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

Drug Registration & Regulatory Affairs (DR&R) Directorate

GUIDELINES FOR RENEWAL OF CERTIFICATE OF REGISTRATION FOR MEDICAL DEVICES MADE IN NIGERIA

1.0. General

1.1. The National Agency for Food and Drug Administration and Control has the responsibility of ensuring that Medical Devices made in Nigeria placed on the Nigerian market for use meet the requirements for Quality, Safety and Efficacy throughout the lifecycle of the product.

1.2. The procedure for registration of Medical Devices made in Nigeria outlines the process to be followed and the technical requirements to be met before a product can be placed on the Nigerian market.

1.3. A product authorized for marketing in Nigeria will be issued a Certificate of Registration valid for 5 years (or less in some cases) and should be renewed upon expiration.

1.4. These guidelines are intended to provide guidance on the technical and other general data requirements when submitting an application for renewal of product license for Medical Devices made in Nigeria.

Step I

2.0. Application for the Renewal of Product License

2.1. An application for renewal should be initiated not later than thirty (30) calendar days to the date of expiration of the current/valid license.

2.2. The Application for the renewal of medical devices 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.

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

2.4. The renewal application should be addressed to the Director-General (NAFDAC), ATTENTION: The Director, Registration & Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.

3.0. Documentation

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

3.2 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.

3.3 Contract Manufacturing Agreement (where applicable)

At the expiration of a product license, the Contract Manufacturing Agreement may have lapsed except in cases when a specific expiration date was specified in the original power of attorney or contract manufacturing agreement or a statement that the power

of attorney is for an indefinite period. Except in the cases stated above, an applicant will be required to submit a new power of attorney or contract manufacturing agreement at renewal.

The document shall give details of:

3.3.1 The Issuer and the Receiver of the Power of Attorney and in the case of a Contract Manufacturing Agreement, the parties involved with their specific roles and the terms of the contract agreement.

3.3.2 A list of the products covered by the power of attorney (this can come as an annexure for large number of products but must form part of the power of attorney with a specific reference to the annexure stated on the power of attorney).

3.3.3 State ownership of Brand name/s or Trademark.

3.3.4 The validity of the power of attorney should be stated and it should not be less than 5 years.

3.3.5 The document must be signed by the authorized person(s) and should be notarized by a notary public in the country of manufacture.

3.4 Certificate of Registration of Brand Name/Trademark

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.

3.5 Expired NAFDAC License

A copy of the Certificate of Registration for the product(s).

3.6 Evidence of Business Incorporation by the Corporate Affairs Commission.

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.

Step III

5.0. **Issuance of Notice of Renewal**

Upon successful submission of all required documents, an electronic Notice of Renewal is issued to theapplicant.

Step IV

6.0 Product Sampling:

5.0. Product sampling for Renewal of marketing authorization will be based on laboratory reports emanating from any of the following activities within the validity of current license:

5.0.1. Pharmacovigilance monitoring

5.0.2. Ports Inspection and Distribution channels sampling

5.0.3. Routine facility Inspections/Audits

5.1. In the event that there is a need to conduct laboratory analysis, there will be a request for samples of the product.

Step V

6.0. **Product Approval meeting**

Upon meeting all regulatory requirements, product is presented for Approval Meeting.

Step VI

7.0. **Issuance of Notification**

For products approved at the meeting, Notification of Renewal of Registration or Listing is issued to the applicant.

8.0 **Labelling Guidelines for Imported Medical Devices**

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

8.2 All 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.

9.0. **Tariff**

9.1 See NAFDAC Tariff section.

10. Note

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

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

10.3. Renewal of 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.

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

10.5. Filing a renewal application and/or paying a renewal application fee does not confer registration status.

10.6. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within 45 working days) will automatically lead to the closure of the Application.

10.7. The timeline for product registration from acceptance of submissions to issuance ofRegistration number is sixty (60) working days.

10.8. 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: bvmregistration2nafdac.gov.ng

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