CLEARANCE AND CERTIFICATE FOR FOREIGN DONATION APPLICATION

Who May Avail : All individuals, organizations, and institutions, both public and private, and all levels of government engaged in the importation, facilitation and management of all regular donations of foreign origin covering pharmaceutical products **during non-emergency situations**

Fees to be Paid : **Administrative Order No. 2020-0001**
PHP 500.00 + LRF

CHECKLIST OF REQUIREMENTS

- **Administrative Order No. 2020-0001: Guidelines in the Importation, Facilitation, and Management of Foreign Donations involving Health and Health-Related Products**

I. Criteria for Acceptable Foreign Drug Donations

1. Listed in the Latest Edition of the Philippine National Formulary
2. For pharmaceuticals which are not included in the Latest Edition of the Philippine National Formulary (PNF), they must satisfy at least one (1) of the following conditions:
   a. Must contain the same active ingredients, dosage form and strength as those products already approved by and registered at FDA Philippines;
   b. Orphan drugs and drugs for compassionate use; or
   c. Critically needed drugs (Note: Subject to approval by the Secretary of Health)
3. Must NOT be classified under the following:
   a. Experimental/investigational drugs and MR registration of FDA Philippines
   b. Regulated, prohibited and/or dangerous drugs of PDEA
4. Must have a shelf-life of at least 12 months (or 1 year) at the expected date of arrival
5. For pharmaceuticals with shelf life below 12 months, must satisfy at least one of the following conditions:
   a. The product has a total shelf-life of less than 2 years AND has a remaining of at least one-third (1/3) of its shelf-life
   b. Recommended as suitable for distribution as per case assessment by the DOH/TWG and approved by the Secretary of Health despite the limited product shelf-life remaining

II. Requirements

II-A. Administrative Data

1. Endorsement Letter from the Bureau of International Health Cooperation (BIHC) – DOH
2. 2. Letter of intent to donate
3. Authenticated Deed of Donation (Philippine Embassy/Philippine Consulate)

4. Letter of Concurrence or Acceptance
5. List of all drug products to be donated with the following information:
   a. International Nonproprietary Name (INN) or Generic name
   b. Brand name (if any)
   c. Dosage Form and Strength
   d. Batch/Lot Number
   e. Expiration Date
   f. Total quantity of batch/lot of products to be donated
6. Distribution plan/ Allocation list of intended beneficiaries
7. Photocopy of shipping documents such as bill of lading airway bill, commercial invoice, and packing list
8. Copy of Post donation report (where applicable)
9. Proof of payment (PHP 510.00)

II-B. Quality

1. Certificate of Pharmaceutical Product (CPP)
2. For countries not issuing CPP, the following shall be submitted:
   a. Current Good Manufacturing Practice (CGMP) Certificate issued by the drug regulatory authority of the product's country of origin
   b. Certificate of Free Sale (CFS) authenticated by the territorial Philippine Consulate
3. Certificate of Analysis (CoA) per batch/lot of product
4. Complete labeling materials, i.e., primary and secondary packaging, and package insert, which must contain texts in English/English translation of ALL of the following mandatory information:
   a. International Nonproprietary Name (INN) or Generic name
   b. Brand name (if any)
   c. Dosage Form and Strength
   d. Mode of Administration
   e. Batch/Lot Number
   f. Expiration Date
   g. Formulation
   h. Storage conditions
   i. Name and Address of the Manufacturer

END