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GUIDELINES FOR IMPORTATION AND EXPORT OF PHARMACEUTICALS

REQUIREMENTS

These guidelines have been drawn in accordance with part V –CONTROL OF TRANSPORTATION, IMPORT AND EXPORT OF DRUGS, sections 43,44,45,and 46 of NDP/A Act CAP 206.

- All drugs to be imported must be registered unless given special clearance by National Drug Authority under section 8(4) of NDPA Act.
- All importers must have a valid import permit issued by NDA. The import permit may be:

a. Annual- which is issued for regular importers like – retail pharmacies, wholesale pharmacies, pharmaceutical manufacturers or any organisation that regularly imports drugs and other related substances. Ministry of Health of Uganda and its affiliated units may also apply for an annual import permit.

b. Provisional import permits which is issued to non-regular importers who may import drugs, for some reason. The provisional import permit is issued per consignment of the items mentioned above. This usually applies to organisations, which receive donations, physicians or individuals who may for specified reasons need to bring limited quantities of specialised drugs that are not available in the country. The permit is valid for one month.

PROCEDURES FOR IMPORTATION

1. An original proforma invoice for the consignment of drugs to be imported is present to NDA accounts department for assessment of proforma verification fees.
2. After the assessment, the intended importer/client is given a bank slip, to go and pay the verification fees in the bank. Depending on the mode of payment, the client is given a bank slip in a quadruple, for cash payments and triplicate, for payments by cheque.
3. After payment of the verification fees, the bank slip is presented to the accounts department for acknowledgement.
4. The accounts department writes a receipt in triplicate. Two copies are given to the client, and one copy remains in the book. The client attaches the green copy to the proforma invoice to be submitted to NDA, and the white copy is retained by the applicant.
5. An original proforma invoice for the consignment of drugs to be imported is submitted to NDA together with application for verification and the receipt of verification fees. These must be submitted in triplicate (proforma invoice).
6. Normally Performa invoice verification takes 5 working days.

   Note: The proforma invoice must be endorsed by the pharmacist in-charge from the importing institution or any other technical person in case the items to be imported are drug related substances. Local technical representative should also endorse on the proforma invoice if the drugs are registered.
7. A verification certificate corresponding to the drugs to be imported is issued by NDA. This is a go ahead that the items specified on the verified proforma invoice **can now be shipped or airlifted**. It is an offence to import drugs before a verification certificate has been issued by NDA. The certificate is valid for 12 months. The verification certificate is issued in accordance with the statutory instruments 1995 No.4 of the NDP/A ACT (issue of licences) Regulations, 1995 section 24.
8. On arrival at the ports of entry, the drugs will be inspected by an NDA inspector to ensure that they comply with the approved specifications and regulations before they are released. Each batch must be accompanied by a corresponding certificate of analysis.

9. During the process of inspection and release of the consignment, the inspector may carry out **Sampling** and even pick drug samples for further investigations. Unless the samples picked from the consignment are used in chemical analysis, the inspector is expected to return them to the imported or his/ her representative.
10. Investigations or consultations may take some time before they are concluded, especially where it involves chemical analysis of the products in the consignment. Where such cases arise, a conditional release is given to the importer with instruction to store the consignment in approved premises until results of the investigations are out.
11. It is important to note that chemical analysis normally takes a period of 2 weeks from the time a consignment is sampled to when the results are released. The time mentioned above applies only if the chemical analysis is to be done in Uganda. Where analysis is to be carried outside Uganda, a longer period may be required.
12. Official entry points for drugs are: Entebbe, Busia, Malaba and Kampala (ICDs and Railways). All drug consignment in buses and unsealed vehicles not moving under URA convoy escort must be inspected at Busia/Malaba.
13. On inspection of the consignment:
    i. An authorisation or clearance may be given.
    ii. A query may arise whereby the consignment may be held pending further investigations.
    iii. An outright rejection of the consignment pending re-export or destruction at owners' expense may be issued.

RE-EXPORT OF REJECTED CONSIGNMENTS

1. Drugs rejected for quality reasons must be re-exported to the supplier in the country of export within a stipulated period of one month after receiving a rejection report.
2. Drugs rejected because for being unregistered in Uganda or neutral labelling may be re-exported to a third country on special request with special clearance from the authorities of the importing country.

RE-EXPORT PROCEDURE

1. Application for verification is lodged in by intending exporter, accompanied by the relevant invoice and documents related to the rejection indicating also the exact point of destination.
2. Re-inspection is carried out by an inspector of drugs to confirm that the consignment is still intact, before a provisional re-export permit is issued by NDA on payment of the appropriate fee.
3. A customs or NDA official must witness loading for re-export.
4. Copies of the re-export documents stamped at exit ports must be submitted to NDA as proof of RE-EXPORT.

REGULAR EXPORT OF DRUGS

This can only be done by licensed pharmacies or manufacturers of drugs in accordance with section 45 of NDP/A Act Cap 2006. Where the exporter has no annual export permit a provisional export permit is issued pre consignment after:-

I. Presentation of the following;

   a) Order from importer
   b) Copy of the authority given to importer by competent authority in country of import
   c) 3 copies of a proforma invoice prepared by exporter showing batch numbers, registration status of the products to be exported and quantities of drugs to be exported.
   d) Application for both a provisional export permit, where applicable, and verification certificate.

II. Payment of the appropriate fees.

III. NDA may from time to time decide which consignment is to be inspected before re-export.

Fees

- Annual import permit……300,000/=
- Provisional import/export permit……100,000/=
- A booklet of applications for verification……8,000/=
- Verification fees……2% FOB value

The word drug in these guidelines refers to all human and veterinary medicines, syringes, medical sundries, laboratory reagents and other diagnostic equipments.

These guidelines also apply in the importation of public health chemicals, condoms, mosquito nets and any other substance as the authority may deem necessary.