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

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR REGISTRATION OF DRUG PRODUCTS MADE IN NIGERIA

(HUMAN AND VETERINARY DRUGS)

1.0. General

1.1. These Guidelines are for the interest of the general public and in particular, manufacturers of pharmaceuticals for Human and Veterinary use made in Nigeria.

1.2. 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.

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

a ICH Harmonised Tripartite Guideline Stability Testing of New Drug Substances and Products Q1A(R2)

https://database.ich.org/sites/default/files/Q1A%28R2%29%20Guideline.pdf

b ICH Harmonised Tripartite Guideline Stability Testing for New Dosage Forms Annex to the ICH Harmonised Tripartite Guideline on Stability Testing for New Drugs and Products Q1C

https://database.ich.org/sites/default/files/Q1C%20Guideline.pdf

C ICH Harmonised Tripartite Guideline Pharmaceutical Development Q8(R2)

https://database.ich.org/sites/default/files/Q8_R2_Guideline.pdf

d ICH Harmonised Tripartite Guideline "Quality Risk Management Q9"

https://database.ich.org/sites/default/files/Q9_Guideline.pdf

e ICH Harmonised Guideline Technical and Regulatory considerations for Pharmaceutical Product Lifecycle Management Q12

https://database.ich.org/sites/default/files/Q12_Guideline_Step4_2019_1119.pdf

1.4. To initiate the registration process for a drug product, the Applicant is required to submit a Dossier of the drug product for screening. (See Guidance Document for Submission of Dossier)

1.5. Dossier clearance is a prerequisite for submission of applications for pharmaceuticals for human use.

2.0. Applications

2.1. The Application for the registration of all drug products should be 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

A separate application form shall be submitted for each product.

Step 1

3.0. Documentation

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

3.1.1. The application letter addressed to the Director-General (NAFDAC), Attention: Director, Drug Registration & Regulatory Affairs Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State.

3.1.2. Evidence of Business Incorporation of the Applicant with the Corporate Affairs Commission (C.A.C) in Nigeria.

3.1.3. Contract Manufacturing Agreement (where applicable).

3.1.4. 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 as the case may be (Trademark Class 5 for Drugs).

3.1.5. Copy of valid Annual License to practice for the Superintendent Pharmacist (for Human Drugs or Veterinary Drugs).

3.1.6. Copy of valid Premises Retention License for the facility.

3.1.7. Evidence of satisfactory Inspection issued by the relevant Directorate or Good Manufacturing Practice (GMP) certificate for product line (companies with registered products).

3.1.8. Label or artwork of the product should be in line with the Drug and Related products Labelling Regulations.

For more Information on the Inspection of manufacturing facility, Applicant should visit the Drug Evaluation and Research (DER) Directorate or Veterinary Medicine and Allied Products (VMAP) Directorate section of the Agency's website.

Step 2

4.0. Product Approval meeting

4.1. Upon satisfactory Dossier review, satisfactory GMP of the production facility and satisfactory laboratory analysis of product (where applicable), the Food and Drug Registration Committee (FDRC) Approval Meetings.

Step 3

5.0. Issuance of Certificate of Product Registration

5.1. For products approved at the meeting, an electronic Certificate of Product Registration is issued to the Applicant.

6.0. Labelling Guidelines for Drugs made in Nigeria

6.1. Labelling should be informative and accurate.

6.2. Minimum requirements on the product label in accordance with the Drug Labelling Regulations include:

6.2.1. Generic name and product brand name (where applicable).

6.2.2. Name and full location address of the manufacturer.

6.2.3. Provision for NAFDAC Registration Number on product label

6.2.4. Batch No., Manufacturing date and Expiry date.

6.2.5. Dosage form & strength

6.2.6. Indications, frequency, route, conditions of administration (Over the counter; OTC drugs).

6.2.7. Dosage regimen on the package (Over the counter; OTC drugs).

6.2.8. Patient Information Leaflet (PIL)

6.2.9. Net content of product

6.2.10. Quantitative listing of all the active ingredients per unit dose

6.2.11. Adequate warnings where necessary.

6.2.12. Storage conditions

6.2.13. Withdrawal Period for all Veterinary drugs

6.2.14. Where a brand name is used, there MUST be the generic name which should be conspicuous in character, written directly under the brand name.

6.2.15. Any drug product whose name or package label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

6.2.16. Any drug product which is labelled in a foreign language shall NOT be considered for registration unless an English translation is included on the label and PIL (where applicable).

6.2.17. See the Agency's Drug Labelling Regulations and other relevant Regulations for specific details.

7.0. Tariff

7.0 Please refer to the NAFDAC Tariff.

8.0. Note:

8.1. For New Chemical Entities (NCE), there must be evidence that Clinical Trials have been undertaken in the relevant population. Such clinical trial reports must be submitted and reviewed

8.2. For generic products, Bioequivalence study report/Biowaiver data shall be submitted on DMS using the CTD Dossier format. The Bioequivalence study report and/or Biowaiver application shall be assessed by the efficacy assessors.

8.3. No combination drug product shall be registered or considered for registration unless there is proven scientific documented evidence that such a product has clinical advantage over the single drug available for the same indication(s).

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

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

8.6. 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. For further information on advert approvals, see NAFDAC Guidelines on Advertisement.

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

8.8. Filing an application or paying an application fee does not confer

registration status.

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

8.10. The timeline for product registration from acceptance of submissions to issuance of Registration number is two hundred and forty (240) working days.

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

All correspondences should be addressed to:-

Director-General (NAFDAC),

Attn: The Director,

Drug Registration and Regulatory Affairs Directorate,

National Agency for Food and Drug Administration and Control (NAFDAC),

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