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

Drug Registration & Regulatory Affairs (DR&R) Directorate

And

Vaccines, Biologics, and Medical Devices Registration & Regulatory Affairs (VBM-R&R) Directorate

Guidelines for Donated Medical Products in Nigeria

1.0. GENERAL

1.1 These guidelines are for the interest of the general public, donors, and recipients of donated medical products.

1.2 It is necessary to emphasize that no donated medical product shall be imported into Nigeria unless it has undergone due processing with the Agency in accordance with the guidelines for donated medical products in Nigeria, and a Permit to Import the specific donated items is issued.

1.3. The recipient organization must demonstrate the capacity to handle the type and quantity of the medicinal products, medical devices, including IVDs, and related products, e.g., cold chain products.

1.4 The recipient organization must liaise with the NAFDAC State Coordinator in the location where the project/ program will be executed.

1.5 Products deleted from the list of products/items during assessment must not be imported.

1.6 The recipient organization, after obtaining approval and having successfully imported and cleared the donated drug products, medical devices, including IVDs and related products, should invite the NAFDAC State and or Zonal offices in the area to witness the event where the donated medicinal products, medical devices, including IVDs, and related products are to be used.

1.7 The NAFDAC State and or Zonal offices would periodically monitor and evaluate the level of compliance with the conditions of approval for each consignment of donated drug products, medical devices, including IVDs, and related products.

1.8 A report detailing the distribution and stock utilization records should be generated regarding the donation exercise and submitted to the Post Market Surveillance (PMS) Directorate and the State Coordinators. This is a requirement for the issuance of subsequent permits.

1.9 The Pharmacovigilance Directorate of the Agency will also be involved in monitoring the public for any unexpected adverse reactions associated with the use of donated medicinal products, medical devices, including IVDs, and related products.

2.0 APPLICATIONS/RECIPIENTS/DONORS

2.1 An application for a Permit to Import Donated Medical Products should be made by the recipient organization in Nigeria to the Agency before the medicinal products, medical devices, including IVDs, and related products leave the country of origin. The recipient organization must be an entity registered by the Corporate Affairs Commission.

2.2 The application should be in the form of a letter addressed to the Director General and attention the Director Vaccines, Biologics and Medical Devices Registration and Regulatory Affairs (VBM R&RA) Directorate (for vaccines, biologics and medical devices, including IVDs and related products) or Director, Drug Registration and Regulatory Affairs (DR&R) Directorate regarding medicinal products.

2.3 The inventory of donated items must be submitted in an editable Microsoft Excel sheet format, including a list of the medicinal products, medical devices, including IVDs, and related products, with the following column headers:

i. Product/brand name.
ii. Product Description/Generic Name.
iii. Strength.
iv. Unit/pack size.
v. Quantity.
vi. Batch details.
vii. Manufacturer's name and address, country of origin.
viii. Expiry dates.

2.4 The identity and contact address of the donor and the expected date of arrival at the port of entry should be stated.

2.5 The applicant should provide information on the port of arrival of the consignment before shipping.

2.6 In addition, the following documents should be attached:

i. Evidence of correspondence between the recipient and donor showing how the donation was initiated, or a certificate of donation.

ii. Evidence of WHO Pre-qualification, or valid Good Manufacturing Practice (GMP) Certificate, or market authorization approval issued by a World Health Organization-Listed Authorities (WLAs), International Medical Devices Forum Management Committee (IMDRF-MC), or Pharmaceutical Inspection Cooperation Scheme (PIC/S) member country.

iii. Certificate of Analysis of the medical product.

iv. Evidence of Quality Management System Compliance for the medical device, including IVD and related products manufacturing facility.

v. Declaration of Conformity with the Essential Principles of Safety and Performance of

the intended Medical Devices, including IVDs and related products.

vi. Manufacturing Facility Certification by an SRA body, e.g., US FDA (where applicable)

vii. A Clearance letter of good standing from the Director, Post-Marketing Surveillance Directorate of NAFDAC, for applicants with previous approvals.

viii. A Memorandum of Understanding (MOU) with the concerned level of Government of Nigeria, where the donated medical products will be utilized, where applicable.

ix. Detailed plan on how the program will be executed, which must include: date, venue, and details of the Nigerian contact/focal person.

x. Evidence that the donated medicinal products/medical devices, including IVDs and related products, are relevant for the purpose and shall be of benefit.

xi. Evidence of skilled professionals, including Pharmacists (for medical products), volunteers validly contracted by the organization (evidence attached) who can handle the medical products.

xii. The Premises (warehouse) where the Donated Medicines will be kept pending usage must be licensed by the Pharmacist Council of Nigeria (PCN), and evidence should be attached alongside the application form. Exceptions of medical devices, including IVDs and related products.

xiii. The premises must not necessarily be owned by the recipient organization but could be owned by a third party which it has an understanding with (copy of agreement attached).

3.0 PRODUCTS

All donated medicinal products/medical devices, including IVDs and related products should meet the following requirements:

3.1 Be of good quality, safe, efficacious, and perform as intended.

3.2 The presentation, strength, formulation, and component should be as much as possible similar to those used in Nigeria, unless specifically requested by the recipient.

3.3 Labelled in English language and bear the generic name, brand name, product description, quantity, batch number, dosage form, composition, strength, name of manufacturer, quantity in each container, storage condition and date markings as

applicable.

3.4 Should be obtained from reliable sources and must comply with quality standards in Nigeria and donor country. (Evidence of complying with the quality standards of the Donor country should be attached).

3.5 Only Generics and brands not already registered shall be allowed. However, any company wishing to import small quantities of an already registered brand or generic should provide a "no objection letter" from the party that registered the medicinal products/medical devices, including IVDs and related products.

3.6 The following products are not qualified under the donated medical product Scheme and should be excluded from the item list:

i. Products for which there is local manufacturing capacity.
ii. Products for which there are safety concerns.
iii. Product on NAFDAC Ceiling list.
iv. Products on Federal Government Import Prohibition List.
v. Products affected by any restrictions as specified by the Agency.

3.7 Where there are Narcotics, Psychotropic substances, and any controlled medicines or drug-device combination and related products containing controlled medicines are part of the items to be imported, an authorization to import and clear such medicines/drug-device combination and related products must be obtained from the Narcotics & Controlled Substances Directorate of the Agency.

3.8 Where a recipient intends to import Schedule I Narcotics, approval or waiver to import must be obtained from the Federal Ministry of Health and Social Welfare.

3.9 No medical products that have expired or have been issued to patients and returned to Pharmacy should be donated.

3.10 Large volume parenterals shall be brought in quantities that can be analyzed if the need arises.

3.11 The Agency, as the need arises, may in some cases demand that donated medicines/ medical devices, including IVDs and related products, be subjected to laboratory analysis to ascertain their quality, safety, efficacy, and performance.

3.12 Donated Medical Products should be packed appropriately according to the storage conditions before shipment.

3.13 Donated Medical Products should not be sold to the general public, exported or diverted.

3.14 In an event that the donated medicinal products/medical devices, including IVDs and related products are not exhausted after a program for which it is imported, the remaining shall be returned to NAFDAC and documented for destruction.

3.15 Products under this scheme are prohibited from Advertisement.

3.16 Upon arrival, all donated medicinal products must have a shelf life of at least six (6) months upon arrival at the ports. Donated medical devices, including IVDs and related products should have a shelf life of six (6) months where applicable, at the time of clearance at the ports of entry.

3.17 It is important that date of arrival and expiry dates of the medicinal products/medical devices, including IVDs where applicable, be communicated to the recipient well in advance.

4.0 PORT CLEARANCE OF DONATED DRUG PRODUCTS/MEDICAL DEVICES INCLUDING IVDs AND RELATED PRODUCTS.

Upon arrival in the country, the following documents are required before clearance at the ports.

4.1 A copy of the approval letter from the Agency to import the donated medical products

4.2 A letter of undertaking as required by the Ports Inspection Directorate attaching the following documents:

4.3 Single Goods Declaration (SGD) form, if applicable.

4.4 Packing List.

4.5 Clean Report of Inspection and Analysis/Evidence of destination inspection (if applicable).

4.6 Narcotics permit to import and clear (if applicable).

4.7 Bill of lading/Airway bill.

4.8 Pre-Assessment Arrival Report (PAAR).

4.9 Invoice or letter transferring the donated medicines/medical devices, including IVDs and related products from the donor to the recipient organization containing the name and quantity of the medical products.

5.0 TARIFF

5.1 The processing fee for donated medical products will be as prescribed in the official tariff document: https://www.nafdac.gov.ng/wp-content/uploads/Publications/NAFDAC-2019-Tariff_Final_Combined.pdf

5.2 Where the need for Product laboratory analysis arises, the recipient shall bear the cost.

6.0 REPORT

On completion of the proposed program, the recipient organization is required within thirty (30) workdays to provide a report to the Agency's Pharmacovigilance (PV) and Post-marketing Surveillance (PMS) Directorates respectively and copy the Drug Registration and Regulatory Affairs (DR&R) and Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs (VBM R&RA) Directorates of NAFDAC where applicable. The report should be detailed and include:

i. Pictorials,
ii. Detailed distribution record,
iii. Stock utilization record of the Donated Medicinal Products/Medical Devices, including IVDs and related products
iv. any other pertinent details.

Failure to do so will result in the denial of future requests.

7.0 CONDITIONS FOR DESTRUCTION

Where donated medical products do not comply with requirements, or are expired upon arrival, the Agency shall seize and destroy the medicines and medical devices, including IVDs. The recipient organization shall bear the cost of destruction as stipulated in the appropriate guidelines with the Investigation & Enforcement Directorate of the Agency.

NOTE

Donated medical products are medicinal products, vaccines, biologics, and medical devices, including IVDs and related products sent by a Donor to a Recipient organization in Nigeria in the event of natural disaster, emergency, and non-emergency situations or on humanitarian basis which may or may not be on request.

All approved applications should be immediately enrolled on the National Single Window to enable importation – https://nsw.gov.ng

All applications and correspondences with respect to processing the Permit to import donated medical products should be addressed in this format:

The Director-General
National Agency for Food and Drug Administration and Control (NAFDAC)
Plot 2032, Olusegun Obasanjo Way,

Zone 7, Wuse, Abuja.

Attention:

Director,
Drug Registration and Regulatory Affairs
Directorate. Plot 1, Isolo Industrial Area,
Apapa-Oshodi Expressway, Isolo, Lagos.
E-mail: registration@nafdac.gov.ng
Website: www.nafdac.gov.ng

or

Attention:
The Director,
Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs (VBM R&RA)
Directorate.
Plot 1, Isolo Industrial Area, Apapa-Oshodi
Expressway, Isolo, Lagos.
Email:
bvmregistration@nafdac.gov.ng
Website: www.nafdac.gov.ng

Dear Ma,

APPLICATION FOR A PERMIT TO IMPORT DONATED MEDICAL PRODUCTS