. A copy of the air waybill.
        iv. The quantity per shipment.
        v. A packing list indicating the number of containers and shipment and the number of doses per container and shipment.
        vi. A detailed temperature monitor check sheet.
        vii. The vaccine lot number and the number of the container and shipment shall be clearly indicated on the document displaying the temperature monitor data. Alternatively, supporting documentation shall be attached showing the serial numbers of electronic monitors used in each container of the shipment.
        viii. Raw data from electronic temperature monitoring devices.
    d. Any other document as may be prescribed by the Agency.

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8. **Procedure for Lot release vaccines and other biological products**

Vaccines and other biological products are subject to;

1. Inspection on arrival and sample collection at relevant point
2. Review of relevant documents
3. Laboratory testing
4. Any other requirement as may be prescribed by the Agency.

9. **Issuance of Lot Release Certificate**

Where the Agency is satisfied that there is need to release the lot of any vaccine and other biological product, it shall do so and issue to the applicant a Lot Release Certificate, subject to such conditions as it may deem.

10. **Issuance of Lot Rejection Certificate**

a. Where the Agency is unsatisfied with the outcome of the review of application for lot release of any vaccine and other biological product, it shall issue to the applicant a Lot Rejection Certificate.

b. Vaccines and other biological products that have been issued Lot Rejection Certificate shall be disposed in accordance with the extant Recall, Handling and Disposal of Substandard and Falsified Medicinal Products Regulations and as may be prescribed by the Agency.

11. **Expedited Lot release**

a. Upon appropriate justification, the Agency may grant Expedited Lot release of Vaccine and other biological products in exceptional cases including;

i. Product shortage in Nigeria

ii. Public health emergency

iii. Biological products donated from international organizations.

iv. Urgent need as may be determined by the Agency

v. Any other case as may be prescribed by the Agency.

b. Vaccines for Expedited Lot Release shall be accompanied by

i. Lot release certificate issued by the responsible NRA/National Control Laboratory (NCL).

ii. Application for Expedited Lot Release submitted to the Agency accompanied with the prescribed fees where applicable.

12. **Further lot release**

a. If consignments with the identical final labelled primary container lot (including identical expiration dates) are imported after the release of the first consignments, it shall be regarded as a further lot release;

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b. A vaccine arrival report (VAR), proof of secondary packaging and a copy of the lot summary protocol shall be submitted to the Agency.
c. The importer shall clearly indicate in the communication to the Agency that the shipment is a further lot release and provide evidence of first lot release certificate.
d. Lot may be released after evaluation of relevant documents

13. **Vaccine Vial Monitor**
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.

14. **Lot Release Timelines**
The timeline for each activity in the lot release process shall be as prescribed by the Agency.

15. **Regulatory reliance**
a. The requirement for routine independent lot release testing will be based on a risk assessment and whether reliance can be applied.
b. The risk assessment considers the post-marketing experience related to the quality, safety and efficacy, of the product.
c. Reliance on some or all tests or reduced independent testing may be considered subject to the availability of a Lot release certificate issued by a releasing NCL that is a full member of the WHO National Control Laboratory Network for Biologicals (WHO-NNB) or as detailed in NAFDAC policy on regulatory reliance.

16. **Offences and Penalty**
(1) Any person who contravenes any of the provisions of these Regulations, commits an offence and shall be 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 N800,000.00 or to both; and
(b) a body corporate, to a fine not exceeding N5,000,000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or 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 sub-regulation,

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is severally liable to be proceeded against and punished for that offence in 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.

17. **Forfeiture after conviction**

A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

(a) any 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 instrumentalities used in any manner to commit or to facilitate the commission of the offence.

18. **Interpretations**

In these Regulations: -

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

"**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. It may sometimes be necessary to divide a lot into several sub-lots, which are later accumulated to form a final homogeneous lot. In continuous manufacture, the lot should correspond to a defined fraction of the production, characterized by its intended homogeneity. The lot size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.

"**Lot Release**" means the process of NRA/ 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 lot summary protocol is 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. The test results shall include the test specification and date of test conducted.

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

"**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.

"**Annual Product Quality Report (APQR)**" means a report submitted annually by manufacturers to the NRA/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.

"**Other Biological Products**" means Biologicals Products except human vaccines

19. **Enforcement of the Regulations**
    The Agency is exclusively responsible for the enforcement of these Regulations**.**

20. **Citation**
    This Regulations shall be cited as the Vaccine and Other Biological Products (Lot Release) Regulations 2022

MADE at Abuja this ..... day of .....2022.

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