



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

Registration & Regulatory Affairs (R & R) Directorate

GUIDELINES FOR REGISTRATION OF IMPORTED DRUGS, VACCINES AND IN-VITRO DIAGNOSTICS UNDER WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

1. General

- 1.1. These Guidelines are for the interest of the general public and in particular manufacturers/Importers of Drugs, Vaccines and In-Vitro Diagnostics into the country which have been prequalified by the World Health Organisation.
- 1.2 This guideline is based on NAFDAC's Regulatory Reliance Policy on adoption regulatory reliance mechanisms to make regulatory decisions as it relates to the granting of Marketing Authorisation. Clinical Trial Approval and conduct of Good Manufacturing Practice (GMP) Inspections.
- 1.3 The collaborative procedure is limited to Drugs, Vaccines and In-Vitro Diagnostics that have been assessed and inspected by WHO/PQP in line with the procedures and standards available at www.who.int/prequal
- 1.4 Overseas manufacturers and non-resident applicants would be required to appoint a agent with the requisite mandate to represent the manufacturer/applicant. The local agent would be required to submit relevant documentation including but not limited to a power of attorney or any other documentation confirming his/her appointment as a legal representative.
- 1.5 It is necessary to emphasize that, no drug 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.

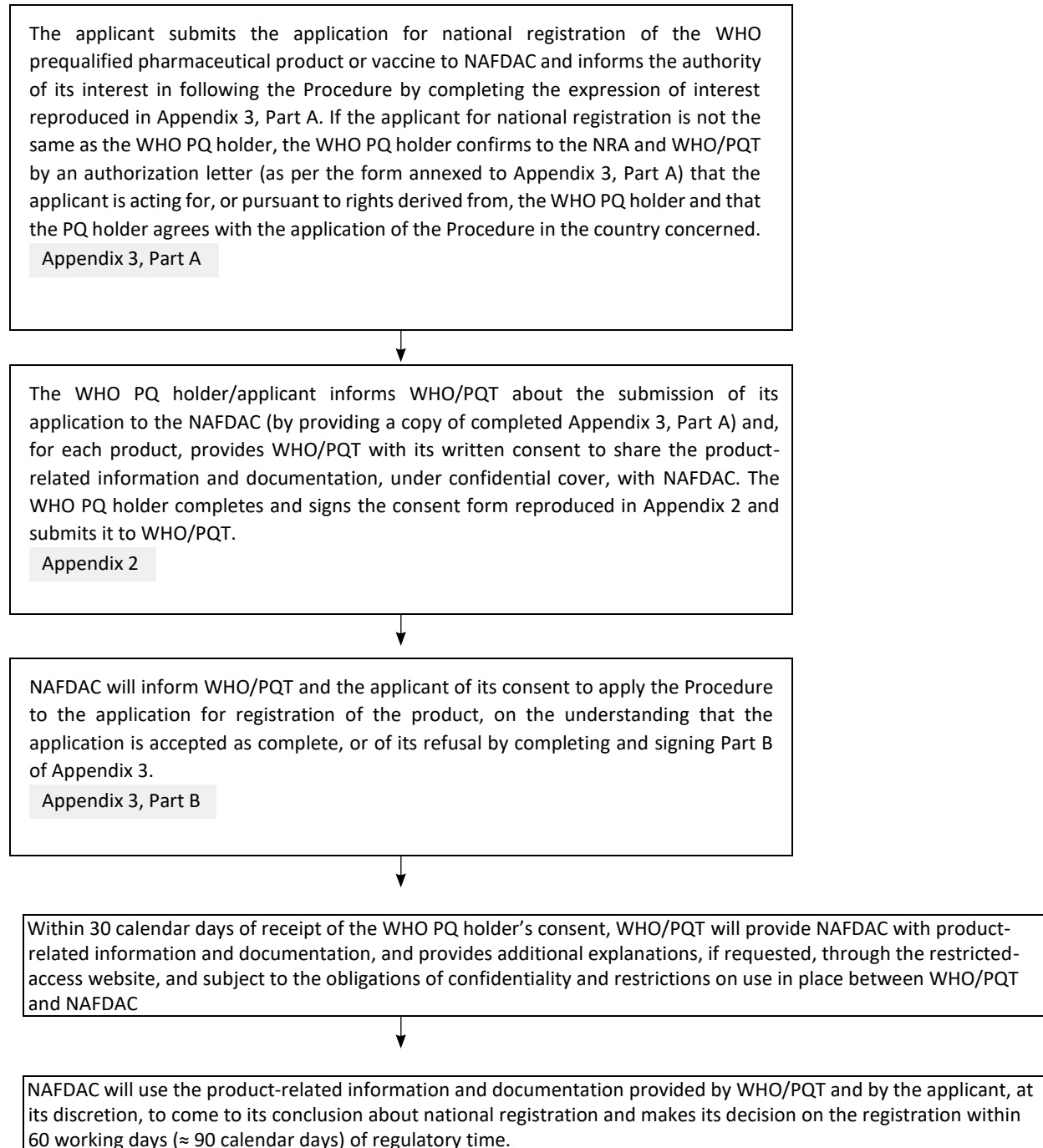
2. Applications

- 2.1. A written application for registration of imported drug should be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Registration & Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.
- 2.2. NAFDAC receives applications for the same pharmaceutical product as the one prequalified by WHO.
Within the context of this Procedure, the same pharmaceutical product is characterized by:
 - the same product dossier;
 - the same manufacturing chain, processes and control of materials;
 - the same active pharmaceutical ingredient (API) and finished pharmaceutical product (FPP) specifications;
 - the same essential elements of product information.
- 2.3. An online application form for Product Registration should be purchased at; <http://registration.nafdac.gov.ng> and completed.
- 2.4. A separate application form should be submitted for each product.

3.0 Steps of the procedure

Flowchart showing the principal steps of the collaborative procedure

Registration Process





Within 20 working days (≈30 calendar days) of having taken its decision, NAFDAC will inform WHO/PQT and the applicant of this decision, together with an indication of the dates of submission and registration and, if applicable, any deviations from the WHO PQ conclusions and the reasons for such deviations, through the restricted-access website. This report is provided to WHO/PQT by completing Part C of Appendix 3.

Appendix 3, Part C



WHO/PQT lists pharmaceutical products registered by participating NRAs according to this Procedure on its public website

Post-registration processes

The WHO PQ holder/applicant submits to participating authorities at the latest 30 calendar days after acceptance of the variation by WHO/PQT those variations which are subject to national regulatory requirements. If regulatory action is deemed to be justified, WHO/PQT promptly provides the participating authorities concerned, through the restricted-access website, and subject to the abovementioned obligations of confidentiality and restrictions on use, with outcomes of its variation assessment and relevant post-prequalification inspection, and any related information it considers relevant.

NAFDAC will not accept differences in the prequalified product and the one submitted for registration from the applicant with regards to variation. Variation applications must be for the same as that which was accepted by WHO/PQT. Variations not already accepted by WHO/PQT will not be processed under CRP..



WHO/PQT will inform NAFDAC, through the restricted-access website, and subject to the above-mentioned obligations of confidentiality and restrictions on use, about withdrawals, suspensions or delisting's of prequalified pharmaceutical products or vaccines. NAFDAC will inform WHO/PQT, through the restricted-access website, of national de-registration or suspension (for any reason) of a prequalified pharmaceutical product or vaccine and the reasons for doing so.

Appendix 4



WHO/PQT removes a product from the list published in line with this procedure:

- if the nationally-registered product is no longer the same (see section 3.2) as the WHO-prequalified product, or
- if the NRA deregisters a WHO-prequalified product, or
- if WHO/PQT delists a WHO-prequalified product.

WHO/PQT will also publish the reasons for the removal from the list.

For full details of the guidelines for the Collaborative Registration Procedure, please follow the links below;

https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex08.pdf?ua=1

<https://extranet.who.int/prequal/content/collaborative-registration-faster-registration>

Step I Documentation

3.1. The following documents (all originals) and two (2) sets of photocopies (including print-out of the completed online Registration form) are to be submitted at the Liaison Office of the Director (LOD), R & R Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos):

3.1.1 A completed Appendix 3, Part A (Expression of Interest)

3.1.1.1. Notarized Declaration (Appendix I). To be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria.

3.1.1.2. Power of Attorney or Contract Manufacturing Agreement. An applicant on behalf of a manufacturer outside Nigeria must file an evidence of Power of Attorney from the manufacturer which authorizes him to speak for his Principal, on all matters relating to the latter's specialties. The Power of Attorney shall be:

3.1.12.1. Issued by the manufacturer of the product.

3.1.12.2. Signed by the Managing Director, General Manager, Chairman or President of the Company, stating the names of the products to be registered. The Power

of Attorney shall also state 'Authority to register product with NAFDAC'.

3.1.12.3. State ownership of Brand name(s)/Trademark.

3.1.12.4. Notarized by a Notary Public in the Country of manufacture.

3.1.12.5. Valid for at least five (5) years.

- 3.1.3 Contract Manufacturer Agreement. An applicant filing an application on behalf of his company, and being the owner of the product, shall provide a Contract Manufacturing Agreement. The Agreement shall be:
- 3.1.3.1. Notarized by a Notary Public in the country of manufacture.
 - 3.1.3.2. 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.
- 3.1.4 Evidence of Business Incorporation of the importing Company with Corporate Affairs Commission in Nigeria.
- 3.1.5 Manufacturing License/Certificate of Free Sale
- 3.1.6 Evidence that they are licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). The license shall be issued by a relevant Health/Regulatory body in the country of manufacture.
- 3.1.7 Certificate of Pharmaceutical Product (COPP-WHO Format)
- 3.1.8 There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country. The Certificate of Pharmaceutical Product (COPP) should;
- 3.1.8.1. Conform to WHO format.
 - 3.1.8.2. Be issued by the relevant Health/Regulatory body.
 - 3.1.8.3. 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 the COPP.
- 3.1.9 Current Good Manufacturing Practice (cGMP) of the manufacturing facility. This is to be:
- 3.1.9.1. Valid at the time of submission.
 - 3.1.9.2. Be issued by the relevant Health/Regulatory body.
 - 3.1.9.3. 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 the document.
 - 3.1.9.4. Reference the Manufacturer's License Nos Form 25 and Form 28
- 3.1.10 Dossiers; The applicant shall submit two (2) copies of the Dossiers which should be;
- 3.1.10.1. In a Compact Disc (CD).
 - 3.1.10.2. Searchable Portable Document Format (pdf).
 - 3.1.10.3. Common Technical Document (CTD) format

- 3.1.10.4 The dossiers should be the same as that which was accepted by the World Health Organisation at the time of prequalification
- 3.1.11 For branded products, evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be registered in the name of the owner of the Trademark/Brand name as the case may be (Trademark Class 5 for Drugs).
- 3.1.12 Copy of valid Annual License to practice for the Superintendent Pharmacist issued by Pharmacists Council of Nigeria.
- 3.1.13 Evidence of valid Premises Retention License for the facility.
- 3.1.15 Label or artwork of the product

Step II Import Permit and Label vetting

- 4.1. Upon successful screening of documentation and review of supporting documents, an Import Permit shall be issued after which products are submitted for vetting.

STEP III Verification Process

- 5.1 The dossier submitted by the applicant shall be compared against the prequalified version shared on the collaborative procedure portal (mednet) to confirm sameness with the prequalified version with respect to API and FPP manufacturing sites, specifications, container closure, packaging type and configuration as well as bioequivalence studies if applicable.

STEP IV Submission of samples for laboratory analysis

- 6.1. Applicants should provide samples for physical and laboratory evaluation along with the following documents;
 - 6.1.1. Evidence of payment to the Agency
 - 6.1.2. Certificate of analysis.

STEP V Issuance of Administrative Approval

- 7.1 Following submission of laboratory samples and forwarding of same to the laboratory, an Administrative Approval is issued and a confirmation of product registration is uploaded on the WHO mednet share point by the focal person. The product is scheduled for the next FDRC product approval meeting.

Step VI Product Approval meeting

- 8.1. Upon satisfactory Dossier review/verification, Risk-Based Categorization of the production facility and satisfactory laboratory analysis of product, products are presented for ratification.

Step IX Issuance of Notification

- 9.1. For products approved at the meeting, Notification of Registration will be issued to the applicant.

10. Product Information for Products Registered Under CRP

Should meet NAFDAC Labelling requirements;

10.1 Patient Information leaflet (PIL) & Summary of Product Characteristics (SmPC):

https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/GENERAL/Quality-Guidelines-for-Registration-of-Pharmaceutical-Products26381.pdf#page=93

10.2 Guidelines for Immediate Label

https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/More_On_R_and_R/Guidelines-for-Labeling-26375.pdf

11 Tariff

The tariff will be same as that for an imported pharmaceutical product.

https://www.nafdac.gov.ng/wp-content/uploads/Publications/Others/NAFDAC-2019-Tariff_hyperlinked_Final.pdf

12. Note

- 12.1. A successful application will be issued a Certificate of Registration with a validity period of five (5) years.
- 12.2. Registration of a product does not automatically confer Advertising Permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised. Simultaneous submission of registration and advertisement applications are allowed.
- 12.3. NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period if the product no longer meets the requirements for the Marketing Authorisation.
- 12.4. Filing an application form or paying an application fee does not confer registration status.

- 12.5. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application will automatically lead to the closure of the Application.
- 12.6. The time line for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (60) working days or 90 calendar days.
- 12.7. Please note that stop clock times are not considered part of the registration time line (see Appendix II)

All correspondences should be addressed to:-

Director-General (NAFDAC),

Attn: The Director

Registration and Regulatory Affairs Directorate,

National Agency for Food and Drug Administration and Control,

Ground Floor, NAFDAC Office Complex

Isolo Industrial Estate

Apapa – Oshodi Expressway, Isolo, Lagos

NAFDAC website: www.nafdac.gov.ng

E-mail: registration@nafdac.gov.ng

Telephone no.: +234-1-4772452

All submissions should be made at the Office of the Director, R & R, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi – Apapa Express Way Isolo, Lagos or the nearest NAFDAC Office (for those outside Lagos).

NOTARIZED DECLARATION

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 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 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 referred 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 _____ 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 product _____ is 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: _____

Registration Process + Time lines

