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

VACCINES, BIOLOGICS AND MEDICAL DEVICES REGISTRATION AND REGULATORY AFFAIRS (VBM-R&RA) DIRECTORATE

GUIDELINES FOR REGISTRATION OF MEDICAL DEVICES INCLUDING 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 and importers of In-Vitro Diagnostic and Non-in-Vitro Diagnostic medical devices, which the World Health Organization (WHO) has prequalified.

1.2. This guideline is based on NAFDAC's Regulatory Reliance Policy on the adoption of regulatory reliance mechanisms to make regulatory decisions as it relates to the granting of Marketing Authorization, Clinical Trial Approval, and conduct of Good Manufacturing Practice (GMP) Inspections.

1.3. The collaborative procedure is limited to medical devices, including In-Vitro Diagnostics, that have been assessed and inspected by the WHO-PQ Team 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 an 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 medical devices, including in vitro diagnostic medical devices, 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.

1.6. Applicants should note that all National administrative and regulatory requirements must be met for the WHO-CRP to be implemented.

NOTE: These Guidelines should be read in conjunction with all relevant IMDRF guidance documents including the following:

a. **GHTF/SG1/N71:2012 "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device"** GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's (imdrf.org)

b. **In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019**
https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-ivd-mdma-toc-n13.docx

c. **GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical Devices"** GHTF SG1 - Label and Instructions for Use for Medical Devices - September 2011 (imdrf.org)

d. **Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL:2019** Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC) (imdrf.org)

2. Application

2.1. To initiate the registration process for an IVD and non-IVD medical devices product via the WHO CRP route, the Applicant is required to initiate the dossier submission process by submitting an email to mdbvmrr@nafdac.gov.ng Upon receipt of the email, a unique link will be generated and communicated to the applicant, facilitating the submission of their dossier (For video description, please click on the Link).

2.2. The Application for the registration or renewal of registration of all Medical Devices products required for each single medical device, medical device group, medical device family, or medical device system 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

2.3. NAFDAC receives applications for the same In-Vitro Diagnostics and Non-In-vitro Diagnostics medical devices as those prequalified by WHO. Within the context of this Procedure, the same In-Vitro Diagnostics and Non-In-vitro Diagnostics medical devices are characterized by:

a. the same product name;
b. the same regulatory version;
c. the same product code(s);
d. the same site of manufacture and quality management system;
e. the same data on quality, safety and performance;
f. The same design with the same components from the same suppliers; and
g. The same information, labelling and packaging, including instructions for use and intended use.

2.4. An online application form for product registration should be purchased at; https://registration.nafdac.gov.ng and completed.

2.5. A separate application form shall be submitted for each product.

Step 1

3. Documentation

The following documents should be uploaded to the NAPAMS portal. After successful submission, all original documents will be presented upon request.

3.1. A written application for registration of imported In-Vitro Diagnostics and Non-In-vitro Diagnostics medical devices using the CRP route, should be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs (VBM-R&RA) Directorate, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway, Isolo, Lagos.

3.2. Notarised Declaration (Appendix 1). To be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria (for imported medical devices)

3.3. Power of Attorney or Contract Manufacturing Agreement. An applicant on behalf of a manufacturer outside Nigeria must file 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 should be:

a. Issued by the manufacturer of the product.
b. 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 should also indicate 'Authority to register product with NAFDAC'
c. State ownership of Brand name(s)/Trademark.
d. Notarized by a Notary Public in the country of manufacture.
e. Valid for at least five (5) years.

3.4. Contract Manufacturing Agreement: An applicant filing an application and being the owner of a Brand name/Trademark shall provide a Contract Manufacturing Agreement, which shall be signed by the applicant and the manufacturer.
The Agreement shall be

a. Notarized by a Notary Public in the country of manufacture.
b. 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.

3.5. Certificate of Manufacture and Free Sale (for imported medical devices). The manufacturer must show evidence that the company is licensed to manufacture medical devices and that the sale of the product does not constitute a contravention of the laws of that country, i.e., Free Sale Certificate (Certificate of Manufacture and Free Sale). The Free Sale Certificate should:

a. Be issued by a relevant Health/Regulatory body in the country of manufacture.
b. Indicate the name of the manufacturer and the products to be registered.
c. 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 he document.

3.6. Comprehensive Certificate of Analysis. The certificate of analysis must be presented on the letter-headed paper of the Quality Control Laboratory where the sample was tested/evaluated and should contain all relevant technical parameters of interest in addition to the underlisted information:

a. The brand name of the product
b. The batch number of the product
c. The manufacturing and expiry dates
d. The name, designation, and signature of the analyst.

3.7. Evidence of Business Incorporation by the Corporate Affairs Commission.

3.8. 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.

3.9. Product Labels/artwork should be in line with the labeling requirement in Section 10.0

3.10. Letter of Invitation for Good Manufacturing Practice (GMP) Inspection (for imported medical devices): A letter of invitation to inspect the factory abroad shall be written by the manufacturer and shall state the following:

a. MANUFACTURER INFORMATION: Name of Company, full location address of factory (not administrative office address), e-mail, and current phone no. Details (name, phone number, and email) of the contact person overseas.
b. LOCAL AGENT INFORMATION: Name of company, full location address, functional phone number, and e-mail address. Details (name, phone number, and email) of the contact person.
c. Names(s) of product(s) for registration.

4. Labelling Guidelines and Instruction for Use for Medical Devices

4.1. Labelling should be informative, accurate and in conformance with the Agency's Medical Devices, in vitro diagnostic and other related products Labelling Regulations and any other relevant Regulations.

4.2. All imported and locally manufactured medical devices should bear the following minimum information on the label:

a. Name of the device
b. Name and address of the manufacturer
c. The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device
d. Family or medical device group family (where applicable) Batch or lot number
e. If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume, or number of units
f. The words "sterile" if the manufacturer intends to sell the device in a sterile condition
g. The words "for single use only" if the device is intended for that purpose
h. The manufacturing and expiry date of the device expressed in month and year (where applicable) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use
i. The directions for use, unless directions are not required for the device to be used safely and effectively, and

j. Any special storage conditions applicable to the device

k. Where a package that contains a device is too small to display all the information in accordance with (a-k) above, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

4.3. Instructions For Use (IFU)

a. The following minimum information should be contained in the IFU:
   i. what the IVD medical device measures or detects.
   ii. its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, or companion diagnostic);
   iii. the specific disorder, condition, or risk factor of interest that it is intended to detect, define, or differentiate;
   iv. whether or not it includes automated components or is intended to be used with automated instruments;
   v. what the IVD medical device reports (e.g., qualitative test, semi-quantitative, quantitative test);
   vi. the type of specimen(s) (e.g. serum, plasma, whole blood, tissue biopsy, urine) required, including the specimen source(s) (e.g. capillary whole blood from arm), matrix (e.g. EDTA tube), time (e.g. 8 hours after injury), and collection method (e.g. self-collected urine); and
   vii. target population (on whom the IVD medical device is used).

b. The instructions for use should include a statement of the test principle(s), such as the general biological, chemical, microbiological, immunochemical, and other principles on which the IVD medical device is based. Proprietary information need not be disclosed, but should provide enough detail to allow the user to understand how the IVD medical device is able to carry out its function.

c. The instructions for use should include a description and the amount of the reagent, calibrators, and controls, and any limitation upon their use (e.g., suitable for a dedicated instrument only).

d. NOTE: IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, where appropriate, these IVD medical devices should comply with the instructions for use content in this section.

e. The instructions for use should include a list of materials provided and a list of any materials required but not provided.

f. The instructions for use should include a description of in-use stability. This may include the storage conditions prior to opening and shelf-life following the first opening of the primary container, together with the storage conditions and stability of working

solutions, where this is relevant.

g. The instructions for use should list the included and excluded conditions for collection, shipping, handling, and preparation of the specimen.

h. Where relevant, the instructions for use should include the traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.

i. The instructions for use should describe the assay procedure, including calculations and interpretation of results, any additional software or reference database required, and, where relevant, if any confirmatory testing should be considered.

j. The instructions for use should list the analytical performance characteristics, such as precision, accuracy, sensitivity, and specificity.

k. Where relevant, the instructions for use should list the clinical performance characteristics (e.g., diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations).

l. Where relevant, the instructions for use should include the reference intervals in normal and affected populations.

m. The instructions for use should include information on any interfering substances or limitations (e.g., visual evidence of hyperlipidemia or hemolysis, age of specimen/sample) that may affect the performance of the assay.

Where relevant, the instructions for use should include a bibliography or references section.

5. Technical Documents

5.1. Declaration of Conformity

a. The manufacturer should attest that its medical device complies fully with all applicable Essential Principles for Safety and Performance as documented in a written "Declaration of Conformity" (DOC). At a minimum, this declaration should contain the following information:

i. A statement that each device that is the subject of the declaration complies with the applicable Essential Principles for Safety and Performance,
ii. The device has been classified according to the classification rules and has met all the applicable conformity assessment elements.
iii. A Global Medical Device code and term for the device(s).
iv. Date from which the Declaration of Conformity is valid.
v. Name and address of the device manufacturer; and,
vi. The name, position, and signature of the person who has been authorized to complete the Declaration of Conformity on behalf of the manufacturer.

5.2. Certificate of Compliance with Recognized Standards (where available) should be submitted.

5.3. Product Dossier for In-vitro Diagnostics (see NAFDAC guidelines for compilation of a product Dossier for Registration of In-vitro Diagnostics (IVD ToC)

5.4. Product Dossier for Non-In-vitro Diagnostics (see NAFDAC guidelines for compilation of a product Dossier for Registration of In-vitro Diagnostics (nIVD ToC)

5.5. Clinical Evaluation Report with Statistical Data for Novel Medical Devices, including in vitro diagnostics.

5.6. In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019

5.7. Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nlVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL:2019

6. GMP Inspection

Applicant should visit the Drug Evaluation and Research (DER) Directorate section of the Agency's website for more Information on the Inspection of manufacturing facilities (for both imported and locally manufactured medical devices)

Step II

7. Import Permit (for imported medical devices)

Upon successful screening of documentation and review of supporting documents, a Permit to Import shall be issued electronically via the NAPAMS Portal to the applicant for the importation of Registration samples for Laboratory testing.

Step III

8. Submission of Products for Laboratory Analysis

8.1. Upon importation of Registration Samples (for imported medical devices), applicants are expected to submit same to the division for onward submission to the Laboratory for analysis. The following documents are expected to accompany the samples.

8.1.01. Letter for submission of Laboratory Samples

8.1.02. Evidence of payment to the Agency

8.1.03. Certificate of analysis

8.1.04. Evidence of submission for vetting

While registration samples for locally manufactured medical devices will be drawn by Drug Evaluation and Research (DER) Directorate.

Step IV

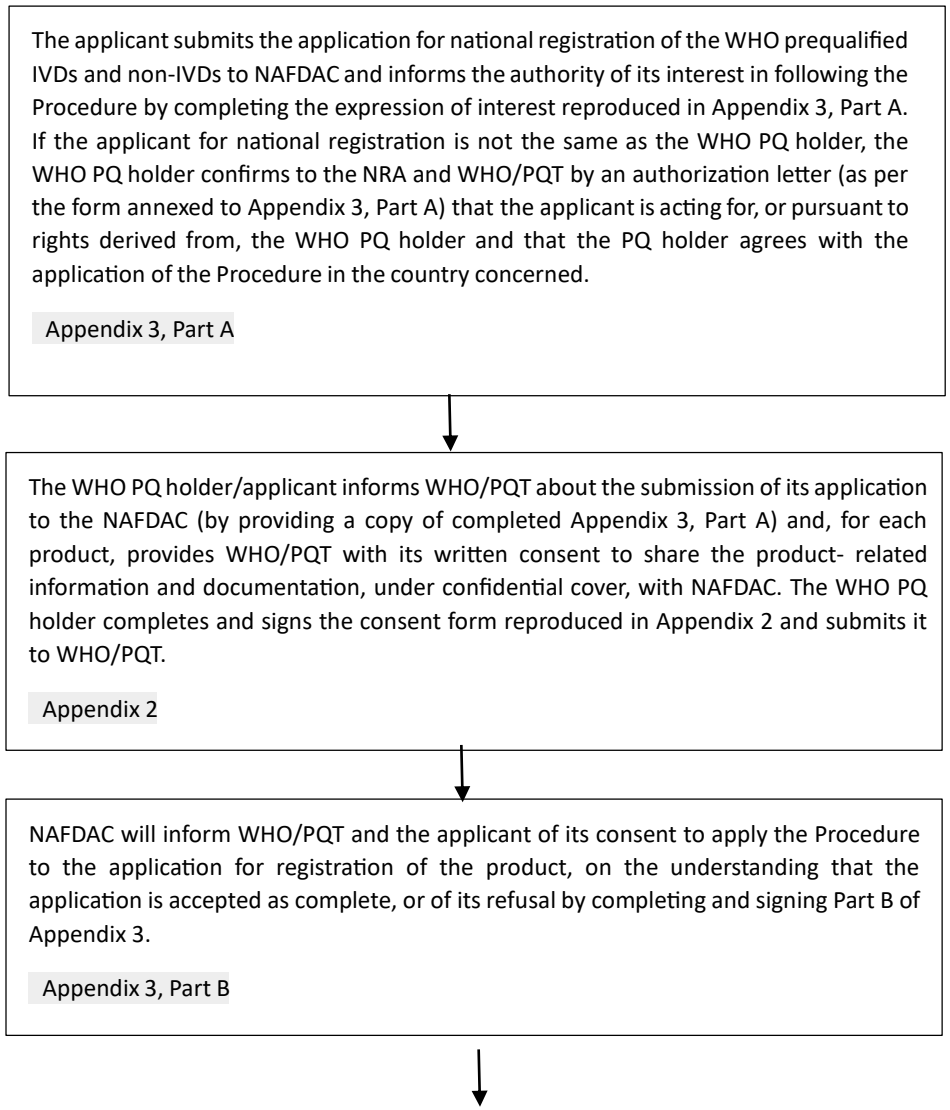
9. Product Approval Meeting

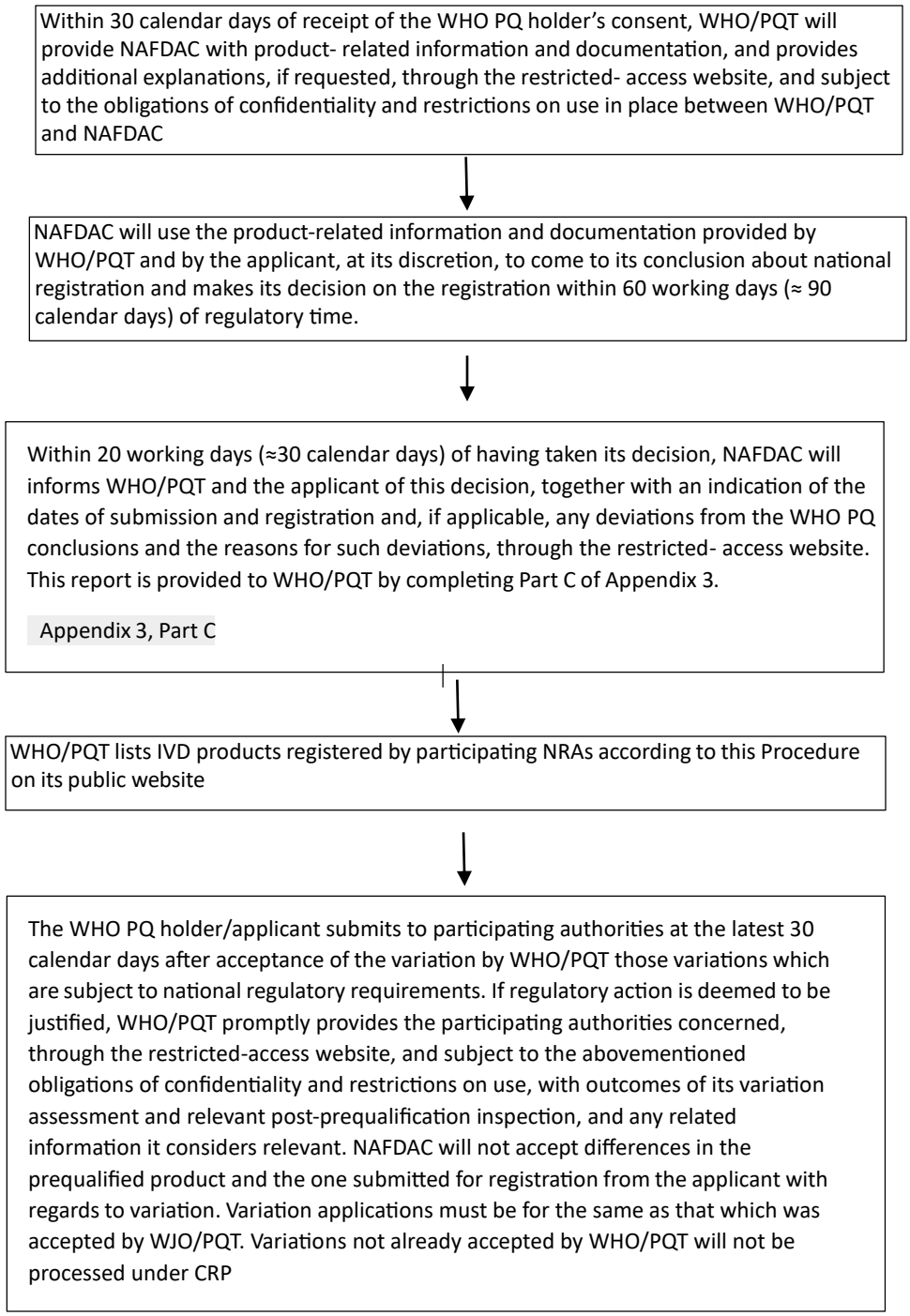
Upon satisfactory Documentation review, GMP inspection of the production facility and laboratory analysis of product (where applicable), products are presented for the Food and Drug Registration Committee (FDRC) Approval Meetings.

10. Tariff

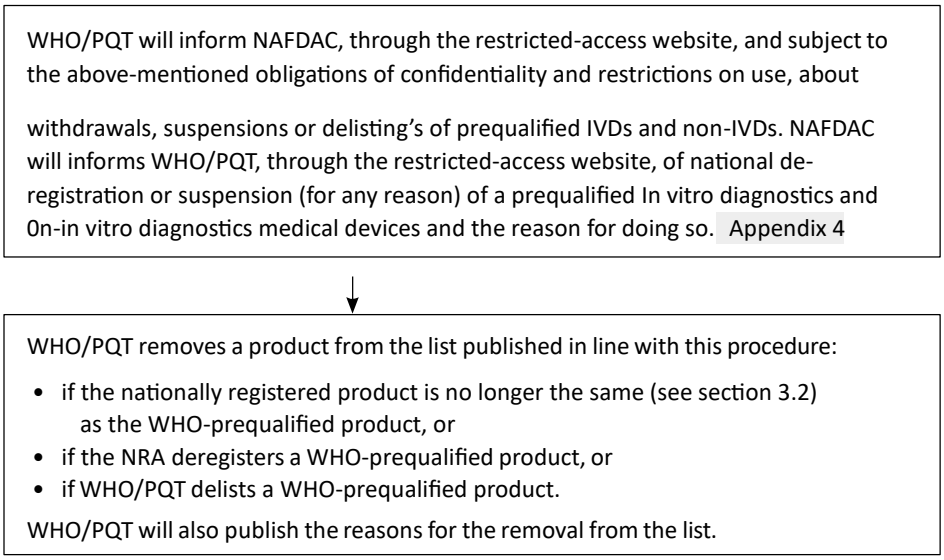
See NAFDAC tariff section

11. Flowchart showing the principal steps of the Collaborative Registration Procedure




Within 30 calendar days of receipt of the WHO PQ holder's consent, WHO/PQT will provide NAFDAC with product- related information and documentation, and provides additional explanations, if requested, through the restricted- access website, and subject to the obligations of confidentiality and restrictions on use in place between WHO/PQT and NAFDAC
NAFDAC will use the product-related information and documentation provided by WHO/PQT and by the applicant, at its discretion, to come to its conclusion about national registration and makes its decision on the registration within 60 working days (≈ 90 calendar days) of regulatory time.
Within 20 working days (≈30 calendar days) of having taken its decision, NAFDAC will informs 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 IVD products registered by participating NRAs according to this Procedure on its public website
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 WJO/PQT. Variations not already accepted by WHO/PQT will not be processed under CRP

Post-registration processes



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

12. Plan for post marketing surveillance

The post market surveillance plan should be developed in accordance with the Section 4.8 (Medical Devices Vigilance System) of the NAFDAC Guidelines for Detecting and Reporting of Adverse Reactions for Pharmaceutical products and Medical Devices.

13. Note

13.1. Failure to comply with these requirements may result in the rejection of the application or lead to considerable delay in the processing of registration.

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

13.3. Registration of a product does not automatically confer an Advertising Permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised. For further information on advert approvals, see NAFDAC Guidelines on Advertisement.

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

13.5. Filing an application and/or paying an application fee does not confer registration status.

13.6. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within ninety (90) days) will automatically lead to the closure of the Application.

13.7. The timelines for product registration from acceptance of submissions to issuance of Registration number under the Collaborative Registration Procedure (CRP) route is sixty (60) workdays.

13.8. Please note that the clock stops once compliances are issued.

All correspondences should be addressed to:
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
NAFDAC website: www.nafdac.gov.ng
E-mail: bvmregistration@nafdac.gov.ng

All submissions should be made via email or at the Office of the Director, VBM -R & RA, First Floor, NAFDAC Office Complex Annex, Isolo Industrial Estate, Apapa-Oshodi Express Way, Isolo, Lagos.

14. Appendices

APPENDIX 1

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:
   i. **List of Products (Product Names)**
2. 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.**
3. 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:
   i. Power of attorney / Contract Manufacturing Agreement and notarization thereof
   ii. Certificates of Pharmaceutical Product/ Certificate of Manufacture and/or Free Sale and the authentication thereof by the Nigerian Mission in the country of origin
   iii. Manufacturing license / Certificate for companies from India and China and the

authentication thereof by the Nigerian Mission in the country of origin

iv. Certificate of Good Manufacturing Practice (GMP) and the authentication thereof by the Nigerian Mission in the country of origin

v. Certificate of Analysis of product

vi. Evidence of Registration of Trademark and the information contained in all the above referred documents is true and correct.

4. That the manufacturer **Manufacturer's Company Name** is or is not the owner of the trademark
5. The product_____is generic
6. That **Applicant's Company Name** of **Applicant's Company Address** is or is not the owner of the Trademark.
7. The product_____is generic
8. 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)**
9. 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: _____