

# NATIONAL DRUG AUTHORITY, UGANDA



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## **GUIDELINES ON DONATION**

### **THE NATIONAL DRUG POLICY AND AUTHORITY REGULATIONS, 1997**

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## **PART I: PRELIMINARY**

1. These regulations are made in exercise of the powers conferred on the Minister by Section 65 of the National Drug Policy and Authority Statute 1993.
2. Whereas the National Drug Policy and Authority Statute 1993 sets the policy and principles under which drugs may be imported into Uganda, and this being implemented in terms of commercial importation in both the Government and Private Sectors, there is need for specific regulations to ensure that drugs entering the country as donations also comply with the National Policy.

Donated drugs may enter as any thing from small scale private donations to individual health Units, usually in the Non-Governmental Organizations (NGO)/Mission Sector, to large scale supply of donated or subsidized drugs for major Ministry of Health Programs such as the Essential Drugs Support Program, Uganda National Expanded Program of Immunization (UNEPI), Sexually Transmitted Infections (STI) project, etc.

Both the World Health Organization (WHO) and the World Council of Churches (WCC) have published guidelines for drug donations and the National Drug Authority has held a workshop and wide consultations on the subject. These present regulations seek to formalize and legalized the requirements in the Ugandan situation.

In the line with the recommendations of both WHO and the WCC, it is recommended that donations of drugs be discouraged, a donation of money to purchase drugs from reliable local sources is preferred.

3. In these regulations, unless the context otherwise requires –

“Statute” means the National Drug Authority Policy and Authority Statute, 1993

“Authority” means the National Drug Authority

“Secretary” means the Secretary to the National Drug Authority

“Inspectorate” means the drugs inspectorate department of the National Drug Authority

**PART II: NEED FOR DONATION**

4.
  - i) All donations of drugs should be based on a specific need expressed by the receiving body or health unit.
  - ii) Needs should be expressed in terms of the range of drugs and the quantities
  - iii) The quantified need should relate to the population to be served and the type of health unit(s) to receive the drugs.
  - iv) Drugs donated to districts must be assessed and justified by the District Medical Officer.

**PART III: ALLOWABLE DRUGS**

5. Donated drugs should be contained in the current edition of the Essential Drugs List of Uganda (EDLU) or in the current edition of the Uganda National Formulary (UNF) or its provisional lists.
6. In exceptional circumstances and to meet specialized needs, drugs not contained in the EDLU or UNF may be allowed for donation provided that:  
  
They are supplied for use by an individual patient or specialized department of a health institution.  
  
They have not at any time been rejected for registration in Uganda.
7. All drugs to be donated must follow the procedure for Verification of Drug Imports set by the National Drug Authority. Any drug, which arrives at a customs port of entry without prior verification, is liable to rejection and return to its source at the expense of the donor or recipient.

**PART IV: QUALITY AND SHELF LIFE**

8. The presentation, strength and formulation of donated drugs should, as far as possible, be similar to those commonly in use in Uganda.
9. No drugs should be donated which have been given to patients and returned to a pharmacy, clinic, etc or given as medial samples to a doctor, pharmacist or other practitioner.
10. All donated drugs should have a remaining shelf life of at least one year after arrival in the country. The only exception to this is in the case of vaccines or other biological products which should have at least three quarters of their stated shelf life remaining on arrival.

## **PART V: PRESENTATION, LABELING AND PACKING**

11. As far as possible all donated drugs should be presented in large size packs or hospital packs, which should be un-opened.
1. All drugs should be labeled in the English language. In case of drugs for which the original label is in a language other than English the container must bear a permanently fixed translation into English without covering or erasing the original label.

The label should bear the following minimum information:

- Name and address of the manufacturer
- Generic name of the drug (INN), its dosage form and strength
- Date of manufacture and/or batch or lot number
- Date of expiry
- Storage conditions

All drugs should be accompanied by prescriber's information in English.

2. All donated drugs should be packed in strong outer cartons, which should be numbered if there is more than one. They must be accompanied by a detailed packing list, which should specify the contents of each numbered carton with the generic name(s), batch number and expiry date(s) and their quantities.

Drugs and their relevant documents must be packed separately from non-drug items.

## **PART VI: MISCELLANEOUS**

14. All costs of international and national transport should be borne by the donor as should customs warehousing and storage, clearing and other ancillary charges unless clearly agreed in advance between the donor and the recipient.
15. The recipient of the donation shall be considered to be the consignee whose name appears on the verification certificate issued by NDA.

The recipient shall make returns to the NDA showing how the drugs have been distributed and used.

Where the recipient is not the end user or health unit, the end user should make the returns through the recipient.

Responsibility for accountability for the use of the drugs in the health unit lies with the registered pharmacist, medical officer, dentist, veterinary surgeon or other responsible person authorized by the recipient.

16. Any transfer or re-export of donated drugs from Uganda must be sanctioned by the Nation Drug Authority.

Any donated drugs rejected by NDA due to non-compliance with these regulations shall be returned to the donor at the expense of the donor or the consignee.