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

Drug Registration & Regulatory Affairs (DR & R) Directorate

Guideline 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 donor medical product.

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 regulations for drug donation.

1.3. The recipient organization must demonstrate the capacity to handle the type and quantity of the drug product e.g. for cold chain products.

1.4 The recipient organization must liaise with the NAFDAC State Co-ordinator in the location of project/ program execution.

1.5 Products deleted from the application during assessment must not be imported.

1.6 All approvals should be forwarded to the Heads of Ports of entry and respective state coordinators.

1.7 Heads of Ports of entry should get the contact of the focal person of the recipient organization for monitoring of program activities.

1.8 The recipient organization after obtaining approval and having successfully imported and cleared any donated drug, shall invite the NAFDAC state and or zonal offices in the area where the donated drugs are to be used to witness the event.

1.9 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 drugs.

1.10 A report should be generated regarding the donation exercise and the utilisation of the donated items and submitted to PVG/PMS state coordinators.

1.11 The Pharmacovigilance and Post Marketing Surveillance directorate of the agency shall also be involved in monitoring the public for any unexpected adverse drug reaction associated with the use of donated drugs.

2.0 APPLICATIONS/RECIPIENTS/DONORS

2.1 An application for drug donation shall be made by the recipient organization in Nigeria to the Agency before the drug leaves the country of origin. The recipient organization must be an entity registered by the Corporate Affair Commission.

2.2 The application shall be in form of letter addressed to the Director General and attention Director Registration and Regulatory Affairs directorate stating the type and quantities of the medical supplies or drug(s); including the generic name, strength, dosage

form, manufacturing and expiry dates. The inventory list should be submitted in a soft editable copy (Ms Word/Excel)

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

2.4 Applicant should provide information on the port of arrival of the consignment before shipping

In addition, the following documents shall be attached:

i. Evidence of correspondence between the recipient and donor showing how the donation was initiated.

ii. Detail plan on how the program will be executed which must include: date, venue and details of Nigeria contact/focal person must be include.

iii. Evidence that the donated drugs are relevant for the purpose and shall be of maximum benefit.

iv. Evidence of skilled professionals (Pharmacists) in the organization, volunteer or validly contracted by the organization (evidence attached) who can handle the drugs safely.

v. The premises (warehouse) where the donated drugs will be kept pending usage must be licensed by the Pharmacist council of Nigeria (PCN) and evidence should be attached alongside application form. Exceptions of medical devices.

iv. 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 drug products shall meet the following requirements:

3.1 Be of good quality, safe and efficacious.

3.2 The presentation, strength and formulation shall be as much as possible similar to those used in this country, unless specifically requested for by the recipient.

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

3.4 Shall 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 must bring a "no objection letter" from the party that registered it and this letter shall be verified by NAFDAC.

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 capacity.
ii. Products for which there are safety concerns.
iii. Product on NAFDAC Ceiling list.
iv. Products on Federal Government Import Prohibition List.

3.7 Where there are Narcotics, Psychotropic substances and any controlled drugs, authorization to import and clear such drugs must be obtained from the Narcotics & Controlled Directorate of the Agency.

3.8 Where a recipient intends to import schedule I narcotics, approval or waiver to import must be obtained Federal Ministry of Health.

3.9 Drugs under the federal government import prohibition list would not be approved.

3.10 No medicinal product that have expired or have been issued to patients and returned to pharmacy shall be donated.

3.11 Large volume parenteral shall be brought in quantities that can be analyzed if the need arises.

3.12 The agency as the need arises may in some cases demand that donated drugs are subjected to laboratory analysis to ascertain their safety.

3.13 Donated medical product shall be properly packed according to the storage conditions before shipment.

3.14 Donated medical product shall not be sold to the general public, exported or diverted.

3.15 In an event that the donated drugs not exhausted after a program for which it is imported for, the remaining shall be returned to NAFDAC or documented for destruction.

3.16 Upon arrival, all donated drugs shall have a minimum shelf life of three (3) months at the time of clearance at the port or six (6) months from the date of arrival. It is important that date of arrival and expiry dates of the drugs be communicated to the recipient well in advance.

3.17 No medical product registered by the agency shall be imported as donated drugs unless the donor recipients has obtained a No Objection from the agency and the owner of the market authorization consents to it.

3.18 Products under this scheme are prohibited from Advertisement.

4.0 PORT CLEARANCE OF DONATED DRUGS

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 drugs.

4.2 A letter of undertaking as required by the port inspection Directorate attaching the following document.

4.3 Single good declaration (SGD) form, if applicable.

4.4 Certificate of analysis.

4.5 Packing list.

4.6 Clean report of inspection/Evidence of destination inspection (if applicable).

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

4.8 Bill of lading/Airway bill.

4.9 Pre-Assessment Arrival Report (PAAR).

4.10 Invoice or letter transferring the donated drug from the donor to the recipient containing the name and quantity of drugs.

5.0. TARIFF

Donated drugs are exempted from all processing fees, however where the need for Product laboratory analysis arises, the recipient may bear the cost.

6.0. REPORT

On completion of the proposed program, the recipient organization is required within thirty (30) calendar days to provide feedback to the Agency's Pharmacovigilance and Post-marketing Surveillance (Pv/PMS) Directorate and a copy to the Drug Registration and Regulatory Affairs Directorate by forwarding a detailed report that must include:

i. pictorials,
ii. detailed distribution record,
iii. stock utilization record of the donated drugs,

iv. any other pertinent details.

Failure to do so may result in denial of future request.

7.0. CONDITIONS FOR DESTRUCTION

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

NOTE

- Donated medical product are drugs, drug products and medical devices sent by a Donor to a Recipient in Nigeria in the face of a disaster and suffering or on humanitarian basis which may or may not be on request.
- A copy of the approval letter issued by Drug Registration and Regulatory Affairs Directorate should always be forwarded to the Ports Inspection Directorate, Directorate Pharmacovigilance and Post marketing Surveillance and Director-General Office.
- The Hon. Minister of Health should be adequately briefed on the challenges encountered under this scheme as well as the atrocities being committed in the name of providing humanitarian services to Nigerians.
- The Ministry of Health should be informed of any infraction committed under this scheme periodically

All applications and correspondences in respect to processing of Donated products should be addressed to:

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