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. 36.

THE NATIONAL DRUG POLICY AND AUTHORITY (CERTIFICATE OF SUITABILITY OF PREMISES) 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. 36.

The National Drug Policy and Authority (Suitability of Premises) Regulations, 2014.

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

IN EXERCISE of the powers conferred on the Minister responsible for health by section 64 of the National Drug Policy and Authority Act, Cap 206, 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 (Suitability of Premises) 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 the National Drug Authority;

"inspecting officer" means a person empowered under Part VII of the Act to enter any premises;

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

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

3. Approval of location by the Authority.
A person who wishes to apply for a certificate of suitability of premises shall, prior to the application, seek an approval of the proposed location

of the premises from the Authority.

4. Certificate of suitability of premises.

(1) A person shall not conduct the business of manufacturing, wholesale, retail of drugs or operate as a licensed seller, without a certificate of suitability of premises issued by the Authority, in respect of the premises where the business is to be conducted.

(2) The Authority shall issue a general certificate of suitability of premises, for premises to be used for manufacturing drugs and for wholesale and retail pharmacies and a limited certificate of suitability of premises, for premises to be used by a licensed seller.

5. Application for certificate of suitability of premises.

(1) A person who wishes to conduct the business of manufacturing, wholesale, retail of drugs or to operate as a licensed seller, shall make an application for a certificate of suitability of premises, in respect of the premises where the business is to be conducted.

(2) An application for a certificate of suitability of premises for premises to be used to manufacture drugs or for premises for wholesale or retail pharmacies shall be accompanied by the name and qualifications of the pharmacist who is to supervise the operations at the premises and the prescribed fees.

(3) An application for a certificate of suitability of premises shall be accompanied by—

(a) the plan of the premises; or

(b) where buildings are to be constructed, the plans of the buildings.

(4) An application for a certificate of suitability of premises shall be made using Forms 9, 10, 11 and 12, in the Schedule to these Regulations, for manufacturing of drugs, wholesale pharmacy, retail pharmacy or for operating as a licensed seller, respectively.

6. Inspection of premises.

(1) The Authority shall, prior to issuing a certificate of suitability of premises, inspect the premises to determine that the premises are

suitable for the purpose for which the certificate is to be issued.

(2) The inspecting officer who inspects premises under this Regulation shall make a report, in the format prescribed in Forms 13, 14 or 15 in the Schedule to these Regulations, for wholesale pharmacy, retail pharmacy and Class C drug shop, respectively.

7. Suitability of premises.

The standards of suitability of premises provided in Parts II, III and IV of these Regulations shall be the minimum standards of suitability of premises required under the law.

PART II—SUITABILITY OF PREMISES TO BE USED FOR THE MANUFACTURE OF DRUGS.

8. Location of premises.

The premises shall be located in a place where the premises cannot be contaminated from the external environment or other activities.

9. Standards of construction.

The premises shall—

(a) be of a permanent nature;

(b) be protected against, adverse weather conditions including dust, ground water seepage, vermin and pest infestation;

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

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

(e) have the plumbing, electrical, ventilation and other services in the manufacturing and processing areas sited in a way that creates ease of cleaning and shall for this purpose run outside the processing and manufacturing areas and be well sealed in place;

(f) have drains that are of an adequate size and that are provided

with sufficient traps and proper ventilation;

(g) have well marked fire exits and the access to the fire exists kept clear at all times;

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

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

10. Premises to be in good state of repair and decoration.

(1) The premises shall be maintained in a good state of repair and decoration.

(2) The process of maintenance and repair shall not while being carried out cause any contamination of ingredients or products.

11. Manufacturing and processing areas to be separate.

Any animal house, cloakroom and any other staff area shall be separated from the processing and manufacturing areas and food shall not be brought into the processing or manufacturing areas.

12. Premises to be clean and tidy.

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

13. Regular water supply.

The premises shall have a regular and sufficient supply of water.

14. Storage areas.

The materials and goods shall be stored under cover and off the floor in an area—

(a) that has sufficient space;

(b) that is laid out to allow clear separation of different materials

and products to minimise the risk of mixing them up;

(c) that is secure; and

(d) where access to the materials and goods is restricted to authorised personnel only.

15. Materials to be protected against light.

(1) The materials to be used in the manufacturing of drugs and the finished products shall be protected from light, heat and moisture.

(2) The ingredients and finished drugs that are temperature-sensitive shall be kept in a temperature controlled storage facility.

16. Unprocessed ingredients to be stored separately.

(1) The ingredients which are not processed shall be stored separately from finished products.

(2) The recalled, expired or rejected drugs shall be stored in a separate area in the storage facility.

17. Quarantine areas for goods awaiting release.

There shall be established designated separate or quarantine areas, for the materials and products due for release.

18. Containers to be cleaned.

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

19. Descriptive materials to be kept secure.

(1) All labels, printed packaging and descriptive materials shall—

(a) be stored in a secure manner; and

(b) be accessed by only authorised personnel.

(2) Proper records shall be kept of the labels, printed packaging and

descriptive materials issued, to avoid any mix-up.

20. Design, location and maintenance of equipment.

The equipment shall be—

(a) designed and located to fit the purpose for which it is to be used; and

(b) maintained in good mechanical, electrical and clean condition as per a regular servicing schedule and written cleaning procedures.

21. Particular maintenance requirements.

The equipment shall be free of leaking joints, lubricants, electrical faults or other faults that may prove a hazard to staff or the products.

22. Fire-fighting equipment.

The premises shall have sufficient fire-fighting equipment which shall, at all times be in good condition and accessible.

23. First-aid box.

The premises shall have a first-aid box complying with the specifications contained in the Occupational Health and Safety Act, 2006.

24. Weighing, measuring, testing and recording equipment to be checked.

The equipment used for weighing, measuring, testing and recording shall be subjected to recorded checks for accuracy in accordance with a regular set schedule.

25. Compliance with Good Manufacturing Practice Guidelines

The premises shall comply with the internationally accepted Good Manufacturing Practice Guidelines approved by the Authority.

PART III—SUITABILITY OF PREMISES FOR WHOLESALE PHARMACIES.

26. Regulations applicable to Part III.

Regulations 8, 9 (a), (b), (c), (h) and (i) and 10, 12, 15 and 16 in Part II of these Regulations apply to this Part.

27. Toilet facilities

(1) The premises shall have adequate toilet facilities, one of which shall not be shared with any other premises.

(2) The toilet facilities shall—

(a) be well ventilated;

(b) not be directly open to any storage area;

(c) be fitted with a sink; and

(d) have running water.

28. Class A and class B drugs to be separated from class C drugs.

(1) Class A and class B drugs shall be kept separate from the class C drugs.

(2) The narcotic and psychotropic drugs shall be kept in a secure, fixed and lockable storage place.

29. Premises to be of sufficient space.

(1) The premises shall have sufficient space to avoid overcrowding of customers and staff.

(2) The minimum floor area for storage of drugs shall be at least 25 square metres and the sales and administrative area shall occupy a continuous space of at least 16 square metres.

(3) The premises shall be well lit, ventilated and secure.

30. Administrative area.

There shall be a separate office or administrative area, with a full view of the sales area, for the pharmacist and the prescriptions, purchase

records and other administrative records shall be maintained in this office or area.

PART IV—SUITABILITY OF PREMISES FOR RETAIL PHARMACIES.

31. Regulations applicable to this Part.

Regulations 8, 9 (a), (b), (c), (h) and (i), and 10, 15, and 16 in Part II of these Regulations apply to this Part.

32. Premises to be of sufficient space.

(1) The premises shall have sufficient space to avoid overcrowding of customers and staff.

(2) The minimum floor area for sales and administrative shall be at least 16 square metres and the dispensing area shall occupy a continuous space of at least 4 square metres.

(3) The premises shall be well lit, ventilated and secure.

33. Drugs in dispensing area to be protected against light.

(1) The drugs in the dispensing and storage areas shall be adequately protected from light, heat and moisture.

(2) The narcotic and psychotropic drugs shall be kept separate from all other drugs and shall be kept in secure, fixed and lockable places.

34. Dispensing area not accessible to public.

(1) The dispensing area shall be a separate lockable area without access for the public and it shall have benches and working surfaces with impervious washable tops and shall be fitted with a sink with running water.

(2) The class A and class B drugs shall be within the dispensing area and shall be kept out of the reach of the public.

PART V—SUITABILITY OF PREMISES FOR SALE OF CLASS C DRUGS.

35. Regulations applicable to premises for sale of class C drugs.

Regulations 8, 9 (h), 10, 13 and 29 of these Regulations apply to this Part.

36. Premises to have direct access.

The premises shall be of a permanent nature with direct access to the public.

37. Premises shall not be shared with similar business.

The premises shall not be shared with any medical clinic, veterinary surgery or any other business.

38. Drugs to be protected against light, heat and moisture.

Class C drugs shall be adequately protected against light, heat and moisture.

39. Premises to be of sufficient space.

(1) The premises shall have sufficient space to avoid overcrowding of customers and staff.

(2) The minimum floor area of the premises shall be at least 4 square metres.

(3) The premises shall be well lit, ventilated and secure.

PART VI—MISCELLANEOUS.

40. Revocation of S.I 206 – 4.

The National Drug Policy and Authority (Certificate of Suitability of Premises) Regulations, S.I 206-4 are revoked.

SCHEDULE.

FORMS.

Form 9.

Regulation 5 (4)

Application for a Certificate of Suitability of Premises for Premises for Manufacturing Drugs.

National Drug Policy and Authority Act, Cap 206.

Full names of applicant _____
P. O. Box No. _____ Tel. _____ Fax _____email
Physical address of premises for which certificate is applied for _____
County_____
Sub county_____

If applying as representative of the applicant indicate:
Name of representative _____
Physical address of registered office _____
P.O. Box No. _____ Tel. _____ Fax _____Email_____
Plot No___ Street Name_____

The form of the drug to be manufactured on the premises (tick as appropppriate)—
Tablets _____ Capsules _____
Antibiotics _____ Injections (vials) _____
Injections (ampoules) _____ Injections (I.V. fluids) _____
Other sterile products _____ syrup/mixtures _____ creams/ointments/loti

Others (specify) _____

I certify that the above information is correct.

_____ _____

Signature of applicant *Date*

FORM 10.

Regulation 5 (4)

Application for a Certificate of Suitability of Premises for a Wholesale Pharmacy.

National Drug Policy and Authority Act, Cap 206.

Full names of applicant _____
P. O. Box No. _____ Tel. _____ Fax _____email
Physical address of premises for which certificate is applied for _____
County_____
Sub county_____

If applying as representative of the applicant indicate:
Name of representative _____
Physical address of registered office _____
P.O. Box No. _____ Tel. _____ Fax _____Email_____
Plot No_____ Street Name_____

Name and approximate distance of nearest wholesale pharmacy to the premises for which certificate is applied for _____

I certify that the above information is correct.

_____ _____

Signature of applicant *Date*

FORM 11.

Regulation 5 (4)

Application for Certificate of Suitability of Premises for a Retail Pharmacy.

National Drug Policy and Authority Act, |Cap 206.

Full names of applicant _____
P. O. Box No. _____ Tel. _____ Fax _____email
Physical address of premises for which certificate is applied for _____
County_____
Sub county_____

If applying as representative of the applicant indicate:
Name of representative _____
Physical address of registered office _____
P.O. Box No. _____ Tel. _____ Fax _____Email_____
Plot No___ Street Name_____

Name and approximate distance of nearest retail pharmacy to the premises applied for _____

Purposes for which premises are to be licensed (tick proposed activities)—

1. Retail pharmacy _____
2. Dispensing prescriptions _____
3. Compounding for prescription _____
4. Compounding for retail sale _____
5. Packing _____

I certify that the above information is correct.

_____ _____

Signature of applicant *Date*

FORM 12.

Regulation 5 (4)

Application For a Certificate of Suitability of Premises for Operating as a Licensed Seller.

National Drug Policy and Authority Act, Cap 206.

Full names of applicant _____
P. O. Box No. _____ Tel. _____ Fax _____email
Physical address of premises for which certificate is applied for _____
County_____
Sub county_____

Name and approximate distance of the premises of the nearest licensed seller to the premises for which application is made _____

Are the premises to be used for the sale of human drugs/veterinary drugs/both (delete as applicable)?

I certify that the above information is correct.

_____ _____

Signature of applicant *Date*

FORM 13.

Regulation 6 (2)

Inspection Report- Wholesale Pharmacy.

National Drug Policy and Authority Act, Cap 206.

Part A—Premises.

Name of the pharmacy _____

Physical address _____

Postal address _____

Telephone _____ Fax _____

Email_____

Street name_____

Plot no: _____

Construction and finish of the premises:

		Good	Needs attention	Poor condition
Walls:	Shop area	.....	.....	.....
	Store			
Roof/ceiling:	Shop area			
	Store			
Floor:	Shop area			
	Store			
Lighting:	Shop area			
	Store			
Ventilation:	Shop area			
	Store			

Toilet(s):

General external environment _____

Part B- Storage area.

Overall size of store _____ x _____ metres
Is the floor dry and sound? Yes/No
Is the roof/ceiling waterproof? Yes/No
Is there adequate cool/cold storage space for temperature-sensitive stocks? Yes/No
Are chemicals and ingredients kept separate from finished products? Yes/No
Are expired/returned/rejected drugs kept separate from salable stock? Yes/No
Is the shelving/racking/palleting in good condition? Yes/No
Is there sufficient security, burglar bars, etc? Yes/No

Part C- Records.

There must be records for all the drugs received and sold for the preceding two years. If the business operates a retail pharmacy from the same premises, transfers from the wholesale to the retail business must be recorded as wholesale sales.

Records maintained for imported goods (tick or Y/N)
Import licence no. _____ Supplier _____ Invoice No. _____ Quantity _____
Date received _____ Batch No(s). _____ Expiry date(s) _____

Records maintained for other receipts (tick or Y/N)
Supplier _____ Quantity _____ Invoice no. _____
Date received _____ Batch no(s). _____ Expiry date(s) _____

Records maintained for wholesale sales (tick or Y/N)
Date of supply _____ Customer _____ Quantity _____
Batch no(s). _____ Expiry date(s) _____
Countersigned by supervising pharmacist _____

Part D-Ownership and staffing.

Name of owner _____ Individual/ Partnership/Company

Professional qualification of owner/senior partner/managing director (if any)
Home or company address (if different from Part A)
P.O. Box No. _____ Tel. _____ Fax _____

Pharmacist in charge—
Name _____ Reg No. _____
Names and registration numbers of the other pharmacists employed (if any)
_____

Certificates on display:
Pharmacist's registration Y/N
Wholesale pharmacy operating licence Y/N

Part E- Operating requirements.

Cleanliness satisfactory (Yes/No)
Tidiness satisfactory (Yes/No)
Shop area
Store
Drugs protected from heat (Yes/No)

Drugs protected from light (Yes/No)
Shop area _____
Store

Comments and recommendations:

Inspection carried out by _____ on _____

FORM 14.

Regulation 6 (2)

Inspection Report- Retail Pharmacy.

National Drug and Policy Authority Act, Cap 206.

Part A- Premises.

Name of pharmacy _____

Physical address _____

Postal address _____

Telephone _____

Email_____

Name, address and approximate distance of next nearest pharmacy _____

Construction and finish of the premises:

		Good condition	Needs attention	Poor
Walls: dispensing area Store	Shop area			
Roof/ ceiling: Store	Shop area dispensing area			
Floors: Dispensary Store	Shop area			
Lighting: Dispensary Store	Shop area			
Ventilation:	Shop area			

Dispensary
Store

Toilet(s):
Dispensary sink:

Storage
shelves and cupboards:

External environment of the area:
Well maintained/dirty/contaminated

Available space, excluding fittings, counters, etc.:

Shop area	Adequate/Inadequate
Dispensary	Adequate/Inadequate
Store	Adequate/Inadequate

Part B—Ownership and staffing.

Name of owner _____
Individual/ Partnership/Company

Professional qualification of owner/senior partners/managing director (if any)

Home or company address (if different from Part A)
P.O. Box No._____ Tel. _____ Fax _____

Pharmacist in charge—
Name _____ Reg. No. _____
Names and registration numbers of other pharmacists employed (if any) _____

Other staff employed in dispensing _____

Certificate on display:
Pharmacist's registration Y/N

Pharmacy operation licence Y/N

Part C- Operating requirements.

Cleanliness satisfactory (Yes/No)

Tidiness satisfactory (Yes/No)
Shop area
Dispensary
Store
Drugs protected from heat (Yes/No)
Drugs protected from light (Yes/No)
Shop area
Dispensary
Store

Which of the following are available—

1. Martindale (recent edition)
2. Uganda National Formulary
3. B.P./B.P.C./U.S.P./B.N.F.
4. Essential Drugs List for Uganda
5. National Standard Treatment Guidelines Other reference books
6. Class A balance
7. Class B balance
8. Weights for above
9. Measuring cylinders
10. Spatulas and slab
11. Counting trays
12. Working refrigerator

Labels satisfactory (Yes/No)
Packing materials satisfactory (Yes/No)

Prescription/patient recording system in use—(briefly describe the system).
Comments and recommendations:

Inspection carried out by _____ on _____

FORM 15.

Regulation 6 (2)

Inspection Report—Licensed seller.

National Drug and Policy Authority Act, Cap 206.

Part A- Premises.

Name of the business _____

Physical address _____

Postal address _____

Telephone _____ Fax _____

Name, address and approximate distance of nearest licensed seller _____

Construction and finish of the premises:

Good	Good	Poor Condition	Needs Attention
Walls: Store	Shop area _____		
Roof: Store	Shop area _____		
Floors: Store	Shop area _____		
Lighting: Store	Shop area _____		
Ventilation: Store	Shop area _____		

Toilet(s):

Storage shelves and cupboards:

External environment of the area: Well maintained/dirty/contaminated

Available space, excluding fittings, counters, etc.:

Shop area Adequate/Inadequate
Dispensary Adequate/Inadequate
Store Adequate/Inadequate

Part B—Ownership and staffing.

Name of owner _____
Individual/ Partnership/Company
Professional qualification/training of owner/senior partner/ managing director (if any) _____

Home or company address (if different from Part A)
P.O. Box. No. _____ Tel. _____ Fax _____
Name of full time person in-charge _____
Professional qualification/training of person in-charge _____

Class C operating licence display (Yes/No)

Part C- Operating requirements.

Cleanliness satisfactory (Yes/No)
Tidiness satisfactory (Yes/No)
Shop area
Store

Drugs protected from heat (Yes/No)
Drugs protected from light (Yes/No)

Shop area
Store

National Drug Policy and Authority Act available Yes/No
Other reference books: _____

Packing materials satisfactory Yes/No
Labels satisfactory Yes/No

Comments and recommendations:

Inspection carried out by _____ on _____ Date _____

RUHAKANA RUGUNDA (DR.),
Minister of Health.