STATUTORY INSTRUMENTS
SUPPLEMENT No. 8 **28th March, 2014**

STATUTORY INSTRUMENTS SUPPLEMENT

to The Uganda Gazette No. 18 Volume CVII dated 28th March, 2014

Printed by UPPC, Entebbe, by Order of the Government.

S T A T U T O R Y I N S T R U M E N T S

2014 No. 34.

THE NATIONAL DRUG POLICY AND AUTHORITY (IMPORTATION AND EXPORTATION OF DRUGS) REGULATIONS, 2014

ARRANGEMENT OF REGULATIONS

Regulation

Regulation

S T A T U T O R Y I N S T R U M E N T S

2014 No. 34.

The National Drug Policy And Authority (Importation And Exportation of Drugs) Regulations, 2014.

(Made under sections 44, 45, 46 and 64 of the National Drug Policy and Authority Act, Cap 206)

IN EXERCISE of the powers conferred upon the Minister responsible for health by regulation 64 of the National Drug Policy and Authority Act, and on the advice of the National Drug Authority, these Regulations are made this 24th day of March, 2014.

PART I—PRELIMINARY

1. Title.

These Regulations may be cited as the National Drug Policy and Authority (Importation and Exportation of Drugs) Regulations, 2014.

2. Interpretation.

In these Regulations, unless the context otherwise requires—

"Act" means the National Drug Policy and Authority Act;

"Authority" means the National Drug Authority;

"drug" means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes.

PART II—IMPORTATION OF DRUGS

3. Importation of drugs.

(1) A person shall not import drugs into Uganda, without an import licence issued by the Authority.

(2) An import licence shall be in the format prescribed in Form 22 in the Schedule to these Regulations.

(3) The Authority shall issue an import licence where it is satisfied that the applicant meets the criteria set out in this Part.

(4) A licence shall be valid during the calendar year in which it is issued.

(5) The Authority shall prior to issuing an import licence, ascertain that the facility from which the drugs to be imported, are manufactured, complies with the internationally accepted Good Manufacturing Practice Guidelines adopted by the Authority.

4. Application for import licence.

(1) An application for a licence to import drugs shall be made using Form 23 in the Schedule to these Regulations and shall be accompanied by the licence of the licensed person and the prescribed fees.

(2) An application for a licence to import drugs shall be made by a licensed person.

(3) An import licence may be cancelled where the licence issued to a licensed person to operate a retail or wholesale pharmacy or to manufacture drugs is cancelled by the Authority.

5. Authorisation for importation of narcotic drugs and psychotropic substances.

(1) A person shall not import narcotic drugs or psychotropic substances without a permit issued by the Authority.

(2) The permit shall be in the format prescribed in Form 24 in the Schedule to these Regulations**.**

(3) An application for permit shall be made by a person issued with an import licence under regulation 3.

(4) Where the application is made by a manufacturer of a drug, the applicant shall furnish the Authority with evidence showing that the reason for the importation of the narcotic drug or psychotropic substances is for the use of the narcotic drug or psychotropic substances as a raw material for the manufacture of a finished or intermediate drug.

(5) An applicant shall furnish the Authority with evidence showing that the narcotic drug or psychotropic substances shall be sold in accordance with the requirements of the Act.

(6) A person authorised to import a narcotic drug or psychotropic substances shall, within 30 days from the date of receipt of the drugs, make returns to the Authority and shall after the importation, hand over the permit to the Authority.

(7) The importation of narcotic drugs and psychotropic substances shall be in accordance with these Regulations.

6. Verification certificate.

(1) A consignment of drugs to be imported into Uganda shall before importation, be issued with a verification certificate which shall be in the format in Form 25 in the Schedule to these Regulations.

(2) A licensed person shall before the importation of a consignment of drugs into Uganda apply for a verification certificate using Form 26 in the Schedule to these Regulations.

(3) An application for a verification certificate, for each drug to be imported shall state—

(a) the generic name of the drug and its strength, and in the case of a drug containing more than one active ingredient, the name and strength of each active ingredient;

(b) the pharmacopoeial specification of the ingredient such as the B.P. U.S.P;

(c) the total quantity of the drug to be imported;

(d) the name of the manufacturer or supplier of the drugs;

(e) the country of origin of the drug;

(f) the proprietary name of the drug, where applicable; and

(g) the registration number of the drugs.

7. Packaging for imported drugs.

(1) The primary packaging of an imported drug shall be clearly labelled in English with the following—

(a) the trade or brand name, where appropriate;

(b) the generic name of the drug;

(c) the quantities of active ingredients in the drug;

(d) the dates of manufacture and expiry of the drug;

(e) the batch or lot number of the drug;

(f) any special conditions of storage applicable to the drug;

(g) the name and address of the manufacturer of the drug;

(h) a unique identification feature, if any; and

(i) the registration number of the drug, where applicable.

(2) The information leaflet enclosed in or accompanying the imported drug shall be in English.

(3) A drug labelled "for sale only in specified countries" shall not be imported into Uganda except where Uganda is one of the specified countries.

(4) Notwithstanding subregulation (3), the Authority may, in special circumstances, authorise the importation of drugs referred to in the subregulation into Uganda.

(5) Where the label of a drug show evidence of alteration in the label, the drug shall be deemed to be adulterated and shall not be allowed entry into Uganda or shall be returned to the manufacturer at the cost of the person who imports the drug.

(6) In subregulation (5), "evidence of alteration in the label" includes circumstances where—

(a) the entire label or a part of the label with the details such as the batch number or the date of manufacture of the drug is removed;

(b) there is evidence of removal of the original label and evidence of attaching another label or evidence of placing a label over the original label; or

(c) there is evidence of erasing or concealing the original details of the label and replacing the details with other details.

8. Container closure system.

The inner primary package of an imported drug shall be sealed in such a way that the drug is not accessible, got in contact with or tampered with without damaging the seal.

9. Verification of drugs by the Authority at port of entry.

(1) The imported drugs shall be accompanied by the certificate of analysis of the drug issued by the country of manufacture and the certificate of conformity or the test report, relating to the specific batch or lot imported.

(2) The Authority shall, on the arrival of a consignment of drugs at a port of entry into Uganda, inspect the drugs to confirm that the drugs comply with the approved specifications and that each batch is accompanied by a certificate of analysis.

10. Re-export of imported drugs not allowed into Uganda.

(1) Where the Authority does not allow imported drugs into Uganda, the importer of the drugs shall re-export the drugs to the supplier, in the country of origin of the drugs, within a period of one month of the decision by the Authority to refuse entry into Uganda.

(2) Subregulation (1) shall apply where the drugs are refused entry into Uganda for reasons other than the quality of the drug.

(3) Where the Authority refuses to allow imported drugs, due to the poor quality of the drugs, the drugs shall be destroyed by the Authority at the cost of the importer.

11. Procedure for re-export of drugs not allowed into Uganda.

(1) For the purposes of regulation 10, the person who re-exports drugs that are refused entry into Uganda, shall make an application for verification to the Authority and the application shall be accompanied by the relevant invoices and other documents related to the drugs including the exact point of destination of the drugs and the prescribed fees.

(2) The Authority shall inspect the consignment to confirm the contents.

(3) The Authority shall issue a re-export permit to the person to re-export the drugs.

(4) The Authority shall witness the loading of the drugs for re-export.

(5) The person who re-exports the drugs shall submit to the Authority a written document of re-export issued by the relevant authorities at a port of exit from Uganda, certifying that the drugs were re-exported.

PART III—IMPORTATION OF DRUGS FOR DONATION

12. Application of this Part.

This Part shall apply to drugs which are imported for donation.

13. Conditions for importation of drugs for donation.

(1) The importation of a drug for donation shall only be allowed where the recipient of the drug or the donor of the drug informs the Authority of the necessity for the drug, which shall be directly related to the disease pattern of the recipient.

(2) For the purposes of subregulation (1), the recipient of the drug or the donor, shall prior to the shipment of the drug, notify the Authority of the range and quantities of the drug to be imported, the population to be served and the particulars of the recipient of the drug.

(3) The Authority shall in writing, authorise the importation of the drug for donation and shall specify the conditions of the donation.

(4) The drug shall on arrival in Uganda, be verified by the Authority.

14. Quality assurance and shelf life of donated drugs.

(1) The drug imported for the purposes of donation shall be obtained from a source approved by the Authority.

(2) The quality of the drug imported for donation shall conform to the authorised pharmacopoeias and the presentation, strength and formulation of the drug shall as far as possible, be similar to the drug which is commonly used in Uganda.

(3) The drug imported for the purposes of donation shall have a remaining shelf life of at least one year, calculated from the date the drug is allowed entry into Uganda, at a port of entry.

(4) A vaccine and any other biological product imported for the purposes of donation shall have at least three quarters of its stated shelf life, remaining, at the time the vaccine or biological product is allowed entry into Uganda at the port of entry.

15. Labelling and packaging.

(1) The drug imported for the purposes of donation shall be delivered in the original primary and secondary containers or packages of the drug.

(2) For the avoidance of doubt, only a drug that is delivered in the original primary and secondary containers or packages and which has not been opened at the time the drug is allowed entry into Uganda, shall be allowed for the purposes of donation.

(3) The label on a primary container or package of the drug imported for donation shall be in English and where the original label on the primary container or package of the drug is not in English, the primary container or package of the drug shall bear an English translation which shall be permanently fixed to the container but which shall not cover or erase the original label.

(4) The label referred to in sub regulation (3) shall bear—

(a) the name and address of the manufacturer of the drug;

(b) the generic name of the drug (INN);

(c) the date of manufacture of the drug and the batch or lot number of the drug;

(d) the date of expiry of the drug;

(e) the conditions under which the drug is to be stored; and

(f) the dosage, form and strength of the drug.

(5) The drug for donation shall be accompanied by the information of the prescriber of the drug, which shall be in English.

(6) The drug imported for purposes of donation shall be packed in a strong tertiary container, and where there are more than one containers, the containers shall be sequentially numbered.

(7) The drug shall be accompanied by a detailed packing list, which shall specify the contents of each container by the generic name of the drug and the batch number, expiry date and the quantity of the drug.

(8) Where the drug imported for donation is imported alongside other items which are not drugs, the drug and the accompanying documents shall be packed separately from the other items.

16. Transport costs and other charges.
The person who donates the drug and the recipient of the drug shall agree, prior to the importation, on the responsibility for the costs of-

(a) the international and national transportation of the donated drug;

(b) the customs warehousing and storage; and

(c) the clearing and other ancillary activities.

17. Certificate of donation.
(1) A donor shall provide to the recipient of the drug a certificate of donation, certified by an authorised person, who shall be a person with authority to sign such a certificate on behalf of the country of origin of the donor.

(2) The certificate of donation shall indicate the conditions to be fulfilled by the recipient, if any, the name of the manufacturer of the drug, the name of the drug and its batch number, the dates of manufacture and expiry of the drug and any other condition as the authorised person may deem fit.

(3) The recipients of drug for donation shall prior to the importation of the drug, furnish the Authority with the certificate of donation issued by the donor.

18. Accountability for the use of donated drugs.
(1) A recipient of donated drug shall appoint a registered pharmacist, medical doctor, dentist or veterinary surgeon or where this is not practicable, appoint any other person to be responsible for the use of donated drug.

(2) Where the person to be appointed to be responsible for the donated drug is not a registered pharmacist, medical doctor, dentist or veterinary surgeon, the appointment shall be approved by the Authority.

(3) The recipient of donated drug shall make returns to the Authority showing how the drug is distributed and used.

(4) Where the recipient of donated drug is not a health unit or the user of the drug, the user shall, through the recipient, make the returns required under subregulation (3).

19. Prohibition of sale or transfer of drugs imported for donation.

(1) A recipient of donated drug shall not sell donated drug.

(2) A recipient shall not transfer the drug, without the written permission of the Authority.

20. Re-export of drugs imported for donation.

(1) Any drug imported for donation that does not comply with the requirements of this Part shall not be allowed entry into Uganda.

(2) Where the Authority does not allow drugs imported for donation into Uganda, the importer of the drugs shall re-export the drugs to the supplier, in the country of origin of the drugs, within a period of one month of the decision by the Authority to refuse entry into Uganda.

(3) Subregulation (2) shall apply where the drugs imported for donation are refused entry into Uganda for reasons other than the quality of the drug.

(4) Where the Authority refuses to allow drugs for donation, due to the poor quality of the drugs, the drugs shall be destroyed by the Authority at the cost of the importer.

(5) The Authority may order the destruction of drugs imported for donation which does not comply with the requirements of these Regulations at the cost of the donor and the recipient.

(6) Where the drugs imported for donation are to be re-exported, regulation 11 shall apply.

21. Exportation of drugs.

(1) A person shall not export drugs out of Uganda without a licence issued by the Authority.

(2) An export licence shall be valid for one year and shall be in the format prescribed in Form 27 in the Schedule to these Regulations.

(3) The Authority shall issue an export licence where it is satisfied that the applicant meets the criteria set out in this Part.

(4) The Authority shall prior to issuing an export licence, ascertain that the facility from which the drugs to be exported, are manufactured, complies with internationally accepted Good Manufacturing Practice Guidelines adopted by the Authority.

22. Application for an export licence.

(1) An application for a licence to export drugs shall be made using Form 28 in the Schedule to these Regulations and accompanied by the licence of the applicant to be a licensed person and the prescribed fees.

(2) An application for a licence to export drugs shall be made by a licensed person.

(3) A licence issued to a person to export drugs may be cancelled where the licence issued to that person to be licensed person under section 14 of the Act is cancelled by the Authority.

23. Verification of drugs by the Authority at port of exit.

(1) The exported drugs shall be accompanied by the certificate of registration, certificate of analysis and the certificate of conformity or the test report, relating to the specific batch or lot of drugs to be exported.

(2) The Authority shall, on the arrival of a consignment of drugs at a port of exit out of Uganda, inspect the drugs to confirm that the drugs comply with the approved specifications and that each batch is accompanied by a certificate of analysis.

24. Container closure system.
The inner primary package of a drug for export shall be sealed in such a way that the drug cannot be reached or tampered with, without damaging the seal.

PART V—MISCELLANEOUS.

25. Conditions of licences.
A licence issued under the Act and these Regulations shall indicate the conditions under which the licence is issued and shall state that the licence may be cancelled where the conditions are not fulfilled or are breached.

26. Renewal of licence.
(1) A person who wishes to renew a licence issued under these Regulations shall make an application for renewal of the licence to the Authority.

(2) An application for renewal of a licence shall be three months prior to the date of expiry of the licence.

(3) The procedure for applying for a licence under these Regulations shall be used for renewing a licence.

27. Cancellation of licence.
The Authority shall cancel a licence issued under these Regulations where the conditions of the licence are not fulfilled or are breached.

28. Approved ports of entry and exit.
Drugs shall be imported or exported through ports of entry and exit approved and Gazetted by the Authority.

29. Notification of change in ownership.
Where the ownership of the licensed person who is granted a licence under these Regulations changes, the licensed person shall notify the Authority of the change and shall submit a certified copy of the documents indicating the change.

30. Revocation of regulations 19 and 20 of S.I 206-1.

Regulations 19 and 20 of the National Drug Policy and Authority Regulations, S.I. 206-1 are revoked.

SHEDULE

FORMS

FORM 22

Regulation 3 (2)

IMPORT LICENCE FOR DRUGS

(Issued under sections 44 and 46 of the Act)

This is to certify that:
the applicant named .....
of address .....
TIN .....
is authorized to import into Uganda, in accordance with sections 44 and 46 of the Act, the following classified drugs and raw materials.
……
……
……
……
……

Conditions

1. This licence does not allow the importation of narcotic and psychotropic drugs.
2. The importation shall be through authorised Customs entry points.
3. Each consignment to be imported shall be verified prior to importation, by the Authority.
4. This permit shall be displayed at the premises for which it is issued.

Permit. No. ..../IMP/..... Date dd/mm/yyy

Fee Paid Ushs ……

This permit expires on ..... (dd/mm/yyyy)

.....
For the Authority

FORM 23

Regulations 4(1)

APPLICATION FOR IMPORT LICENCE FOR DRUGS

I hereby apply for an importation licence for drugs

1. Name of pharmacist-in-charge of the business ……

2. Name of the business for which application is made …….

3. File No.……

4. P.O. Box Number: …….. Tel: …… Fax: …….

5. This is a retail pharmacy/wholesale pharmacy/manufacturer of drugs/others (Specify)……

6. Licence Number ……... (the operating licence of the Authority)

7. I hereby apply for the issue of an importation licence for (Delete what is not applicable)
   (a) Materials and ingredients for the production of drugs
   (b) Materials and ingredients for the production of veterinary drugs
   (c) Finished drugs for human use.
   (d) Finished drugs for veterinary use.

I understand that a separate verification certificate has to be obtained for each order placed and that a consignment coming into Uganda shall be issued with an authorization certificate by the Authority, at the port of entry into Uganda.

I have read and understood the regulations relating to the importation of drugs and raw materials for the manufacture of drugs into Uganda.

Signed (pharmacist-in-charge of the business of the applicant)

…… Date …….

For NDA Use only: **APPLICATION APPROVED/REJECTED**

If rejected state reasons ……
……
……

Licence Number…… Issued on …….. *(Date)*

Signed……. *For the Authority*

SEAL/STAMP

FORM 24

Regulation 5(2)

PERMIT FOR THE IMPORTATION OF NARCOTICS AND PSYCHOTROPIC DRUGS

Import licence No. .....

I, being the person charged with the administration of the law relating to the dangerous drugs to which the International Convention on Narcotic and Psychotropic Drugs apply, hereby certify that I have authorised

.....

.....

(hereinafter called the importer) to import the drugs specified in this permit, which I am satisfied are required:

(1) *for legitimate purposes (in the case of raw opium or coca leaf), or

(2) *solely for medicinal or scientific purposes (in the case of Indian hem or drugs to which Chapter III of the International Opium Convention 1925, apply) from .....

.....

Specify the narcotic and psychotropic drugs and the quantities of the drugs authorised for importation .....

.....

.....

.....

.....

.....

This authorisation is issued subject to the following:

1. The drugs shall be imported before ..... (dd/mm/yyyy)
2. This permit is not a licence to be in possession of or to supply the drug imported.
3. This permit does not relieve the importer from compliance with any custom regulations in force for the time being relating to the importation of goods into or transhipment of goods in Uganda or any Post Office regulation for the time being in force in Uganda.
4. This permit is valid only for the import and may be revoked at any time and in that event shall be immediately surrendered.

5. The permit shall be produced for inspection when required by any duly authorised person.

6. This permit, unless sooner revoked, shall be endorsed by the custom officer and inspector of drugs at the time of importation, or, if the importation is not effected before the date specified in condition No. 1, shall immediately after the date be surrendered to the Authority.

7. The consignment shall be imported by registered parcel post addressed to .....
.....
.....

....
STAMP AND DATE *For the Authority*

ENDORSEMENT BY INSPECTOR OF DRUGS AND CUSTOMS OFFICER AT THE TIME OF IMPORTATION

I hereby certify that the person named in the permit has today imported the consignment specified in the permit * ..... under Customs entry No. ..... dated ..... or by registered parcel post or insured Box Post (Parcel No. ..... dated .....).

....
Signature of Inspector of Drugs *Signature of Customs Officer*

Name: ..... Name: .....
Title: ..... Rank: .....
Date: ..... Date: .....

*If not all the drugs for which this authorisation was granted are not imported, the Inspector of Drugs or Customs Officer shall indicate the actual amount of drugs imported.

Description of narcotic and psychotropic drugs	Amount

FORM 25

Regulation 6(1)

VERIFICATION CERTIFICATE FOR THE IMPORTATION OF DRUGS

Name of person (company or partnership) ……... T.I.N …….
Address……
Import licence No. …….....

Are the drugs registered by the Authority? YES/NO (Delete whichever is not applicable)

If "no" list the drugs that are not registered …….……
…… ……

If "no", the applicant has to apply to the Authority for registration of the drugs prior to importation.

The drugs are for: prescription only, pharmacy sale only, class C drugs, raw materials. (*delete those which do not apply*).

This certificate authorizes the above named company /partnership to import the following drugs …….....……...
.....…….. through ..... (indicate the approved entry point).

Name of supplier/exporter ……

Address ……

Date …… Signature ……
(For the Authority)

On arrival of the drugs specified in this certificate, at the specified port of entry, the consignment shall be inspected by an Inspector of Drugs in order to verify the information in this certificate and to check the quality of the drugs before clearance by the Customs. This certificate and all the other relevant documents shall be presented to the Inspector of Drugs at the port of entry into Uganda.

FORM 26

Regulation 6(2)

APPLICATION FOR A VERIFICATION CERTIFICATE FOR THE IMPORTATION OF DRUGS

A. Details of the applicant

(**delete as appropriate*)

1. Name of company ……
2. P.O Box ……4. Tel:.....
3. Physical address……
5. Fax:……
6. Email:……
7. Import Licence No..... 9. TIN:……..

B. Details of the drugs (Note: Standard means pharmacopoeial standard, e.g. BP, BPC, USP, Ph Eur, etc.)

Generic name	*Proprietary Name*	*Strength*	*Standard*	*Reg. No*	*Pack size*	*No. of packs*	*Manufacturer (name and site)*	*Supplier*	*Country of manufacture*

Name of pharmacist in charge of the business .....

Signature:…….. *Date:*……..

FORM 27

Regulation 21(2)

EXPORT LICENCE FOR DRUGS

(Issued under sections 44 and 45 of the Act)

This is to certify that the applicant named .....
of address .....
TIN .....
is authorized to export from Uganda, in accordance with sections 45 and 46 of the Act, the following classified drugs and raw materials.

……
……
……
……
……

Conditions

1. This licence does not authorise the exportation of narcotic and psychotropic drugs.

2. This licence is valid only for exportation through authorised Customs exit points.

3. Each consignment to be exported shall, prior to exportation be verified by the Authority.

4. This permit shall be displayed at the premises for which it is issued.

Permit. No. 000/EXP/YEAR Date: *dd/mm/yyyy*

Fee Paid Ushs

This permit expires on ..... *(dd/mm/yyyy).*

……
For the Authority

Form 28

Regulation 22 (1)

APPLICATION FOR EXPORT LICENCE FOR DRUGS

I hereby apply for an export licence for drugs

1. Name of pharmacist-in-charge of the business
……...

2. Name of the business for which application is made ……
……

3. File No. ……

4. P.O Box Number: ……. Tel: ……. Fax: ……..

5. This is a retail pharmacy/wholesale pharmacy/manufacturer of drugs

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For NDA Use only: **APPLICATION APPROVED/REJECTED**

If rejected state reasons
……
Licence Number……. Issued on ……. (Date)

Signed…….
For the Authority SEAL/STAMP

6. Manufacturer of drugs /others (Specify)
……

7. Licence Number …… *(Operating licence of the Authority)*

8. I hereby apply for an exportation licence for (Delete what is not applicable)
   (a) Materials and ingredients for the production of human drugs
   (b) Materials and ingredients for the production of veterinary drugs
   (c) Finished drugs for human use.
   (d) Finished drugs for veterinary use.

I have read and understood the regulations relating to the exportation of drugs.
Signed (pharmacist-in-charge of the business) …… Date ……

RUHAKANA RUGUNDA (DR.)
Minister of Health.