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

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;

(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 12 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.