National Agency for Food & Drug Administration & Control (NAFDAC)

Vaccines, Biologics, and Medical Devices Registration & Regulatory Affairs (VBM-R&RA) Directorate

GUIDELINES FOR RENEWAL OF CERTIFICATE OF PRODUCT REGISTRATION FOR BIOLOGICAL PRODUCTS

1.0. General

1.1. These Guidelines are for the interest of the general public and, in particular, importers and local manufacturers of biological products for human and veterinary use in Nigeria.

1.2. It is necessary to emphasize that no biological product shall be manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations, and the accompanying Guidelines.

1.3. A product authorized for marketing in Nigeria will be issued a Certificate of Registration valid for 5 years and should be continually renewed upon expiration.

1.4. These guidelines are intended to provide guidance on the technical and other general requirements when applying for renewal of a product license for all biological products.

1.5. NAFDAC will not entertain applications for renewal of the registration of imported regulated products on the Federal Government Import Prohibition List, NAFDAC Ceiling List, and NAFDAC 5 + 5 List.

1.6. NOTE: These Guidelines should be read in conjunction with all relevant ICH guidance documents, including the following;

a. ICH Harmonised Tripartite Guideline Pharmaceutical Quality System Q10 https://database.ich.org/sites/default/files/Q10%20Guideline.pdf

b. ICH Harmonised Tripartite Guideline "Quality Risk Management Q9(R2)" https://database.ich.org/sites/default/files/Q9_Guideline.pdf

c. ICH Harmonised Guideline Technical and Regulatory considerations for Pharmaceutical Product Lifecycle Management Q12" https://database.ich.org/sites/default/files/Q12_Guideline_Step4_2019_1_119.pdf

Step I

2.0 Application for Renewal of Certificate of Product Registration

2.1 An application for renewal should be initiated not later than six (6) months before the current/valid registration certificate expires with Periodic Safety Update Report (PSUR) submitted to Pharmacovigilance Directorate for review.

2.2 **The application letter:** should be written on the company's letterhead and contain the applicant's current/valid email address and telephone number.

2.3 The renewal application letter should be addressed to:

The Director-General (NAFDAC),
ATTENTION: The Director, Vaccines, Biologics and Medical Devices Registration & Regulatory Affairs (VBM-R&RA) Directorate,

NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, Lagos State.

2.4 **Application form:** A separate application form should be submitted for each biological product and each pack size.

2.5 The application should be submitted and processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal - https://registration.nafdac.gov.ng. For more information, see the NAPAMS User Manual

Step II

3.0 **Documentation**

The following documents are required for applying for renewal of a certificate of product registration on the NAPAMS portal:

3.1 **Annual License/Premises Registration**: The current Annual License to practice and the Certificate of Retention of Premises for the Superintendent Pharmacist issued by the Pharmacy Council of Nigeria (PCN) should be submitted.

3.2 **Manufacturing License.**

3.2.1 Issued by a relevant health/regulatory body in the country of manufacture (For products manufactured outside Nigeria).

3.2.2 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian embassy exists, any Commonwealth or ECOWAS country can authenticate.

3.2.3 Indicate Name and address of manufacturer and the products to be registered.

3.3 **Certificate of Pharmaceutical Product (COPP-WHO Format)**

3.3.1 Issued by a relevant health/regulatory body in the country of manufacturer (For products manufactured outside Nigeria).

3.3.2 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian embassy exists, any Commonwealth or ECOWAS country can authenticate. Indicate Name and address of manufacturer and the products to be registered.

3.4 **Evidence of expired or about to expire NAFDAC license**: A copy of the expired Certificate of Registration for the product(s).

3.5 **Evidence of Registration of Brand Name/Trademark**: Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be done in the name of the owner of the Trademark/Brand name.

3.6 **Notarized Declaration**

A declaration by the applicant regarding the correctness, completeness and accuracy of all documents submitted should be provided. The format should be in line with the template attached as Annex 1 in this guideline. This document must be notarized by a notary public

3.7 **Power of Attorney** (where the applicant does not own the product brand name) or **Contract Manufacturing Agreement** (where the applicant owns the Brand name):
At the expiration of a certificate of product registration, the validity of the Power of Attorney or Contract Manufacturing Agreement used for the initial registration may have lapsed, except in cases where an expiration date was not specified in the original power of attorney or contract manufacturing agreement or a statement that the power of attorney is for an indefinite period. Except in the abovementioned cases, an applicant must submit a new power of attorney or contract manufacturing agreement at registration renewal.
The document should give details of:

3.7.1 The Issuer and the Receiver of the Power of Attorney, and in the case of a Contract Manufacturing Agreement, the parties involved with their specific roles and the terms of the contract agreement.

3.7.2 A list of the products covered by the power of attorney (this can come as an annexure for many products but must form part of the power of attorney with a specific reference to the annexure stated on the power of attorney).

3.7.3 State ownership of Brand name/s or Trademark.

3.7.4 The validity of the power of attorney should be stated, and it should not be less than 5 years.

3.7.5 Notarized declaration by a Notary Public in the country of manufacture.

3.7.6 Signed by both parties, stating names and designations of the signatories, with the names of all the products to be registered, and other relevant clauses clearly explained in an unambiguous language.

3.8 **Product images, and labels:** The labelling information should comply with the Agency's Drug and Related Products Registration, Advertisement and Labelling Regulations.

3.9 **List of Approved Variations for the product and the approval letters** (where applicable).

This should indicate the type of variations and respective dates of approval in a tabulated form. Where no changes have been made, the applicant will provide an official declaration from the manufacturer(s) stating that no changes to the product have been made since the latest approval.

3.10 **Product Quality Review (PQR) and current Quality Information Summary (QIS):** Please see Annexure 2 for the template.

3.11 **Summary of Product Characteristics (SmPC).** Please see Annexure 3 for the template.

Step III

6.0 **Good Manufacturing Practice (GMP)**

For information on the inspection of manufacturing facilities, applicants should consult the relevant section of the Agency's website. Specifically:

- The **Drug Evaluation and Research (DER) Directorate** section for vaccines and biologics intended for human use.
- The **Veterinary Medicine and Allied Products** section for vaccines and biologics intended for veterinary use.

Please note that the **Good Manufacturing Practice (GMP) status** of the manufacturing facility will be taken into account before the renewal of the product license is granted.

Step IV

7.0 **Issuance of Notice of Renewal**

Upon successfully submitting all required documents and completing the processing of the manufacturing facility's GMP status on the NAPAMS e-reg portal, the applicant will receive a Notice of Renewal.

Step V

8.0 **Submission of Retention Samples to the Laboratory:**

8.1 To ensure that laboratory samples are preserved under the recommended storage conditions, applicants are required to submit them directly to the Laboratory. A letter authorizing this direct submission will be issued upon receipt of the required documents, which should be sent via email to **vb.vbmrr@nafdac.gov.ng**. The required documents are as follows:

8.2 An application requesting authorization to submit samples of a biological product directly to the laboratory for analysis. The application should include the following information:

a. Physical description of the product
b. Batch number

c. Date of manufacture

d. Expiry date

Note: Items (b), (c), and (d) above must match the details stated on the label of the product being submitted to the Laboratory.

8.3 Evidence of payment of processing fee.

Step VI

9.0 **Inspection of Local Cold Chain Storage**

9.1 For further information regarding the inspection of local cold chain storage , applicants are advised to contact the relevant directorates of the Agency as follows:

9.2 Drug Evaluation and Research (DER) Directorate at: der.headquarters@nafdac.gov.ng for inquiries related to human vaccines and biologics.

9.3 Veterinary Medicines and Allied Products (VMAP) Directorate at vmap@nafdac.gov.ng for inquiries related to veterinary vaccines.

Step VII

10.0 **Product Approval meeting**

Upon satisfactory technical documents review, GMP inspection of the production facility, cold chain storage facility, and laboratory analysis of product (where applicable), the product will be presented for consideration at the Food and Drug Registration Committee (FDRC) Approval Meetings.

Step VI

11.0 **Issuance of New Certificate**

For products approved at the meeting, an electronic certificate of Renewal of Product Registration is issued to the applicant.

12.0 **Product Label:**

The product label at renewal should be the same as the first approval unless an approval for a change in labelling was received.

13.0 **Tariff**

Please refer to the relevant section of the NAFDAC Tariff.

14.0 **Note**

14.1 Failure to comply with these requirements may result in the disqualification of the renewal application or considerable delay in the registration processing.

14.2 A successful renewal application will be issued a Certificate of Registration with a validity period of five (5) years.

14.3 Renewal of product registration does not automatically confer an Advertising Permit. If the product is to be advertised, a separate application and subsequent approval by the

Agency are required. Simultaneous submission of renewal and advertisement applications is allowed.

14.4 NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.

14.5 Filling an application form or paying an application fee does not indicate the renewal of the certificate of registration.

14.6 The timeline for renewing a certificate of product registration from acceptance of submissions to issuance of the Registration Number is one hundred and twenty (120) workdays.

14.7 Please note that the process clock stops once a compliance directive is issued.

All correspondence should be addressed to:

The Director-General (NAFDAC)
Attn: The Director (Vaccines, Biologics and Medical Devices-Registration and Regulatory Affairs Directorate
National Agency for Food and Drug Administration and Control,
NAFDAC Office Complex
Isolo Industrial Estate
Apapa-Oshodi Expressway,
Isolo, Lagos.
Email: bvmregistration@nafdac.gov.ng

NAFDAC website: www.nafdac.gov.ng

Annex 1

Notarized Declaration Template

I, (applicant's name), the Managing Director of (Applicant's Company Name), hereby declare on oath and state as follows:

1. That (Applicant's Company) of (Name of Applicant's Company Address) forwarded an application to the National Agency for Food and Drug Administration and Control for the Registration of regulated products hereinafter, listed:
   a. List of Products (Product Names)
   b. .....

Pursuant to the provisions of the Food and Drugs and Regulated Products (REG etc.) Act Cap F33 LFN 2004 and all relevant Regulations as representatives of (Manufacturer's Company Name)

2. That the said application, before the National Agency for Food and Drug Administration and Control, for the registration of the above-listed Products, the application No: (Applicant Form No.) thereof, and the attached documents viz:
   a. Power of Attorney/Contract Manufacturing Agreement and notarization thereof
   b. Certificates of Pharmaceutical Product/ Certificate of Manufacture and/or Free Sale and the authentication thereof by the Nigerian Mission in the country of origin
   c. Manufacturing license / Certificate for companies from India and China and the authentication thereof by the Nigerian Mission in the country of origin
   d. Certificate of Good Manufacturing Practice (GMP) and the authentication thereof by the Nigerian Mission in the country of origin
   e. Certificate of Analysis of product
   f. Evidence of Registration of Trademark and the information contained in all the above-mentioned documents is true and correct.
3. a. That the manufacturer (Manufacturer's Company Name) is or is not the owner of the trademark
   b. The product name(s)_____ is generic
4. a. That (Applicant's Company Name) of (Applicant's Company Address) is or is not the owner of the trademark.
   b. The products generic
5. That (Applicant's Company Name) and the declarant shall indemnify the National Agency for Food and Drug Administration and Control against any suit, claim, damages or liability arising from the use of all documents submitted and information declared by us in the processing, approval and grant of any certificate of registration in respect of (Product Name(s))
6. We agree to be held criminally liable for any false declaration made herein and forged

documents submitted to the National Agency for Food and Drug Administration and Control in respect of the application for the registration of (Product Name(s))

Signature & Date
DECLARANT (Applicant)
BEFORE ME

NOTARY PUBLIC (NBA Seal)

NAME: …… ADDRESS: …… SIGNATURE: …….. DATE: ……

Annexure 2
Product Quality Review (PQR)

1.0 A product quality review should be submitted with the objective of verifying the consistency of the quality of the Finished Pharmaceutical Product and its manufacturing process.

2.0 Rejected batches should not be included in the analysis but must be reported separately, and together with the reports of failure investigations, as indicated below.

3.0 Reviews should include at least:

1. a review of starting and primary packaging materials used in the FPP, especially those from new sources.
2. a tabulated review and statistical analysis of quality control and in-process control results;
3. a review of all batches that failed to meet established specification(s);
4. a review of all critical deviations or non-conformances and related investigations.
5. a review of all changes carried out to the processes or analytical methods.
6. a review of the results of the stability monitoring program;
7. a review of all quality-related returns, complaints and recalls, including export- only medicinal products.
8. a review of the adequacy of previous corrective actions.
9. a list of validated analytical and manufacturing procedures and their revalidation dates.
10. review of all adverse drug reactions observed, and action taken- to be submitted to the Pharmacovigilance Directorate. (Part of PSUR review)
11. review of Periodic Risk-Benefit Evaluation (PBRER) Reports- to be submitted to
12. review of Post-Marketing Surveillance activities- to be submitted to Pharmacovigilance Directorate. (Part of PSUR review).

Further Notes

1. Reviews must include data from all batches manufactured during the review period.
2. Data should be presented in tabular or graphical form when applicable.
3. The above listing of requirements is specific to the p r o d u c t q u a l i t y r e v i e w requirements and does not relieve the applicant of related GMP requirements.

Annexure 3
Summary of Product Characteristics (SmPC)

1. Name of Product
    - 1.1 Strength
    - 1.2 Pharmaceutical/Dosage form
2. Qualitative and Quantitative Composition
    - 2.1 Quality declaration
    - 2.2 Quantitative declaration
3. Pharmaceutical form
4. Clinical Particulars
    - 4.1 Therapeutic Indication
    - 4.2 Posology/Dosage and method of administration
        - 4.2.1 Posology/Dosage
        - 4.2.2 Special Population
        - 4.2.3 Method of Administration
    - 4.3 Contraindications
    - 4.4 Special warnings and precautions for use
    - 4.5 Interaction with other drug products and other forms of interaction
    - 4.6 Fertility, pregnancy and lactation
    - 4.7 Effects on ability to drive and use machines
    - 4.8 Undesirable effects
    - 4.9 Overdose
5. Pharmacological properties
    - 5.1 Pharmacodynamics properties
    - 5.2 Pharmacokinetics properties
    - 5.3 Preclinical safety data
6. Pharmaceutical Particulars
    - 6.1 List of excipients
    - 6.2 Incompatibilities
    - 6.3 Shelf life
    - 6.4 Special precautions for storage
    - 6.5 Nature and contents of container
    - 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product
7. Applicant/Holder of Certificate for Product Registration
8. Drug Product Manufacturer
    - Name and factory address or site address of the product manufacturer.

9. NAFDAC Registration Number(s)
    - The assigned NAFDAC Registration number should be stated here

Format/Font Size:

i. The SmPC should be worded in clear and concise language
ii. The headings (e.g., "NAME OF THE DRUG PRODUCT") should be set in 8-point Helvetica Bold Italic, left justified.

iii. The subheadings (e.g., "Therapeutic indications") should be set in 6-point Helvetica Bold, left justified
iv. The information should be set in 5-point Helvetica Regular, left justified
v. Text-selectable pdf and MS word Copy of the SmPC for each drug product should be provided.