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

STATUTORY INSTRUMENTS SUPPLEMENT

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

2014 No. 35.

THE NATIONAL DRUG POLICY AND AUTHORITY (LICENSING) REGULATIONS, 2014

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

2014 No. 35.

The National Drug Policy and Authority (Licensing) Regulations, 2014.

(Made under section 64 of the National Drug Policy and Authority Act, Cap 206)

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 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 (Licensing) Regulations, 2014.

2. Interpretation.

In these Regulations, unless the context otherwise requires—

"Act" means the National Drug Policy and Authority Act, Cap. 206;

"Authority" means National Drug Authority;

"licenced person" means a person licensed under section 14 of the Act;

"licensed seller" means a person licensed under section 15 of the Act.

3. Obligation to obtain a licence.

A person shall not without a licence issued by the Authority in accordance with the Act and these Regulations—

(a) operate as a licensed seller or import or export drugs; or

(b) carry on the business of manufacturing or supplying by wholesale or retail of drugs.

PART II—LICENCE TO SELL CLASS C DRUGS.

4. Application for a licence to sell Class C drugs.

(1) A person shall not sell Class C drugs without a licence issued by the Authority.

(2) An application for a licence to sell Class C drugs shall be made using Form 16 in the Schedule to these Regulations.

(3) The application referred to in sub regulation (2) shall be accompanied by a certified copy of the certificate of registration issued to the applicant or an employee of the applicant by the relevant allied health professional council, authorising the person to practice as a professional.

5. Licence to operate as a licensed seller.

The Authority shall issue to an applicant a licence to sell Class C drugs where the applicant—

(a) holds a certificate of suitability of premises issued by the Authority;

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

(c) complies with the internationally accepted Good Distribution Practice Guidelines adopted by the Authority; and

(d) pays the prescribed fees.

6. Licensed seller to sell only class C drugs.

(1) A person who is issued a licence by the Authority to operate as a licensed seller shall sell only Class C drugs specified in the Third Schedule to the Act and shall not sell any Class A or B drugs, specified in the First and Second Schedules to the Act.

(2) A licensed seller who contravenes subregulation (1) commits an offence.

7. Requirements for operating as a licensed seller

(1) A licensed seller or an employee of a licensed seller shall hold a qualification in a relevant pharmaceutical, medical, veterinary, nursing or other paramedical field, approved by the National Drug Authority.

(2) A licensed seller shall—

(a) keep the drugs in suitable containers, which shall be appropriately labelled;

(b) keep records of all drugs procured by the licensed seller; and

(c) comply with any other requirements as may be specified by the Authority.

8. Records to be kept by licensed seller.

(1) The records referred to in regulation 7(2) (b) include—

(a) the source of supply of the drugs;

(b) the date of purchase of the drugs;

(c) the name and quantity of the drug;

(d) the Dispensing Register containing the details of the patient and drug information; and

(e) the batch number and date of expiry of the drugs.

(2) The records shall be retained for a minimum of five years and shall be available for inspection by an inspector of drugs at all reasonable times.

9. Location of premises of licensed sellers.

(1) The premises of a licensed seller shall be located at a distance of at least one and a half kilometres from a retail pharmacy.

(2) Where the premises of a licensed seller who is licensed before the commencement of these Regulations do not conform to the requirements of subregulation (1), the licensed seller shall within one year from the date of commencement of these Regulations—

(a) apply for a licence to operate as a licensed person, where the licensed seller is qualified to operate as a licensed person;

(b) relocate the business to another underserved area; or

(c) operate the business of licensed seller for one year from the commencement of these Regulations and then cease operation.

(3) A licensed seller who wishes to relocate the business to another premises under subregulation (2) (b), shall obtain the authorisation of the Authority prior to the relocation.

PART III—LICENCE TO OPERATE A RETAIL PHARMACY.

10. Application for licence to operate retail pharmacy

An application for a licence to operate a retail pharmacy shall be made to the Authority using Form 17 in the Schedule to these Regulations and shall be accompanied by—

(a) where the business is to be carried on as a partnership, the partnership deed;

(b) where the business is carried on as a body corporate, the memorandum and articles of association;

(c) the certificate of suitability of premises; and

(d) evidence that the pharmacist to be in charge of the pharmacy is a director or partner respectively.

11. Licence to operate retail pharmacy.

The Authority shall issue a licence to operate a retail pharmacy where the applicant complies with the requirements of regulation 5 of these Regulations.

12. Dispensing of Class A and Class B drugs.

(1) The dispensing of Class A and Class B drugs shall be under the supervision of the pharmacist whose certificate of registration is submitted with the application under regulation 10.

(2) A pharmacy shall not dispense Class A and Class B drugs when the pharmacist is not present at the pharmacy.

(3) A Class A or Class B Group 1 drug shall not be dispensed except under a valid prescription written by a registered medical practitioner, dental surgeon or veterinary surgeon.

13. Equipment for dispensing drugs.

(1) A retail pharmacy shall keep and maintain adequate equipment for the dispensing of drugs including—

(a) sufficient balances and weights;

(b) measures;

(c) spatulas;

(d) ointment slabs;

(e) counting trays; and

(f) a refrigerator.

(2) The pharmacy shall keep and use suitable dispensing containers and labels.

14. Reference books.

(1) A pharmacy shall keep and maintain current editions of—

(a) the Uganda National Formulary;

(b) the Martindales Extra Pharmacopoeia;

(c) the Essential Drug List for Uganda;

(d) the list of pharmacists, medical, dental and veterinary practitioners registered to practice in Uganda;

(e) the Uganda National Standards Treatment Guideline;

(f) the National Drug Policy and Authority Act and the Regulations made under the Act.

(2) A retail pharmacy shall have a prescription and patient recording system which shall consist of—

(a) a well indexed and up to date prescription record;

(b) a profile of the patients, maintained using a suitable and adequate computerised or other appropriate recording system;

(c) records of the stock received, the batch number of the stock and the source of the stock; and

(d) the date of expiry of the drugs and quantity of received drugs.

(3) All records shall be retained for a minimum of five years.

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

PART IV—LICENCE TO OPERATE A WHOLESALE PHARMACY.

15. Application for licence to operate wholesale pharmacy.
An application for a licence to operate a wholesale pharmacy shall be made to the Authority using Form 18 in the Schedule to these Regulations and shall be accompanied by—

(a) where the business is to be carried on as a partnership, the partnership deed;

(b) where the business is carried on as a body corporate, the memorandum and articles of association;

(c) the certificate of suitability of premises; and

(d) a certified copy of the certificate of registration of the pharmacist to be in charge of the pharmacy.

16. Licence to operate a wholesale pharmacy.

(1) The Authority shall issue a licence to operate a wholesale pharmacy where the applicant complies with the requirements of regulation 5 of these Regulations.

(2) A licensed person who is issued a licence to carry on the business of supplying drugs by wholesale under section 37 of the Act shall import or supply by wholesale the Class A and Class B drugs only under the supervision of the pharmacist whose certificate of registration is submitted with the application under regulation 15.

(3) For avoidance of doubt, a licensed person shall not sell Class A or Class B drugs where that pharmacist is not present at the pharmacy.

17. Records of wholesale pharmacies.

(1) A wholesale pharmacy shall keep for Class A or Class B drugs the following—

(a) receipts, records of the suppliers and quantities of the drugs, the batch numbers, dates of expiry of the drugs, and date of importation and the verification certificate, where the drugs are imported;

(b) for the sales made, the persons to whom drugs are supplied, the quantity supplied, the batch number and date of expiry of the drugs; and

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

(2) The records of the drugs that are rejected or expired shall be kept for a minimum of five years.

18. Application for licence to manufacture drugs.

(1) An application for a licence to manufacture drugs shall be made using Form 19 in the Schedule to these Regulations.

(2) The application shall be accompanied by—

(a) a certified copy of the certificate of registration of the pharmacist to be in charge of the manufacturing process;

(b) a list of the drugs to be manufactured and proof of registration of the drugs;

(c) the certificates of qualification of the key personnel to be involved in the manufacturing process, as may be determined by the Authority;

(d) a certificate of compliance with the internationally accepted Good Manufacturing Practice Guidelines adopted by the Authority; and

(e) the prescribed fees.

19. Good Manufacturing Practice Guidelines

(1) The Authority shall, for the purposes of assessing the manufacturing practices of the manufacturer, adopt with the necessary modifications, internationally accepted Good Manufacturing Practice Guidelines.

(2) A manufacturer who manufactures drugs in Uganda or outside Uganda for importation into Uganda shall comply with the Good Manufacturing Practice Guidelines adopted by the Authority.

(3) The manufacturer shall, prior to manufacturing drugs or importation of drugs, as the case may be, make an application to the Authority for assessment of the facility to be used for manufacturing drugs, for compliance with Good Manufacturing Practice Guidelines.

(4) An application for assessment for compliance with Good Manufacturing Practice Guidelines shall be made using Form 20 in the Schedule to these Regulations.

(5) Where a manufacturer complies with the Good Manufacturing Practice Guidelines, the Authority shall issue to the manufacturer a certificate of compliance with Good Manufacturing Practice Guidelines in Form 21 in the Schedule to these Regulations.

20. Persons authorised to supervise the manufacture of drugs.

(1) The manufacturing process shall be carried out by a suitably qualified pharmacist.

(2) The manufacturing process shall be supervised by the pharmacist whose registration is submitted with the application in regulation 18 (2).

(3) The process of quality control and quality assurance shall be under the supervision of a registered pharmacist and shall be conducted by a team of qualified pharmacists approved by the Authority.

21. Administration of manufacturing process.

(1) A pharmacist who is in charge of the manufacturing process shall not be in charge of the quality control and quality assurance process.

(2) The pharmacist in charge of the manufacturing process and the pharmacist in charge of quality control and quality assurance shall be independent of each other.

(3) The personnel involved in the manufacturing of drugs shall undergo a medical check-up to determine that they do not suffer from any contagious disease which may be transmitted during the manufacturing process.

(4) A person issued with a licence to manufacture drugs, shall provide the personnel involved in the manufacturing process with appropriate personal protective clothing.

22. Records to be kept by manufacturer.

(1) A person who manufactures drugs shall keep—

(a) the records of the batches of the starting materials and ingredients, which shall indicate the source, batch numbers and the dates of expiry of the starting materials and ingredients and which shall include the certificates of analysis;

(b) the records of each batch of manufactured drug including the master formula, the batch manufacturing records and the batch processing records;

(c) samples of the starting materials and samples of each batch of manufactured drug, for six months after the expiry date;

(d) the analytical and quality control results, records of supplies made to the customers and records of the quantities and batch numbers supplied on specified dates; and

(e) other records relevant to the manufacturing process.

(2) Except where expressly specified, all records shall be kept for a minimum of five years and shall be available for inspection by the inspector of drugs at all reasonable times.

23. Quality control and quality assurance.

(1) The batches of the starting materials shall be tested to determine that they comply with the prescribed standards.

(2) A manufacturer shall have facilities for quality control testing with the necessary equipment and reagents for carrying out the prescribed tests for the raw materials, packaging materials, in process materials and finished products.

(3) A manufacturer may, with the approval of the Authority, use facilities outside the facilities of the manufacturer for quality control testing.

(4) For the products which are manufactured to a set standard of a recognised pharmacopoeia or pharmaceutical codex and which are so labelled, the tests and standards prescribed in the relevant monograph shall be carried out and the results recorded.

(5) The manufacturer of classified drugs shall minimise or where possible, eliminate the possibility of cross contamination of products during the manufacturing process.

PART VI—VALIDITY, RENEWAL, SUSPENSION AND REVOCATION OF LICENCES

24. Validity and conditions of licences and certificates.

(1) A licence and a certificate issued under these Regulations, as the case may be, shall, unless cancelled by the Authority, remain valid for the period stated in the licence or certificate.

(2) A licence and a certificate shall indicate the conditions under which the licence or certificate is issued and shall state that the licence or certificate may be cancelled where the conditions are not fulfilled or are breached.

25. Renewal of licence.

(1) A person who wishes to renew a licence or certificate issued under these Regulations, as the case may be, shall make an application for renewal of the licence to the Authority.

(2) An application for renewal of a licence or a certificate shall be made to the Authority, at least three months before the expiry of the licence or certificate for the local manufacturer and six months for the foreign manufacturer respectively.

(3) The requirements and procedure for renewal of a licence or certificate shall be the same as the requirements and procedure for application of the licence or certificate.

26. Suspension and revocation of licences and certificates.

(1) The Authority may suspend or revoke a licence or a certificate issued under these Regulations where—

(a) the person granted the licence or a certificate contravenes a provision of the Act or of any other applicable law or breaches a condition of the licence or certificate;

(b) the person granted the licence or certificate fails to remedy a contravention of the Act or repeats a contravention of the Act or of a condition of the licence or certificate; or

(c) the person to whom the licence or certificate is granted, as the case may be ceases to be fit to carry on the business for which the licence or certificate is granted.

PART VII—MISCELLENEOUS

27. Delivery of drugs.

(1) A delivery of drugs shall only be made to a customer on the basis of previously placed orders.

(2) A licensed person and a licensed seller shall not sell drugs from a delivery vehicle.

(3) For avoidance of doubt, hawking of drugs is prohibited.

28. Notification of change in ownership.

(1) Where there is a change in the ownership of the business, the person to whom the licence is issued under these Regulations shall, within thirty days of the change, notify the Authority.

(2) The person to whom a licence is issued under these Regulations shall submit to the Authority, a certified copy of the articles of association or partnership deed reflecting the change.

(3) Where a licensed person or a licensed seller ceases to be responsible for the business for which the licence is issued before the expiry of the licence, the licensed person or licensed seller, as the case may be, shall return the licence to the Authority.

29. Compliance with other requirements.

A licensed person and a licensed seller shall comply with any other requirements as may be specified by the Authority.

30. Display of signposts.

The premises, in respect of which a licence is issued by the Authority, shall have a conspicuous signpost indicating the name and type of business carried out at the premises.

31. Revocation of S.I 206 – 3 and regulation 16 of S.I 206-1.

(1) The National Drug Policy and Authority (Issue of Licences) Regulations, S.I 206- 3 is revoked.

(2) Regulation 16 of SI 206 - 1 is revoked.

SCHEDULE

FORMS

FORM 16

Regulations 4(2)

Application for a Licence to Sell Class C Drugs

Physical address of premises _____
P. O. Box No. _____ Tel. _____ Fax _____
Name of applicant _____
Qualifications—(pharmaceutical) _____
(Other) _____

Is the application made for—

(a) an individual _____
(b) a partnership _____
(c) a company _____
(tick as appropriate)

If applying on behalf of a company—
Physical address of registered office_____
P.O. Box No._____ Tel. _____ Fax _____
Name of managing director _____

If applying on behalf of a company or partnership, give the following information for all partners or directors—
Name _____
Address_____
Qualification_____

Has the applicant or any partner or director been convicted, of any offence involving the wrongful or illegal dealing or supply or possession of drugs within or outside Uganda? Yes/No

If "yes", give details _____

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of business under the Act been refused or cancelled? Yes/No

If "yes", give details _____

Does the applicant or any partner or director currently hold a licence to operate any type of business under the Act, including the business of selling class C drugs, at any other premises? Yes/No

If "yes", give details _____
Name of person to be in charge of the premises _____
Qualification/training _____

I have been informed of and understand the restrictions on the range of drugs and drugs which may be sold by a class C drug shop.

I certify that the above information is correct and apply for a licence to sell Class C drugs at the above-named premises.

Signature of applicant _____ Date _____

For Authority use:

Suitability of premises certificate checked Yes/No _____

Applicant's information checked and verified Yes/No
_____ *(signature)*

Licence to operate a class C drug shop for selling of drugs included in the Third Schedule of the Act.

Approved/not approved _____

If not approved, give reasons _____

_____ _____
_
For the Authority *Date*

FORM 17.

Regulations 10

Application For a Licence to Operate Retail Pharmacy.

Physical address of premises _____
P.O. Box No. _____ Tel. _____ Fax _____
Name of applicant _____
Qualifications—
(pharmaceutical) _____
(Other) _____

Application is made for—
a partnership _____
a company _____

If applying on behalf of a company—
Physical address of registered office_____
P.O. Box No. _____ Tel. _____ Fax _____

Name of managing director _____

If applying on behalf of a company or partnership, give the following information for all directors or partners —

Name_____

Address_____

Qualifications_____

Has the applicant or any partner or director been convicted , of any offence involving the wrongful or illegal dealing in or supply or possession of drugs within or outside Uganda? Yes/No
If "yes", give details _____

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of business under the Act, including the business of selling class C drugs, been refused or cancelled? Yes/No

If "yes", give details _____

Purposes for which premises are to be used (tick proposed activities)—
retail pharmacy _____
dispensing prescriptions _____
compounding for prescription _____
compounding for retail sale _____
packing _____
Name and registration number of pharmacist to be in charge of the premises
_____

I certify that the above information is correct and apply for a licence to operate retail pharmacy at the above-named premises.

Signature of applicant_____
Date_____

For Authority use:

Suitability of premises certificate checked Yes/No

_____ *(signature)*

Applicant's information checked and verified Yes/No _____
Licence to operate a retail pharmacy approved/not approved

If not approved, give reasons _____

_____ _____
For the Authority *Date*

FORM 18.

Regulations 15

Application for a Licence to Operate Wholesale Pharmacy.

Physical address of premises _____
P. O. Box No. _____ Tel. _____ Fax _____
Name of applicant _____
Qualifications —
(pharmaceutical) _____
(Other) _____

Is the application made for—
a partnership _____
a company _____

If applying on behalf of a company_____
Physical address of registered office_____
P. O. Box No. _____ Tel. _____ Fax _____
Name of managing director _____

If applying on behalf of a company or partnership, give the following information for all the directors or partners -

Name_____

Address_____

Qualifications_____

Has the applicant or any partner or director been convicted, of any offence involving the wrongful or illegal dealing in or supply or possession of drugs within or outside Uganda? Yes/No

If "yes", give details _____

Has any previous application by the applicant or any partner or director for a licence to operate any type of business under the Act, including the business of selling class C drugs, been refused or cancelled? Yes/No

If “yes”, give details _____

Will a retail pharmacy be operated from the same premises? Yes/No

Does the applicant or any partner or director currently hold a licence to operate any type of business under the Act, including the business of selling class C drugs, at any other premises? Yes/No

Will the licensed person import drugs from outside Uganda? Yes/No

Will the business sell human drugs/veterinary drugs/both?
Name and registration number of pharmacist to be in charge of the business
_____

I certify that the above information is correct and apply for a licence to operate a wholesale pharmacy at the above-named premises.

Signature of applicant_____
Date_____

_____ _____
For the Authority *Date*

FORM 19.

Regulation 18 (1)

Application For a Licence to Manufacture Drugs

Physical address of premises _____
P. O. Box No. _____ Tel. _____ Fax _____
Name of applicant _____
Qualifications (pharmaceutical) _____
(Other) _____

Is the application made for—
a partnership _____
a company _____

If applying on behalf of a company—

Physical address of registered office _____
P. O. Box No. _____ Tel. _____ Fax _____
Name of managing director _____

If applying on behalf of a company or partnership give the following information for all partners or directors—

Name_____

Address_____

Qualifications_____

Has the applicant or any partner or director been convicted, of any offence involving the wrongful or illegal dealing in or supply or possession of drugs within or outside Uganda? Yes/No

If "yes", give details _____

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of business under the Act been refused or cancelled? Yes/No

If "yes", give details _____

Does the applicant or any partner or director currently hold a licence to operate any type of business under the Act, including the business of selling class C drugs, at any other premises? Yes/No

If "yes", give details _____

Name and registration number of the pharmacist in charge of the manufacturing processes _____

Name and registration number of pharmacist or name of the chemist to be in charge of quality control and assurance _____

Names, qualifications and registration number of the other pharmacists employed and names of the other or chemists employed _____

I certify that the above information is correct and apply for a licence to manufacture drugs at the above-named premises.

_____ _____

Signature of applicant *Date*

For Authority use:

Suitability of premises certificated checked Yes/No

_____ *(Signature)*

Applicant's information checked and verified Yes/No

_____ *(Signature)*

Licence to manufacture drugs approved/not approved

If not approved, give reasons _____.

_____ _____

For Authority *Date*

FORM 20

Regulations 19 (4)

Application for Assessment for Compliance with Good Manufacturing Practice Guidelines

(A separate application form should be filled for each site)

1. Particulars of applicant/licence holder

   Name_____

   Physical Address_____

   Country_____Telephone_____

   Fax_____E-mail_____

2. Particulars of site to be inspected

   Name of manufacturing site_____

   Physical address (if different from number 1)

   Country_____Tel_____

   Fax_____E-mail:_____

3. Contact person at manufacturing site

   Name of contact person_____

   Tel:_____Fax:_____

   E-mail:_____

4. Type of drugs manufactured (*Tick where applicable*)

   (a) Human only (b) veterinary only (c) human & veterinary

5. Inspection type *(Please tick where applicable*)

   (a) First inspection
   (b) Routine re- inspection (previous inspection date……)
   (c) Re-inspection after failure ……....
   (d) Other (please specify)……

6. Lines to be inspected

Dosage form	*Tick where applicable*	**category*	***activities*
Tablets			
Capsules			
Injections (SVP)#			
Injections (LVP) #			
Oral liquids			
Powders for oral suspension			
Creams/Ointments/lotions			
Others (specify)			

*Category means, Beta lactam (Penicillin), Beta lactam (Cephalosporins), Non-beta lactam, Biologicals, Vaccines, Hormones, Cytotoxic products.

**Activity means any step in the manufacturing process that is conducted at the site such as the complete manufacture of dosage form, primary or secondary packaging, quality control and warehousing.

Small Volume Parenterals (SVP) refers to packs of 100ml or less and Large Volume Parenterals (LVP) are packs of more than 100ml.

7. Registration of drugs
Has the applicant applied for registration of the drugs?
Yes ☐ No ☐
If yes, list the drugs. (*Attach a separate sheet if needed*) …….

8. Inspection dates
In order to schedule an inspection, the applicant should indicate an approximate date from which the applicant may be ready for the inspection. If this date changes after the application is submitted, the applicant shall notify the Authority as soon as possible.

Approximate date when the facility is to ready for inspection ……/…../……
(For re-inspections, not more than three months after expiry of GMP validity)
The actual date of the audit will be advised to the applicant by the Authority.

Site master file
It is requested that the applicant encloses with this application form a copy of the site master file (not more than 25 pages).
Enclosed -Yes ☐ No ☐

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site or sites.

Signature of applicant……. Date……

Name of applicant……..

FORM 21

Regulation 19 (5)

Certificate of Compliance with Good Manufacturing Practice Guidelines

The National Drug Policy and Authority Act, Cap 206

Certificate No. ……

This is to certify that the drug manufacturing facility:
Name of facility _____

Physical address of facility _____
Licence number of the manufacturer _____

Has been inspected by the Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the inspection carried out _____ [dd/mm/yyyy], it is certified that the facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table 1 below.

Table 1: Approved lines

No.	*Dosage form*	*Category*	*Activities*
1.			
2.			
3.			

The responsibility for the quality of the individual batches of the drugs manufactured through this process lies with the manufacturer.

This certificate remains valid until _____ [dd/mm/yyyy]. It becomes invalid if the activities or the categories certified change or if the facility is no longer considered to be in compliance with GMP.

…….
For the Authority

RUHAKANA RUGUNDA (DR.),
Minister of Health.