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. 31

THE NATIONAL DRUG POLICY AND AUTHORITY (FEES) REGULATIONS, 2014.

ARRANGEMENT OF REGULATIONS.

Regulation

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

2014 No. 31

The National Drug Policy And Authority (Fees) Regulations, 2014.

(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.

1. Title and commencement.

(1) These Regulations may be cited as the National Drug Policy and Authority (Fees) Regulations, 2014.

(2) These Regulations shall be deemed to have come into force on the 22nd of July, 2013.

2. Fees.

(1) The Authority shall charge the fees specified in the Schedule to these Regulations, in respect of the activities and functions specified in the Schedule.

(2) The fees paid under these Regulations to the Authority, in respect of any activity or function is non-refundable whether an application is successful or not.

(3) The prescribed fee is payable at the time of making the application to the Authority.

(4) The Authority shall not receive an application in respect of which the prescribed fee is not paid.

3. Applicant to pay fees according to location.

(1) Where in the Schedule, fees are classified according to the location of the premises for which the applicant wishes to be licensed, the applicant shall pay the fees specified for the location as may be determined by the Authority.

(2) For the avoidance of doubt, the fees classified as “municipal” are payable by applicants in a municipality or town.

4. Repeal of S.I 206-2.

The National Drug Policy and Authority (Prescriptions of Forms) Regulations is repealed.

SCHEDULE

Regulation 2

FEES

PART 1- FEES FOR REGISTRATION OF DRUGS, RETENTION, NOTIFICATION AND AMENDMENT

REGISTRATION / RETENTION/NOTIFICATION/AMENDMENTS	Fees in US $ except where indicated in Shillings
1. First registration	
(a) Registration of imported human and veterinary drugs and preparations	US $1250
(b) Registration of locally manufactured drugs by a large scale manufacturer	US $ 200
(c) Registration of locally manufactured drugs by a small scale manufacturer	150,000/=
(d) Registration of imported drugs and preparations which are repackaged in Uganda	US $ 300
2. Annual retention of registration of drugs and preparations on register	
(a) Retention of human and veterinary drugs and preparations on the register	US $500
(b) Retention of foreign herbal medicines on the register	US $250
(c) Retention of locally manufactured drugs by a large scale manufacturer	US $100
(d) Retention of locally manufactured drugs by small scale manufacturer	US $100
3. Fees for notification of registration of herbal medicine	
(a) Notification of local traditional medicine	10,000/=
(b) Notification of imported traditional medicine	US $250
4. Fees for amendment of application for registration of drugs (human and veterinary)	
(a) Major amendment of application	US$ 700
(b) Minor amendment of application	US$ 400
5. Amendment of notification for imported herbal medicine	
(a) Major amendment of notification for imported herbal medicine	US $ 350
(b) Minor amendment of notification for imported herbal medicine	US $ 200

PART 2- FEES TO BE PAID TO THE AUTHORITY IN RESPECT OF A LICENSED SELLER

ITEM	New Application for a licence			Application for renewal of licence		
	Kampala	Municipal	Rural	Kampala	Municipal	Rural
1.Inspection for suitability of premises	135,000/=	90,000/=	67,500/=	75,000/=	52,500/=	45,000/=
2.Application for a licence	120,000/=	75,000/=	45,000/=	120,000/=	75,000/=	45,000/=

PART 3- FEES FOR RETAIL PHARMACIES

(a) Within Kampala

Item for fees payment	Application for a licence		Application for renewal of licence	
	Central division	Other divisions	Central division	Other divisions
1.Inspection for suitability of premises	1,060,000/=	645,000/=	660,000/=	420,000/=
2.Application for a licence	600,000/=	300,000/=	600,000/=	375,000/=

(b) Outside Kampala

Item	Application for a licence		Application for renewal of licence	
	Municipal	Rural	Municipal	Rural
1. Inspection for suitability of premises	276,000/=	276,000/=	156,000/=	156,000/=
2.Application for a licence	120,000/=	120,000/=	120,000/=	120,000/=

PART 4- FEES FOR WHOLESALE PHARMACIES

(a) Within Kampala

Item	Application for a licence		Application for renewal of licence	
	Central division	Other divisions	Central division	Other divisions
1. Inspection for suitability of premises	1,070,000/=	652,500/=	570,000/=	352,500/=
2. Application for a licence	850,000/=	450,000/=	850,000/=	450,000/=

(b) Outside Kampala

Item	Application for a licence		Application for renewal of licence	
	Municipal	Rural	Municipal	Rural
1. Inspection for suitability of premises	282,000/=	282,000/=	162,000/=	162,000/=
2. Application for a licence	250,000/=	250,000/=	250,000/=	250,000/=

PART 5-FEES FOR A PHARMACEUTICAL MANUFACTURING LICENCE

Local manufacturers

(a) Fees for operating licences and certificate of suitability of premises

		Application for a licence		Application for renewal of licence	
	Licence Category	Application for operating licence	Certificate of Suitability of premises	Application for operating licence	Certificate of Suitability of premises
i	Licence to manufacture external preparations or oral liquid preparations	420,000/=	350,000/=	350,000/=	350,000/=
ii	Licence to manufacture external preparations and oral preparation	480,000/=	400,000/=	400,000/=	400,000/=
iii	Licence to manufacture sterile preparations, the preparations in paragraphs (i), (ii) and other types of dosage forms	700,000/-	700,000/=	600,000/=	600,000/=

iv	Approval of primary packaging for the local manufacturer	350,000/=	300,000/=	300,000/=	300,000/=
v	Approval of secondary packaging for the local manufacturer	300,000/=	250,000/=	250,000/=	250,000/=

(b) Inspection fees for the categories in paragraph (a)

1	Inspection of facilities for manufacturing drugs in paragraph (a) categories (iv) and (v)	**70,000/=**
2	Inspection of facilities for manufacturing drugs in paragraph (a) categories (i) (ii) and (iii)	**130,000/=**

(c) Re-inspection fees for the categories in paragraph (a)

1	Re-inspection of facilities for manufacturing drugs in paragraph (a) categories (iv) and (v)	**200,000/=**
2	Re- inspection of facilities manufacturing drugs in paragraph (a) categories (i), (ii) and (iii)	**500,000/=**

(d) Application to amend the conditions of manufacturing licence

1	Application to amend the conditions of manufacturing licence with site inspection for manufacturers in paragraph (a) categories (i) , (ii) and (iii)	**250,000/=**
2	Application to amend the conditions of a manufacturing licence with site inspection for manufacturers paragraph (a), categories (iv) and (v)	**150,000/=**
3	Application to amend the conditions of a manufacturing licence for all categories without inspection	**100,000/=**

PART 6- FEES FOR IMPORTATION OF DRUGS

	Description	Fees
1.	Application for a general import or export permit	300,000/=
2.	An application for limited import or export permit	100,000/=
3.	Verification fees for commercial consignments and donations to commercial organizations and Government Ministries, departments, projects, programmes and institutions	2.0% of FOB Price
4.	Verification fees for unregistered drugs from authorized and approved sources	2.0% of FOB price
5.	Verification fees for donations of up to US $ 1000, to non-profit making charitable NGOs	100,000/=
6.	Verification fees for donations of US $ 1001-5000, to non-profit making charitable NGOs	200,000/=
7.	Verification fees for donations of over US $ 5000 to non-profit charitable NGOs	300,000/=
8.	Verification for consignments for disasters, outbreaks, vaccines and raw materials	exempted
9.	Fees for a consignment of drugs imported without prior authorization by the Authority which consignment arrives at the port of entry before the product is registered; or amendments are applied for and approved	$1000

PART 7- FEES FOR ANALYSIS OF SAMPLES IN A LABARATORY

	DESCRIPTION	FEES
1.	Application for routine drug analysis of one batch of drugs in the laboratory of the Authority after registration	**$300**
2.	Application for testing of latex condoms per batch at the request of the owner or importer	**$280**
3.	Application for testing of mosquito nets per batch of up to 30, 000 nets at the request of the owner or importer	**$200**
4.	Fee for samples analyzed by the Authority in laboratories not owned by the Authority	**Cost of testing +10% surcharge**
5.	Fee for re-analysis of a sample at the request of the owner of the manufacturer or the importer	**$1000**
6	Fee for a detailed certificate of analysis at the request of the manufacturer or importer	**$100**
7	Fee for analysis of gloves	**$150**
8	Fee for analysis of more than three batches	**100,000/= per batch**

PART 8- FEES FOR INSPECTION FOR GOOD MANUFACTURING PRACTICES FOR FOREIGN MANUFACTURING PLANTS

(A) On site GMP inspection per manufacturing site

	Processes at the site	Within East Africa	Within the rest of Africa	Outside Africa (Asia/Europe/America/New Zealand/Australia)
1	Inspection of manufacturing site with all processes at one site for 5 product lines	US$3,000	US$4,000	US$6,000
2	Fee for inspection of any additional production line	$ 1000 per line		

	Fees for inspection of sites where the manufacturing process is carried out in more than one site in the country where the main site is located			
1	Inspection of warehousing of raw materials up to finished bulk product	US $1,500	US$2,000	US$3,000
2	Inspection of sites for final packaging, quality control and final release	US$1,000	US$1,500	US$2,000
3	Inspection of sites for quality control and final release	US$500	US$750	US$1,000
4	Fees for GMP documents evaluation (Desk Audits)	US $ 5000 per manufacturing site		

PART 9- FEES FOR CLINICAL TRIALS (HUMAN)

	Stage of clinical trial	**Fees in US $**
1	Application to undertake clinical trial for a registered drug	2500
2	Application to undertake clinical trial for unregistered drug	4000
3	Application to amend clinical trial application	200

PART 10 FEES FOR ECTOPARASITICIDES FIELD TRIALS

Application to conduct ectoparasiticides field trials	$ 1000

PART 11- FEES FOR CHANGES IN PARTICULARS REGISTERED WITH THE AUTHORITY

	Nature of change	Fees in Shs
1.	Application for change of name, ownership or management of a pharmacy	500,000/=
2.	Application for change of name, ownership or management of a drug shop	100,000/=
3.	Application for change of pharmacist or in-charge person during the licensing period	100,000/=
4.	Application for change in professional auxiliary staff	50,000/=
5.	Application for change of person in charge of a drug shop during licensing period	50,000/=

PART 12-FEES FOR NATIONAL DRUG AUTHORITY PUBLICATIONS

	Nature of publication	Fees in Shs
1.	Copies of the Act and Regulations made under the Act	25,000/=
2.	Purchase Order Book	25,000/=
3.	Classified Drug Book	25,000/=
4.	Delivery Book	25,000/=
5.	Drug Prescription Book	25,000/=
6.	List of licensed drug outlets	25,000/=
7.	GMP Audit Checklist	25,000/=
8.	Drug Register(Human)	25,000/=
9.	Drug Register(Veterinary)	25,000/=
10.	Application for verification of Proforma invoices- (booklet of forms)	25,000/=

PART 13- FEES FOR VETTING DRUG PROMOTIONAL MATERIALS

	Nature of task	**Fees in Shs**
1.	Screening of Promotional materials per language:	
(a)	written materials	200,000/=
(b)	audio, video and written Scripts	200,000/=
(c)	posters or bill boards on any medium including internet	200,000/=
(d)	posters on vehicles	200,000/=
(e)	T- shirts	200,000/=
(f)	Other materials including caps, wall clocks, watches, umbrellas and bags.	200,000/=

14. FEES FOR DESTRUCTION OF DRUGS

Supervision of destruction of drugs	100,000/= per hour

DR. RUHAKANA RUGUNDA,
Minister of Health.