E/NL.2005/30-31
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English only

UNITED NATIONS

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative text / texts

UGANDA

Communicated by the Government of Uganda

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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STATUTORY INSTRUMENTS

1995 Nº 3

The National Drug Policy and Authority (Certificate of suitability of Premises) Regulations, 1995

(Under section 65 of the National Drug Policy and Authority Statute, 1993)

Statute Nº 13 of 1993

IN EXERCISE of the powers conferred on the Minister responsible for health under section 65 of the National Drugs Policy and Authority Statute, 1994[1] these regulations are made this 1st day of January, 1995.

PART I-PRELIMINARY

Citation

1. These Regulations may be cited as the National Drug Policy and Authority (Certificate of Suitability of premises) Regulations, 1995.

Interpretation

2. In these regulations unless the context otherwise requires-

"Statute" means the National Drug Policy and Authority Statute, 1993.

and any word used shall have the same meaning as is assigned to it in the Statute.

Suitability of premises

3. Any Standards of Suitability of premises provided by these regulations shall be regarded as the minimum standards of Suitability of premises required under the law.

PART II-PREMISES FOR PHARMACEUTICAL MANUFACTURING

Location of premises

4. Premises shall be located in a place where they cannot be contaminated from the external environment or other nearby activities.

Standards of Construction

5. Premises shall be constructed in a such a way that-

(a) they are of a permanent nature;

(b) they are protected against adverse weather conditions, ground water seepage, vermin and pest infestation;

(c) they have sufficient space for the carrying out and supervision of the necessary operations;

(d) air intakes, exhausts, and associated pipe work and trucking are sited so as to avoid contamination;

(e) plumbing, electrical, ventilation and other services in manufacturing and processing areas are sited so as to create ease of cleaning and for this purpose, they shall run outside the processing and manufacturing areas and, be well sealed in place;

(f) drains are adequate in size, and provided with sufficient traps and proper ventilation;

(g) they have sufficient well marked fire exists the access to which must be kept clear at all times;

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[1] Note by the Secretariat: E/NL.1994/32

(h) they have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning;

(i) they are well lighted, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

Premises to be in good repair and decoration

6. Premises shall be maintained in a good state of repair and decoration which processes shall not while being carried out cause or tend to cause any contamination of ingredients or products.

Manufacturing and processing areas to be separate

7. Animal houses, clockrooms and any other staff areas shall be separated from processing and manufacturing areas and no food shall be brought into these areas.

Premises to be clean and tidy

8. All premises, including the external surroundings, shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

Regular water supply

9. Premises shall have a regular and sufficient supply of mains water.

Set of Plans

10. All applications for a certificate of suitability of premises shall be accompanied by a set of plans of those premises and, in the case of buildings to be constructed, plans of the buildings must be submitted to the National Drug Authority.

Storage areas

11. All materials and goods shall be stored under cover and off the floor in areas that are

(a) of sufficient space;

(b) laid out to allow clear separation of different materials and products to minimise the risk of mix-up; and

(c) secure and, access to them restricted to authorised personnel.

Materials to be protected against light

12. All materials and finished products shall be protected from light, heat and moisture and, there shall be temperature controlled storage facilities for ingredients and finished drugs which are temperature-sensitive.

Unprocessed ingredients to be stored separate

13. Un-processed ingredients must be stored separately from finished products and recalled, expired or rejected drugs shall be stored in a separate area.

Quarantine areas for goods awaiting release

14 Designated, separate or quarantine areas shall be established for materials and products awaiting release.

Containers to be cleaned

15. All containers shall be cleaned before they are stored and shall be rechecked for cleanliness before being issued out to the manufacturing areas.

Descriptive materials to be kept secure

16. Labels, other printed packaging and descriptive materials shall be stored in a secure manner with access to them restricted to authorised personnel and, proper records of their issue shall be kept in order to avoid any mix-up.

Standard of Equipment

17. Equipment shall be designed and located to fit the pupose for which it is to be used and shall be maintained in a good mechanical, electrical and clean condition as per a regular Servicing Schedule and written cleaning procedures.

Maintenance of Equipment in good condition

18. Equipment shall be free of any leaking joints, lubricants, electrical faults or any other faults that may prove a hazard to staff or products.

Fire-Fighting equipment

19. Premises shall have sufficient fire-fighting equipment which shall at all times be in good condition and be accessible.

First Aid box. Cap. 198

20. Premises shall have a First Aid box complying with the specifications contained in the Factories Act.

Weighing etc. equipment to be checked

21. Any Equipment used for weighing, measuring, testing and recording shall be subject to recorded checks for accuracy as per a regular Set Schedule.

Fee for applications

22 All applications for a certificate of suitability of premises shall be accompanied with an appropriate fee.

PART III-PREMISES FOR A WHOLE SALE PHARMACY

Regulations applicable

23. Regulations 5, (a), (b), (c), (h), (i), 6, 10, 12,13, 22 in Part II shall apply to this part of the Regulations.

At least one Ttoilet not to be shared

24. Premises shall have at least one toilet not shared with any other premises and it shall be well ventilated, not directly open to any storage area and shall be fitted with a hand-basin.

Pharmacy only drugs separated from over counter drugs

25. Pharmacy only drugs shall be separated from over the counter drugs and narcotic and psychotropic drugs shall be kept in a secure, fixed and lockable storage place.

Premises to be of sufficient space

26. Premises shall be of sufficient space so as to avoid over-crowding of customers and staff thereby promoting efficient flow of work, effective communication and supervision.

Premises to be lighted

27. Premises shall be well lighted, ventilated and secure.

Drugs in dispensary to be protected against light

28. Drugs in the dispensary and storage areas shall be adequately protected from light, heat, moisture and all narcotic and psychotropic drugs shall be kept separate from all other drugs in secure, fixed and lockable places.

Dispensary not accessible to public

29. (1) The dispensary must be a separate lockable area with no access to the public, fitted with a sink with running water and, having benches and working surfaces with impervious washable tops.

(2) Prescription drugs shall be kept out of public reach and the "pharmacy only" medicines shall be within view of the dispensary.

Administrative offices to be separate

30. There shall be a separate office or administrative area for the pharmacist, where prescriptions, purchase records and other administrative records may be maintained and it shall be situated as to have a full view of the dispensary.

PART IV-PREMISES FOR A RETAIL PHARMACY

Regulations applicable

31. Regulations 5, (a), (b), (c), (h), (i), 6, 10, 12,13, 22 in Part II and regulations 24, 25, 26, 27 and 30 in Part III shall apply to this part of the Regulations.

PART V-PREMISES FOR THE SALE OF CLASS 'C' DRUGS

Regulations applicable

32. Regulations 4, 5 (h), 6, 10, 22, 26 shall apply to this part of the Regulations.

Premises to have direct access

33. Premises shall be of a permanent nature with direct access to the public.

Premises shall not be shared with similar Business

34. The premises shall not be shared with any medical clinic, veterinary surgery or any other business of a similar nature.

Premises shall be new retail pharmacies

35. Except where premises under this part of the regulations are already in existence at the commencement of these regulations, no such premises shall be located within a radius of one and half kilometres from any existing retail pharmacy.

Drugs to be protected against light

36. Drugs shall be adequately protected against light, heat and moisture.

PART VI-MISCELLANEOUS

Inspection report

37. (a) All applications for a certificate of suitability shall be in the prescribed form as set out in the Schedule and shall be accompanied with an Inspection Report of the premises to be issued by the Inspector or Assistant Inspector of Drugs.

(b) The Inspection Report shall be in the prescribed form as set out in the Schedule[2] to these Regulations.

[…]

[2] Note by the Secretariat: Schedule is not reproduced in this document and is available from the Secretariat on request

E/NL.2005/31

THE NATIONAL DRUG POLICY AND AUTHORITY (ISSUE OF LICENCES) REGULATIONS, 1995

ARRANGEMENT OF REGULATIONS

Regulation

STATUTORY INSTRUMENTS

1995 No. 4

The National Drug Policy and Authority (Issue of Licences) Regulations, 1995

(Under Section 65 of the National Drug Policy and Authority Statute, 1993)

Statute Nº 13 of 1993

IN EXERCISE of the powers conferred on the Minister by section 65 of the National Drugs Policy and Authority Statute, 1993,[1] these Regulations are made this 1st day of January, 1995.

PART I-PRELIMINARY

Citation

1. These Regulations may be cited as the National Drug Policy and Authority (Issue of Licences) Regulations, 1995.

Interpretation

2. In these regulations unless the context otherwise requires-

"Statute" means the National Drug Policy and Authority Statute, 1993.

Any words used in these Regulations shall have the same meaning as assigned to them in the Statute.

PART II-LICENCE TO SELL CLASS 'C' DRUGS

Issue of Licence

3. An applicant shall be issued with a licence to sell drugs if-

(a) the applicant holds a certificate of suitability of premises issued by the Registrar of the National Drug Authority;

(b) the applicant has not been previously convicted of an offence involving wrongful or illegal dealing in, supply and or possession of drugs;

(c) the applicant is recommended by a member of the Local Authority or a prominent member of the local community; and

(d) he pays the prescribed fees.

Licence to sell only Class 'C' drugs

4. (1) A licensed seller holding a valid licence issued under section 16 of the Statute shall not sell any classified or restricted drugs except Class 'C' licensed drugs as in Schedule 3 to the Statute.

(2) Any person who fails to comply with the provisions of paragraph (1) of this regulation commits an offence.

Persons engaged in business to hold relevant pharmaceutical qualifications

5. (1) Every person engaged in the business of selling drugs or at least one person in his employment shall hold a qualification in a relevant pharmaceutical, medical, veterinary nursing or other paramedical field approved by the National Drug Authority.

Material necessary for the business

(2) Every shop where Class 'C' drugs are sold shall-

(a) keep and use suitable containers and labels;

(b) ensure that the containers in which the drugs are kept are safe and in usable condition;

(c) keep records of all drugs procured by the seller;

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[1] Note by the Secretariat: E/NL.1994/32

(d) keep a copy of the National Drug Policy and Authority Statute, 1993 and any statutory instruments made thereunder; and

(e) comply with any other requirements as may be specified from time to time by the National Drug Authority.

Preservation of records

6. (1) The records referred to in paragraph (c), sub-regulation (1) of regulation 5 shall include-

(a) source of supply of the drugs;

(b) date of purchase;

(c) name and quantity of the medicine;

(d) Batch Number and expiry date.

(2) The records shall be retained for a minimum period of two years and shall be available for inspection by an Inspector of Drugs at all reasonable times.

PART III-LICENCE TO OPERATE A RETAIL PHARMACY

License to operate retail pharmacy

7. (1) No person shall be issued with a licence to operate a retail pharmacy unless he complies with the requirements in paragraphs (a), (b) and (d) of regulation 3.

(2) Every person holding a valid licence under section 15 of the Statute to operate a retail pharmacy shall ensure-

(a) that at least one of the partners is a pharmacist, resident in Uganda, if the business is carried on as a partnership;

(b) in case of a body corporate, at least one of the directors must be a pharmacist resident in Uganda.

Persons authorised to dispense prescriptions and sale of pharmacy-only medicines

8. (1) The dispensing of prescriptions and sale of pharmacy-only medicines shall be under the supervision of a named pharmacist provided that, such a pharmacist shall be an active member of the pharmaceutical society of Uganda.

(2) The pharmacy shall not dispense any prescription or sale any pharmacy-only drug when the pharmacist is not present.

(3) No prescription-only drug, is to be dispensed except in compliance with a valid prescription written by a registered Medical Practitioner, Dental Surgeon or Veterinary Surgeon.

Equipment for dispensing

9. (1) Every retail pharmacy shall keep and maintain adequate equipment for the dispensing being carried out, that is to say, there shall be sufficient. balances and weights, measures, spatulas, ointment slabs, counting trays and a refrigerator in working order.

(2) The pharmacy shall keep and use suitable dispensing containers and labels, that is to say, the containers shall be capable of keeping the dispensed drugs in a safe and useable condition.

Reference books

10. (1) The pharmacy shall keep and maintain a sufficient range of satisfactory reference books and in particular there shall be the latest or next to latest edition of the Uganda National Formulary, Martindales Extra Pharmacopocia, a recent edition of the British National Formulary, or similar, current editions of Essential Drug List for Uganda. The Uganda National Standards Treatment Guidelines, a Copy of the National Drug Policy and Authority Statute, 1993 together with any subsequent amendments and statutory instruments made thereunder.

(2) The pharmacy shall also keep a current gazetted list of Medical, Dental and Veterinary Practitioners.

Records

11. (1) A suitable and adequate prescription/patient recording system shall be maintained which shall consist of a prescription record ledger well indexed and up-to-date and may be supplemented by patient profile cards, a computerised system, or other approved recording system.

(2) Records of all stocks received, their source, batch number, expiry date and quantity received shall be maintained.

(3) All records shall be retained for a minimum of two years, and five years in the case of records of Narcotic Drugs.

(4) All records shall be available for inspection by an Inspector of Drugs at all reasonable times.

Compliance with other requirements

12. The retail pharmacy shall comply with any other requirements as may be specified by the National Authority, from time to time.

PART IV-LICENCE TO OPERATE WHOLESALE PHARMACY

Issue of licence to operate wholesale pharmacy

13. (1) No person shall be issued with a licence to operate a wholesale pharmacy unless he complies with the requirements in paragraphs (a), (b) and (d) of regulation 3.

(2) Every person holding a valid licence under section 38 of this Statute to operate a wholesale pharmacy shall-

(a) ensure that the importation and sale of pharmacy-only medicines is under the supervision of a named pharmacist who shall be an active member of the pharmaceutical society of Uganda and registered to practise in Uganda;

(b) not sell prescription-only drugs or pharmacy-only medicines when the pharmacist is not present;

(c) ensure that one of the partners is a pharmacist resident in Uganda in case the business carried on as a partnership and in the case of a body corporate, at least one of the directors must be a pharmacist resident Uganda.

Deliveries of prescription and pharmacy-only drugs

14. (1) Deliveries of prescription and pharmacy-only drugs may only be made to customers on the basis of previously placed orders.

(2) Selling from a delivery vehicle of prescription and or pharmacy-only drugs is prohibited.

Records

15. (1) Every wholesale pharmacy shall keep adequate records for prescription and pharmacy-only drugs.

(2) These records shall include-

(a) receipts, supplier, quantity, batch numbers, expiry dates, number and date of importation, verification certificate (if imported by wholesaler);

(b) in case of sales, records shall show persons to whom drugs have been supplied, the quantity supplied, batch number and expiry date.

(c) up-to-date records of stock on hand for each batch and consignment; and

(d) records of rejected and expired drugs must be kept for a minimum of five years.

Notification to Inspector of Drugs

16. The Chief Inspector of Drugs must be notified of all drugs destroyed or otherwise disposed of and methods used.

Compliance with any other requirements

17. The wholesale pharmacy shall comply with any other requirements as may be specified by the National Drug Authority from time to time.

PART V-LICENCE TO OPERATE BUSINESS OF PHARMACEUTICAL MANUFACTURE

Issue of licence to manufacture drugs

18. No person shall engage in the business of manufacturing classified drugs unless he has obtained a licence to do so.

Persons authorised to supervise pharmaceuticals manufacture

19. (1) Manufacturing process shall be carried out under the direct supervision of a registered pharmacist with the support of suitably qualified personnel such as pharmacist, pharmacy technicians and dispensers.

(2) Quality control must be under the supervision of a qualified pharmacist or chemist with the support of suitably qualified personnel such as pharmacy technicians and chemists.

Administration and staff of wholesale pharmacy

20. (1) The General Manager of the business shall not be the manager of the production or quality control functions.

(2) Neither of the persons in charge of production and quantity control should be responsible to the other.

(3) (a) all staff engaged in processing, packing and quality control shall have a pre-employment medical check-up to ensure that they do not suffer from any contagious disease which could be transmitted in the course of their work;

(b) all staff should have periodic health check-ups;

(c) records of the dates of health check-ups of individual employees must be available for inspection at all times;

(d) staff engaged in production and Packaging shall be provided with appropriate protective clothing, both for their own protection and to avoid, contamination of the products.

Records

21. (1) Every person carrying on the business of pharmaceutical manufacture shall keep records and in particular-

(a) comprehensive records must be kept of all batches of starting materials and ingredients, including source, batch numbers, expiry dates, certificates of analysis and any other relevant documents, and samples of starting materials shall be retained;

(b) records of each batch of each finished product shall include master formula and methodology check lists. Samples of each batch of finished product must be kept until six months after expiry date;

(c) other records to be kept shall be of yield reconciliation, all analytical and quality control results, supplies to customers, quantities and batch numbers supplied on specified dates;

(d) unless expressly specified, all other records must be kept for a minimum of five years and shall be available for inspection by the Inspector of Drugs at all reasonable times.

Quality control

22. (1) The functions of quality control must be independent of the manufacturing function and must be adequately staffed with properly qualified personnel.

(2) All batches of starting materials shall be tested to ensure that they comply with the prescribed standards and limits.

(3) Quality control facilities shall have the necessary equipment and reagents to carry out all prescribed tests for the product produced.

(4) Products manufactured to a set standard of a recognised pharmacopoeia or pharmaceutical codex and so labelled, all tests and standards prescribed in the relevant monograph must be carried out and the results recorded.

(5) The possibility of Cross Contamination of products during processing and parking should be minimised, and in particular, toxic or sensitising materials such as hormones, cytotoxics and antibiotics.

PARTVI- LICENCE FOR IMPORTATION OF DRUGS

Import licence

23. (1) An import licence may be granted to a holder of a licence for operating a retail, wholesale or pharmaceutical manufacturing plant to import into Uganda drugs.

(2) An import licence will be valid until the end of the calendar year in which it is issued but may be cancelled at any time if the applicant's pharmaceutical operating licence is withdrawn by the Authority for breach of any requirement specified by the National Drug Authority.

Verification certificate

24. (1) Each consignment of drugs to be imported must receive a verification certificate before importation.

Guidelines on packaging of imported drugs to be followed by inspecting agency customs and Inspector of Drugs

25. (1) The inspecting agency, customs and Inspectors of Drugs shall follow the following guidelines for imported drugs

(a) The immediate packaging of the drugs clearly labelled in English language with the following-

(i) the trade or brand name where appropriate;

(ii) clearly stated International Non-Proprietory Name (INN) (GENERIC) name;

(iii) quantities of active ingredients in the given formulation;

(iv) dates of manufacture and expiry;

(v) Batch or Lot number,

(vi) any special conditions of storage;

(vii) name and address of manufacturer;

(viii) enclosed and accompanying literature shall be in English language;

(ix) drugs labelled for sale only in specified countries must not be imported into Uganda unless it is one of the countries so specified.

(2) Pharmaceutical products with labels which show evidence of alteration will be regarded as fake or sub-standard and shall be shipped back to the manufacturer at the cost of the importer, and such alterations shall include-

(i) entire labels or parts with details such as batch numbers, dates of manufacture cut off;

(ii) evidence of labels being removed and new attached or new labels being pasted over old ones;

(iii) details being erased or painted out and replaced with new details.

Seals

26. (1) The inner. primary package should be sealed in such a way that the product cannot be reached or tampered with without damaging the Seal.

(2) The verification certificate will be issued by the Registrar of the National Drug Authority on behalf of the National Drug Authority Commission.

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

(i) the INN (generic) name of the drug and its strength and in the case of a product containing more than one active ingredient; the name and strength of each shall be stated;

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

(iii) the total quantity to be imported;

(iv) name of supplier;

(v) name of manufacturer;

(vi) country of origin;

(vii) trade or proprietory name if appropriate;

(viii) the product registration number allocated by the National Drug Authority for drugs approved for importation in Uganda .

(b) The application shall be accompanied by-

(i) a copy of the proforma invoice;

(ii) a copy of the certificate of Good Manufacturing practice issued by the drug regulatory authority of the country of origin for the manufacturer;

(iii) a copy of the Free Sale Certificate issued the Drug Regulatory Authority of the country of origin for the specified product.

(4) The requirements for Good Manufacturing practice and Free Sale Certificate may be waived for certain manufacturers at the discretion of the National Drug Authority.

(5) On receipt, the drugs shall be accompanied by certificate of analysis relating to the specific batch received, and a clean pre-shipment report of findings issued by an agency selected for that purpose.

(2) Manufacturers shall be asked to seal their packs in conformity with paragraph (1) of this regulation.

MISCELLANEOUS

Application forms

27. (1) An application for a licence under regulations 3, 7, 13, 18 and 23 of these Regulations shall be in the appropriate Form 1, 2, 3, 4 and 5 as the case may be of Schedule 1[2] to these Regulations.

(2) Any licence issued under these regulations shall remain valid until the date stated thereon.

(3) A licence issued under these regulations may be revoked or suspended any time.

[…]

[2] Note by the Secretariat: Schedule is not reproduced in this document and is available from the Secretariat on request