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

DRUG REGISTRATION & REGULATORY AFFAIRS (DR&R) DIRECTORATE

GUIDELINES FOR REGISTRATION OF VECTOR CONTROL PRODUCTS 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 Vector Control Products which have been prequalified by the World Health Organization.

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, Field Trial Approval and conduct of Good Manufacturing Practice (GMP) Inspections.

1.3 The collaborative procedure is limited to Vector Control Products that have been assessed and inspected by WHO/PQP in line with the procedures and standards available at https://extranet.who.int/prequal/vector-control-products/what-we-do.

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 Vector Control 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.

1.6. 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 WHO Vector Control guidance documents under Vector Control Products/WHO-Prequalification of Medical products -IVDs, Medicines, Vaccines & Immunization, Devices, Vector Control at extranet.who.int/prequal/vector-control-products

2. Application

2.1. To initiate the registration process for a Vector Control product via the WHO CRP route, the Applicant is required to initiate the dossier submission process by submitting an email to ahfc@nafdac.gov.ng.

2.2. The Application for the registration or renewal of registration of VCPs 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

2.3. NAFDAC receives applications for the same vector control product as the one prequalified by WHO. Within the context of this Procedure, the same vector product is characterized by:

- the same formulation,
- the same active ingredient and strength
- intended use
- the same specifications, the same site of manufacture and quality management system,
- the same data on quality, efficacy, and safety,
- same information, labelling[1] and packaging including instructions for use and intended use.

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

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

[1] Labelling includes labels and the instructions for use.

Step I

3. Documentation

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

3.1. A written application for registration of imported Vector Control Product using the CRP route, should be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Drug Registration & Regulatory Affairs (DR&R) Directorate, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway, Isolo, Lagos.

3.2. A completed Appendix 3, Part A (Expression of Interest)

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

3.4. Power of Attorney or Contract Manufacturing Agreement.

Power of Attorney - 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:

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 shall also state '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.

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:

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 Evidence of Business Incorporation of the importing Company with Corporate Affairs Commission in Nigeria.

3.6 Certificate of Manufacture and Free Sale (for imported vector control product). The manufacturer must show evidence that the company is licensed to manufacture vector control products and that the product is freely sold in the country of origin i.e., Free Sale Certificate. 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 the document.

3.7 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.

3.8 Current Good Manufacturing Practice (cGMP) of the manufacturing facility. This is to be:

a. Valid at the time of submission.

b. Be issued by the relevant Health/Regulatory body.

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 the document.

d. Reference the Manufacturer's License Nos Form 25 and Form 28

3.8 Dossiers; The applicant shall submit two (2) copies of the Dossiers which should be;

a. In a Compact Disc (CD).

b. Searchable Portable Document Format (pdf).

c. Common Technical Document (CTD) format

d. The dossiers should be the same as that which was accepted by the World Health Organization at the time of prequalification.

3.9 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 VCPs).

3.10 Label or artwork of the product

Product Information for Products Registered Under CRP

Should meet NAFDAC Labelling requirements.

https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Regulations/REGULATIONS_2021/Pesticide-Registration-Regulations-2021.pdf

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 to confirm sameness with the prequalified version with respect to AI and FP manufacturing sites, specifications, packaging material and packaging type 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 Product Approval meeting

7. Upon satisfactory Dossier review/verification, Risk-Based Categorization of the production facility and satisfactory laboratory analysis of product, products are presented for ratification at the Food and Drug Registration Committee(FDRC) Approval meeting

8. **Tariff**

The tariff will be same as that for a pesticide product.
https://www.nafdac.gov.ng/wp-content/uploads/Publications/Others/NAFDAC-2019-Tariff_hyperlinked_Final.pdf

9. Flowchart showing the steps of the Collaborative Registration Procedure

The applicant submits the application for national registration of the WHO prequalified vector control product to NAFDAC and informs the authority of its interest in following the Procedure by completing the expression of interest reproduced in Appendix 3, Part A. If the applicant for national registration is not the same as the WHO PQ holder, the WHO PQ holder confirms to the NRA and WHO/PQT by an authorization letter (as per the form annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder and that the PQ holder agrees with the application of the Procedure in the country concerned.
Appendix 3, Part A

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The WHO PQ holder/applicant informs WHO/PQT about the submission of its application to the NAFDAC (by providing a copy of completed Appendix 3, Part A) and, for each product, provides WHO/PQT with its written consent to share the product- related information and documentation, under confidential cover, with NAFDAC. The WHO PQ holder completes and signs the consent form reproduced in Appendix 2 and submits it to WHO/PQT.
Appendix 2

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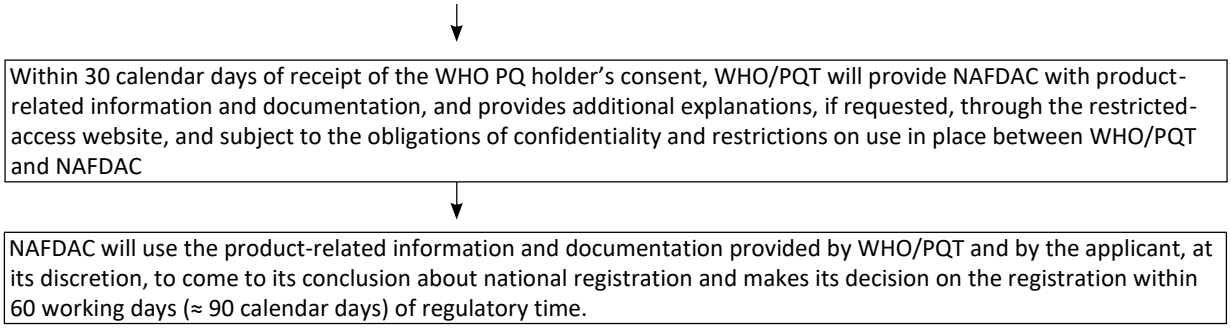
NAFDAC will inform WHO/PQT and the applicant of its consent to apply the Procedure to the application for registration of the product, on the understanding that the application is accepted as complete, or of its refusal by completing and signing Part B of Appendix 3.
Appendix 3, Part B


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 vector control 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 WJO/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 informs WHO/PQT, through the restricted-access website, of national de-registration or suspension (for any reason) of a prequalified vector control product 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://extranet.who.int/prequal/vector-control-products/what-we-do

https://extranet.who.int/prequal/vector-control-products/prequalified-product-list

10.Note

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

10.2 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.

10.3 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.

10.4 Filing an application form or paying an application fee does not confer registration status.

10.5 Failure to respond promptly to queries or enquiries raised by NAFDAC on the application will automatically lead to the closure of the Application.

10.6 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.

10.7 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).

APPENDIX I

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** thereofand 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)

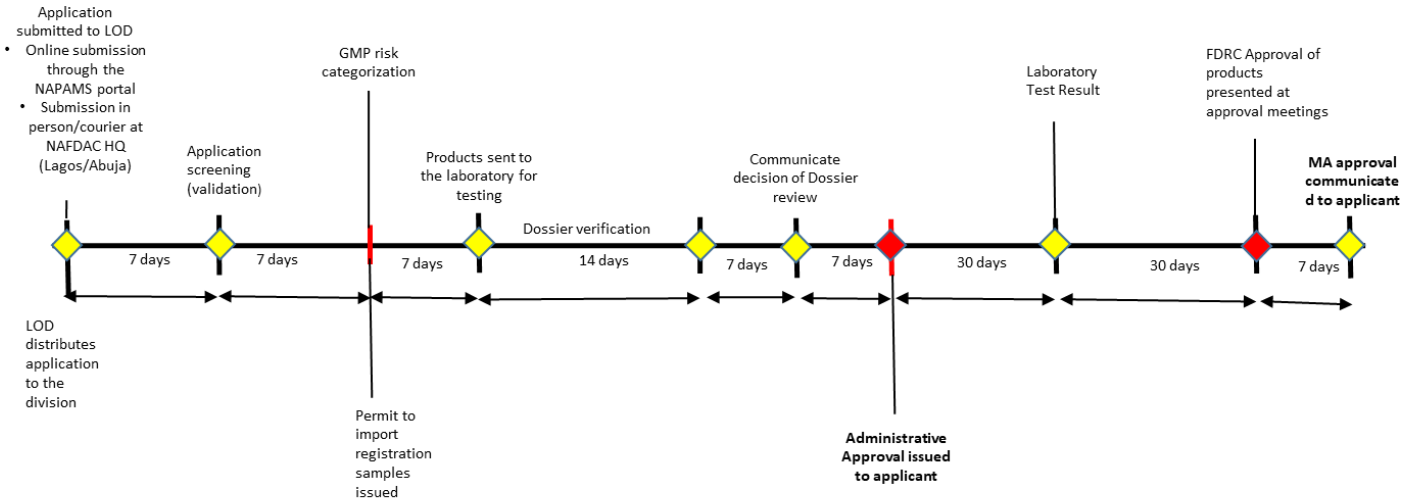
NAME:_____

ADDRESS:_____

SIGNATURE:_____

DATE: _____

Registration Process + Time lines



Total 49 days

Worst case: 60 days