Registration of Drugs and Medicinal Products in Nigeria

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INTRODUCTION

Drug is defined to include any substance of vegetable, animal or mineral origin or any preparation or admixture thereof which is used for internal or external application to the human body in the treatment of disease (Pharmacy Ordinance Cap. 152). An extension of this interpretation can be seen in Food & Drug Decree No 35 of 1974. According to the decree, drug includes any substance or mixture of substances, manufactured, sold or advertised for use in:-

(i) the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state, or the symptoms thereof, in man or animals.

(ii) restoring, correcting or modifying organic functions in man or animals.

(iii) disinfection, to the control of vermin, insects or pest, or contraception.

THE NEED FOR DRUG REGISTRATION

Drug registration is a valuable means whereby government attempts to control the way drugs are offered for sale in a country. It ensures drugs for unrestricted distribution in the country pass test of need, efficacy, safety, Good Manufacturing Practice (GMP) and good quality.

Drug registration is an essential tool in limiting the number and types of drugs imported or manufactured in the country. Besides it aids in the introduction of new preparation and the removal of unsuitable product from the trade.

However, it must be admitted that registration of drug is not just a simple administrative activity but is the very climax of all in built, processes designed to ensure the safety, efficacy and quality of medicinal products circulating in any country.

REGULATORY AUTHORITY

Following the promulgation of Decree 15 of 1993, National Agency for Food and Drug Administration and Control (NAFDAC) has been given the legal mandate to control and regulate all food, drug, medical devices, bottled water and chemical.

Therefore, the establishment of National Agency for Food and Drug Administration and Control arose from the need for government to identify an Agency which essentially would render to the general public the most effective and safe pharmaceutical products with established quality through the process of regulations, monitoring, control and registration.

To further strengthen the hands of NAFDAC, government also promulgated decree 19 of 1993 called drugs and related products (registration etc) decree.

Section 1 (i) of the decree says: "No Drug, Drug product, cosmetic or medical device shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of this decree or regulations made under it".

To discharge these duties, the Agency has drawn up guidelines and procedures which are meant to adequately acquaint every person involved in drug registration matters.

MODE OF APPLICATION - Imported Drug

Application for drug registration has to be made by the manufacturer or in the case of manufacturers outside Nigeria, by the manufacturer's accredited representative. Such a representative must be a duly registered pharmaceutical company.

The application which should be typed on the letter headed paper should be accompanied by:-

(a) A copy of current annual licence to practice as a Pharmaceutical Chemist of the Superintendent Pharmacist (issued by Pharmacists Council of Nigeria [PCN]).

(b) A copy of current certificate of the retention of premises where the drug business would be conducted (issued by Pharmacists Council of Nigeria [PCN]).

(c) Power of Attorney (from the manufacture and original to be submitted).

(d) A copy of certificate of manufacture and free sale which is issued by the competent Regulatory authority of the country of manufacture.

(e) A copy of product license (to be issued by the competent regulatory authority of the country of manufacture).

(f) A copy of batch certificate of analysis.

d & e above should be authenticated by Nigerian Mission in the country of manufacture while the originals of a, b, d & e would be sighted during registration process.

LOCALLY MANUFACTURED DRUGS

The application which is made in writing by the local manufacturer must be accompanied by:

(a) A copy of the current annual license to practice of the Superintendent Pharmacist (issued by Pharmacy Council of Nigeria [PCN]).

(b) A copy of the current premises retention certificate (issued by Pharmacists Council of Nigeria [PCN]).

(c) Evidence of pre-production letter - issued by NAFDAC after a thorough inspecton of the facilities and premises where the production is to conducted.

Pre-production inspection is necessary to ensure that the premises comply with good manufacturing practice (GMP) guidelines.

The application which is typed on the letter headed paper of the applicant/manufacturer is forwarded to:-

The Assistant Director
Registration Division
NAFDAC
Medical Compound
Yaba.

If the application is in order, a payment advice is issued to enable the applicant purchase "Application form" which cost N500.00 per product. The money should be in a bankdraft made payable to NAFDAC in Lagos. Thereafter the applicant returns the completed application form with the treasury receipt of N500.00 and applies for permit to bring in samples for registration purpose as provided for in section 2 of Decree 19 of 1993 which says "Not withstanding the provision of section (1) of this section, the National Agency for Food and Drug Administration and Control (NAFDAC) may grant a permit for the importation or manufacture of a sample of drug, drug product cosmetics or medical device for the purpose of registration or clinical trial, and the importation or manufacture shall be in accordance with the conditions specified in the permit.

In the case of narcotics and psychotropic substances, the drug permit for registration purposes issued by Drug Registration Division is sent to Narcotic Division to be validated before a Narcotic permit in compliance with INCB IS ISSUED TO THE APPLICANT. Without the narcotic permit the applicant would be acting ultra vires if he should import/manufacture a controlled drug for registration purposes.

DRUG SAMPLE ASSESSMENT

On receipt of drug samples, which should be submitted together with the dossier, the package/ label would be vetted to ensure that they comply with drug labelling requirement.

A properly labelled drug product which must be in English language should carry the following on the label:-

A. Outer package

1. Name of drug product
2. Where there is a trade name, the generic name ***MUST*** be written directly under the trade name.
3. Strength per unit dose
4. Indication for use
5. Dosage regimen
6. Location address of the manufacturer
7. Date of manufacture
8. Expiry date based on well controlled stability studies.
9. Batch number
10. Warning for children
11. Direction for storage
12. Quantity/Net volume of the drug product

B. Inner label & Blister packs

The inner label which is the immediate label on the container should carry such information as:-

Name of the drug, where there is a trade name the generic name must be written

- Batch No.
- Date of manufacture
- Expiry date
- Strength per unit dose
- Name and address of manufacturer etc.

INFORMATION LEAFLET

It is mandatory that all prescription and hospital packed drugs must carry extra information in the form of "Information Insert".

This is particularly useful to the Pharmacist, Physician & Nurses who are expected to be properly informed about the drugs they use during patient medication and care so as to avoid health risks.

Drug information leaflet therefore should be detailed and should cover the following:-

- Pharmacology of the drug
- Pharmacokinetics of the drug
- Indication for use
- Dosage and administration
- Adverse effect
- Drug/Drug or Drug/Food interaction

- Contra-indications
- Warnings especially during pregnancy & patient with some organ malfunction e.g. kidney, heart diseases etc.
- Precautions
- Over-dosage etc.

DOSSIER ASSESSMENT

The compilation of Drug Dossier is a documentary attempt to look into the efficacy, safety and quality of the drug product.

It is therefore extremely important that all the 26 sections that form the base of the dossier are treated in a professional manner.

The sections covered in the dossiers are:

Section 1: Name and Address of applicant
Section 2: Status of the applicant i.e. importer, manufacturer etc.
Section 3: Name of product
Section 4: Indication(s)
Section 5: Presentation and packaging (i.e. the type of package and pack size)
Section 6: Name and quantity of each ingredient (both active and excipients). What is needed here is a breakdown of the formulation by listing the ingredients by its generic name per unit dose. Names of colours should also be stated.
Section 7: Chemicals name and structural formula of each active ingredient.
Section 8: Method of manufacture
Section 9: Route and condition of administration.
Section 10: Dosage form
Section 11: Side effect
Section 12: Contral-indications
Section13: Adverse effect
Section 14: Antidote in the event of overdosage
Section 15: Teratogenicity
Section 16: Analytical method of each ingredient, chemical or microbiological
Section 17: Shelf life; stability data
Section 18: Toxicological data
Section 19: Clinical data
Section 20: Bioavailability/Bioequivalence
Section 21: Give the name(s) of the countries in which product is being marketed/registered.
Section 22: How long has the product been in the market in Nigeria?
Section 23: Signature of applicant
Section 24: Attached Certificate of manufacture, certificate or licence to import and Power of Attorney
Section 25: Samples of the drug to be registered
Section 26: Indicate if the product has been registered in the country of origin.

COLLATION OF REPORTS

During this process of drug documentation and dossier evaluation the applicant is expected to pay a processing fee of N5000.00 per dosage form. All reports concerning the drug to be registered is now collated after detailed and painstaking assessment. These reports are:

- analytical report
- pre-registration inspection report (in case of locally made drugs)
- Packaging/labelling assessment
- evaluation of the Dossier

The overall aim of drug registration remain to register only quality drugs which are safe and effective. Based on this premise, a drug is approved for registration if the drug satisfies all aspects which guarantee safety, efficacy and quality. A registration fee of N5000.00 is paid by the applicant before the Certificate is signed which is to last 5 years but NAFDAC reserves the right to revoke withdraw or suspend such registration status during its validity period if

(a) Information that form the basis of its registration are no more relevant
(b) If the product is being marketed unprofessionally outside the authorised category.

PROBLEM

One obvious problem which many applicants complain about is the duration for the registration of a new drug application. But to a large extent, the cause of such delay is the inability of the applicants to comply with the various requirements highlighted in this paper.

CONCLUSION

In conclusion, it is a very established fact that the importance of drug registration cannot be over-emphasised. More than anything else, it is a veritable instrument for ensuring the safety and quality of drug products meant for human consumption. It is therefore illegal to offer for sale, distribute, promote advertise any of the regulated products without registration. A breach of which may earn the offending person or organisation serious sanctions as stipulated in the enabling Decree.

It is my fervent belief that with the efforts being made by the Agency through the process of registration, the Nigerian drug market would be sanitized in the nearest future and wholesome drugs would equally be ensured.