

GUIDELINES FOR DRUG REGISTRATION IN NIGERIA

ISSUED BY

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

A. GENERAL

1. THESE GUIDELINES ARE FOR THE INTEREST OF THE GENERAL PUBLIC AND IN PARTICULAR, PHARMACEUTICAL INDUSTRIES IN NIGERIA.
2. IT IS NECESSARY TO EMPHASIZE THAT, NO DRUG PRODUCT SHALL BE MANUFACTURED, IMPORTED, EXPORTED, ADVERTIZED, SOLD OR DISTRIBUTED IN NIGERIA UNLESS IT HAS BEEN REGISTERED IN ACCORDANCE WITH THE PROVISIONS OF DECREE 19 OF 1993 AND THE ACCOMPANYING GUIDELINES.

B. APPLICATION / MANUFACTURER

1.
 - (a.) An application for registration of a drug product shall be made by the manufacturer.
 - (b) In case of a manufacturer outside Nigeria such shall be represented in Nigeria by a duly registered Pharmaceutical Company.
 - (c) An applicant for 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 original Power of Attorney is to be notarized and submitted to NAFDAC.

NOTE: The representative in Nigeria, whether a corporate body or an individual with the Power of Attorney, will be held responsible for ensuring that the competent authority in the country is informed of any serious hazard newly associated with a product imported under the provisions of the decree or of any criminal abuse of the certificate in particular to the importation of falsely labeled, spurious, counterfeited or sub-standard medicinal products.

(d) The manufacturer, in the case of imported products, must show evidence that he or she is licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). Such evidence must be by the competent Health Authority of the country of manufacture, and shall be authenticated by the Nigerian Mission in that Country.

2.

a. The applicant must submit to the office of the Director (Registration and Regulatory Affairs) NAFDAC, a written application, stating name of manufacturer, generic name (brand name, where applicable) strength, indications and obtain the prescribed application form which must be properly filled with all information required. This form, labeled "FORM D-REG/001" shall be obtained on payment of N500.00 per product in Bank Draft (MICR) issued in favour of NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC, Lagos).

b. A separate application form shall be submitted for each drug product. In this context, a drug product means a separate drug formulation. However the application for registration of one dosage form with different strengths may be made on a different application form.

C. PRODUCT

1. A drug product shall not be manufactured in Nigeria, unless the factory is inspected and Certification of Recognition is issued by NAFDAC.
2. In case of imported products:-
 - a. There must be evidence of registration of such product by the competent Health Authority of the country of manufacturer i.e., Product License / Certificate of Registration.
 - b. There must be evidence by the competent Health Authority, that the sale of the Products does not constitute a contravention of the drug laws of the country i.e. Certificate of Pharmaceutical Product (COOP) that conforms to the WHO format.
 - c. The documents in respect of (a) and (b) shall be authenticated by the Nigerian Mission in that country.

3. In the case of an imported new drug substance, there must be evidence that limited local clinical trials have been

undertaken, and that such product is registered in the country of origin and also, in at least 2 or more developed countries.

4. No combination drug product shall be registered or considered for registration unless there is proven evidence that such a product has clinical advantage over the single drug available from the same indication(s).
5. Identification marks must be embossed on all tablets and capsule shells.
6. The application should indicate the class or type of registration required – whether it is a prescription-only product.
7. Products found to be of doubtful, little or no therapeutic value and those which are sometimes rather harmful and subject to misuse, shall not be considered for registration.
8. An applicant shall not be allowed to register a drug formulation in more than one brand name even where different doses of the active ingredient(s) are used.
9. The product information must be in 2 copies with hard covers per product (dossiers) made out in accordance with application format (the content of the dossier must be in compliance with the items on the format).
10. All dosage forms of a particular brand name must contain the same active ingredient(s) or at least the major active ingredient(s) e.g.
11. Evidence of Trade Mark Approval from Federal Ministry of Commerce in Nigeria.
12. Notarized declaration to be notarized by a Notary Public.
13. Comprehensive Certificate of analysis of the batch of product to be registered.
14. Current premises license.
15. Annual Licence for the Superintendent Pharmacist.
16. Certification of Incorporation of the applicant.

D. LABELING

1. Labeling shall be informative and accurate.
2. Minimum requirements on the package label:-
 - a. Name of product- brand name and generic, name where applicable. The generic name must be in similar characters with the brand name.
 - b. Location address of the manufacturer.
 - c. Provision of NAFDAC Registration Number on product label.
 - d. Batch No. Manufacturing date and Expiry date.
 - e. Dosage regimen on the package.
 - f. Leaflet insert, if prescription product and hospital packs.
 - g. Indications, frequency, route and conditions of administration.
 - h. Quantitative listing of all the active ingredients per unit dose.
 - i. Adequate warnings where necessary.
3. Where a brand is used, there **MUST** be the generic name which should be conspicuous in character, written directly under the brand name e.g.:- VENTOLIN
“SALBUTAMOL”
4. Any drug product whose name, package or 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.
5. Any drug product which is labeled in a foreign language shall **NOT** be considered for registration unless an English translation is included on the label and package insert (where applicable).
6. Information on indication carried on packages and leaflet insert of imported drug product shall not differ from that in other countries, and in particular the country of origin of the product.
7. Failure to comply with these requirements may result in the disqualification of the application or lead to considerable delays in processing and registration.
8. A successful application attracts a Certificate of Registration with a validity period of 5(five) years.

N.B.

(i) Registration of a product does not automatically confer Advertising Permit. A separate approval by the Agency shall be required if the product is to be advertised.

(ii) NAFDAC may withdraw the Certificate of Registration in the event that the product is advertised without the express approval from the Agency.

(iii) NAFDAC reserves the right to revoke, suspend or vary the certificate during the validity period.

(iv) FILLING AN APPLICATION FORM OR PAYING FOR AN APPLICATION FORM DOES NOT CONFER REGISTRATION STATUS.

(vi) FAILURE TO RESPOND PROMPTLY TO QUERIES ON ENQUIRIES RAISED BY NAFDAC ON THE APPLICATION, WILL AUTOMATICALLY LEAD TO SUSPENSION OF FURTHER PROCESSING OF THE APPLICATION.

G. All correspondence in respect of Drug Registration should be addressed to:

The Director,
Registration & Regulatory Affairs
NAFDAC
Federal Secretariat Phase II
Ikoyi, Lagos.

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