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

Drug Registration and Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR REGISTRATION OF IMPORTED MEDICAL DEVICES IN NIGERIA

1.0 General

1.1 These Guidelines are for the interest of the general public and in particular, importers of Medical Devices in Nigeria.

1.2. It is necessary to emphasize that, no Medical Device 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. NAFDAC will not entertain new application for the registration of imported regulated products on the Federal Government Import Prohibition List and NAFDAC Ceiling List.

2.0 Application

2.1. The Application for the registration of all Medical Devices products 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

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

Step 1

3.0 Documentations

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

3.1 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.

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

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 shall (be):

- 3.3.1 Issued by the manufacturer of the product.
- 3.3.2 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 indicate 'Authority to register product with NAFDAC'.
- 3.3.3 State ownership of Brand name(s)/Trademark.
- 3.3.4 Notarized by a Notary Public in the country of manufacture.
- 3.3.5 Valid for at least five (5) years.

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

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

3.4.2 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. 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:

3.5.1 Be issued by a relevant Health/Regulatory body in the country of manufacture.

3.5.2 Indicate the name of manufacturer and products to be registered.

3.5.3 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.

3.6 Comprehensive Certificate of Analysis. The certificate of analysis must be presented on a 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 the under listed information:

3.6.1 The brand name of the product

3.6.2 The batch number of the product

3.6.3 The manufacturing and expiry dates

3.6.4 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 labelling requirement in Section 10.0

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

3.10.1 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 contact person overseas.

3.10.2 LOCAL AGENT INFORMATION: Name of company, full location address, functional phone number. and e-mail address. Details (name, phone

number and email) of contact person. Names(s) of product(s) for registration.

4.0 Technical Documents

4.1 Declaration of Conformity

4.1.1 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:

a. A statement that each device that is the subject of the declaration–

i. complies with the applicable Essential Principles for Safety and Performance,

ii. has been classified according to the classification rules, and,

iii. has met all the applicable conformity assessment elements.

b. A Global Medical Device code and term for the device(s).

c. Date from which the Declaration of Conformity is valid.

d. Name and address of the device manufacturer; and,

e. The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity on behalf of the manufacturer.

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

4.3 Product Dossier for In-vitro Diagnostics (Appendix II)

4.4 Clinical Evaluation Report with Statistical Data for Novel Medical Devices including In-vitro diagnostics.

Note: All technical documents must be submitted in electronic format e.g., Flash drive

5.0. For more Information on the Inspection of manufacturing facility, Applicant should visit the Drug Evaluation and Research (DER) Directorate section of the Agency's website.

Step II

6.0 Import Permit

6.1 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

7.0 Submission of Products for Laboratory Analysis

7.1 Upon importation of Registration Samples, 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.

7.1.1 Letter for submission of Laboratory Samples

7.1.2 Evidence of payment to the Agency

7.1.3 Certificate of analysis

7.1.4 Evidence of submission for vetting

Step IV

8.0 Product Approval meeting

8.1 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.

STEP V

9.0 Issuance of Notification

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

10.0 Labelling Guidelines for Imported Medical Devices

10.1 Labelling should be informative, accurate and in conformance with the Agency's Medical Devices Labelling Regulations and any other relevant Regulations.

10.2 All imported 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)

e. Batch or lot number

f. 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

g. The words "sterile" if the manufacturer intends to sale the device in a sterile condition

h. The words "for single use only" if the device is intended for that purpose

i. 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

k. the directions for use, unless directions are not required for the device to be used safely and effectively and

l. any special storage conditions applicable to the device

m. 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 sell.

11.0 Tariff

11.1 See NAFDAC Tariff section.

12.0 Note

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

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

12.3 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 Advert

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

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

12.6 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.

12.7 The timeline for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (120) working days.

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

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

BVM: bvmregistration@nafdac.gov.ng

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** thereof and 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
   c. 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: _____

APPENDIX II

DOSSIER REQUIREMENT FOR IN VITRO DIAGNOSTICS

1.0 ADMINISTRATIVE INFORMATION

- **1.1** MANUFACTURER INFORMATION
  - 1.1.1 Name
  - 1.1.2 Address
  - 1.1.3 Contact (e-mail, website, phone no.)
  - 1.1.4 Brief overview of company (Business summary)
- **1.2** LOCAL AGENT INFORMATION
  - 1.2.1 Name
  - 1.2.2 Address
  - 1.2.3 Contact (e-mail, website, phone no.)

2.0 PRODUCT DESCRIPTION, SPECIFICATION, VARIANTS AND ACCESSORIES

- **2.1** Device Description
- **2.2** Intended Use
- **2.3** Regulatory Classification
- **2.4** Statement on Medicinal Substances, Animal Materials and Human Tissue
- **2.5** Product Composition & Specification
- **2.6** Reference to similar and previous generations of the device
- **2.7** Accessories
- **2.8** Applicable Standards

3.0 LABEL, LABELLING, AND INSTRUCTIONS FOR USE

4.0 DESIGN AND MANUFACTURING INFORMATION

- **4.1** Product Design
- **4.2** Manufacturing Site(s)
- **4.3** Manufacturing Processes

5.0 PRODUCT PERFORMANCE EVALUATION

- **5.1** Diagnostic Sensitivity
- **5.2** Diagnostic Specificity
- **5.3** Analytical Sensitivity
- **5.4** Analytical Specificity
- **5.5** Limit of Detection
- **5.6** Interference
- **5.7** Repeatability and Reproducibility

6.0 RISK ANALYSIS AND RISK MANAGEMENT

- **6.1** Summary of Risk Analysis
- **6.2** Summary of Risk Management plan

7.0 PRODUCT VERIFICATION AND VALIDATION

- **7.1** General
- **7.2** Biocompatibility and Biological Safety
- **7.3** Sterilization
- **7.4** Software Verification and Validation
- **7.5** Animal Studies
- **7.6** Clinical Trial Data/Records

8.0 DECLARATION OF CONFORMITY

9.0 CHANGE HISTORY

10.0 PLAN FOR POST MARKETING SURVEILLANCE

11.0 APPENDICES