STATUTORY INSTRUMENTS
SUPPLEMENT No. 3 **4th February, 2022**

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

2022 No. 5.

The National Drug Policy and Authority (Fees) Regulations, 2022

(*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 4th day of February, 2022.

1. Title and commencement

(1) These Regulations may be cited as the National Drug Policy and Authority (Fees) Regulations 2022.

(2) These Regulations shall come into force on 1st March, 2022.

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 are 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.

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

4. Revocation of S.I 31 of 2014.

The National Drug Policy and Authority (Fees) Regulations are revoked.

SCHEDULE

Regulation 2

FEES

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

REGISTRATION / RETENTION /NOTIFICATION/AMENDMENTS	Fees in shillings except where indicated in US $
1. First registration	
(a) Registration of imported human and veterinary drugs and preparations.	US $2,000
(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
(e) Registration of imported surgical instruments and appliances.	US$ 1,500
(f) Registration of locally manufactured surgical instruments and appliances.	US$ 200
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 drugs 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 a small scale manufacturer.	US $ 100
(e) Retention of imported surgical instruments and appliances on register.	US$200
(f) Retention of locally manufactured surgical instruments and appliances on register.	US$100

3. Notification of local herbal drugs and registration of imported herbal drugs(human and veterinary)	
(a) Notification of local herbal drugs.	50,000/=
(b) Registration of imported herbal drugs.	US $500
4. Amendment of application for registration of drugs (human and veterinary)	
(a) Major amendment of application for registration of imported drugs.	US$ 700
(b) Minor amendment of application for registration of imported drugs.	US$ 400
(c) Amendment of application for notification of imported drugs.	US$ 100
(d) Major amendment of application for registration of locally manufactured drugs.	US$ 200
(e) Minor amendment of application for registration of locally manufactured drugs.	US$ 100
(f) Amendment of application for notification of locally manufactured drugs.	US$ 50
(g) Major amendment of application for registration of imported herbal drugs.	US $ 350
(h) Minor amendment of application for registration of imported herbal drugs.	US $ 200
((i) Amendment of application for registration of imported herbal drugs.	US$ 20
(j) Major amendment of application for registration of imported surgical instruments and appliances.	US$ 500
(k) Minor amendment of application for registration of imported surgical instruments and appliances.	US$ 200
(l) Notification amendment of application for registration of imported surgical instruments and appliances.	US$ 50
5. Fees for fast track registration application	
(a) Registration of imported human and veterinary drugs and preparations.	US $ 10,000
(b) Major amendment of application for imported drugs.	US$ 2,100
(c) Minor amendment of application for imported drugs.	US$ 1,200

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

ITEM	Application for a licence			Application for renewal of licence		
	Kampala Capital City	Municipal/ City	Rural	Kampala Capital City	Municipal/ City	Rural
(a) Inspection for suitability of premises.	135,000/-	90,000/-	67,500/-	75,000/-	52,500/-	45,000/-
(b) 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 Capital City

ITEM	New Application for a licence		Application for renewal of licence	
	Central Division	Other Divisions	Central Division	Other Divisions
(i) Inspection for suitability of premises.	3,180,000/-	1,935,000/-	1,980,000/-	1,260,000/-
(ii) Application for a licence.	1,800,000/-	900,000/-	1,800,000/-	1,125,000/-

(b) Outside Kampala Capital City

ITEM	New Application for a licence		Application for renewal of licence	
	Municipal/ City	Rural	Municipal/ City	Rural
(i) Inspection for suitability of premises.	828,000/-	828,000/-	468,000/-	468,000/-
(ii) Application for a licence.	360,000/-	360,000/-	360,000/-	360,000/-

PART 4—FEES FOR WHOLESALE PHARMACIES

(a) Within Kampala Capital City

Item	Application for a licence		Application for renewal of licence	
	Central Division	Other Divisions	Central Division	Other Divisions
(i) Inspection for suitability of premises.	3,210,000/=	1,957,500/=	1,710,000/=	1,057,500/=
(ii) Application for a licence.	2,550,000/=	1,350,000/=	2,550,000/=	1,350,000/=

(iii) Inspection for suitability of premises for surgical instruments and appliances.	2,385,000/=	1,451,250/=	1,485,000/=	945,000/=
(iv) Application for licence for surgical instruments and appliance.	1,350,000/=	675,000/=	1,350,000/=	843,750/=

(b) Outside Kampala Capital City

Item	Application for a licence		Application for renewal of licence	
	Municipality/City	Areas outside Municipality/ City	Municipality/ City	Areas outside Municipality/City
(i) Inspection for suitability of premises.	846,000/-	846,000/-	486,000/-	486,000/-
(ii) Application for a licence.	750,000/-	750,000/-	750,000/-	750,000/-
(iii) Inspection for suitability of premises for surgical instruments and appliances.	621,000/=	621,000/=	351,000/=	351,000/=
(iv) Application for licence for surgical instruments and appliances.	270,000/=	270,000/=	270,000/=	270,000/=

PART 5—FEES FOR PHARMACEUTICAL MANUFACTURING LICENCE

1. Fees for licences for local manufacture and certificate of suitability of premises

No.	Licence Category	Application for a licence		Application for renewal of a licence	
		Application for licence	Application for certificate of Suitability of premises	Application for licence	Application for certificate of Suitability of premises
(a) Licence for local manufacture of drugs					
(i)	Licence to manufacture external preparations or oral liquid preparations.	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(ii)	Licence to manufacture external preparations. and oral preparations.	2,880,000/=	2,400,000/=	2,400,000/=	2,400,000/=

(iii)	Licence to manufacture sterile prepa-rations, the preparations in para- graphs (i), (ii) and other types of dosage forms.	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(iv)	Approval of the primary packaging activity for the local manufacturer.	2,100,000/=	1,800,000/=	1,800,000/=	1,800,000/=
(v)	Approval of the secondary packaging activity for the local manufacturer.	1,800,000/=	1,500,000/=	1,500,000/=	1,500,000/=
(vi)	Licence to manufacture surgical instruments and appliances.	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(b)	**Licence for manufacture of herbal drugs**				
(i)	Licence to manufacture external preparations or oral liquid preparations.	900,000/-	900,000/-	900,000/-	900,000/-
(ii)	Licence to manufacture external preparations and oral preparations.	900,000/-	900,000/-	900,000/-	900,000/-
(c)	**Licence for manufacture of herbals that comprise class B, Group I derivatives**				
(i)	Licence to manufacture external preparations or oral liquid preparations.	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=

(ii)	Licence to manufacture external preparations and oral preparations.	2,880,000/=	2,400,000/=	2,400,000/=	2,400,000/=
(d)	**Licence for manufacture of class A drugs from cannabis, papaver somniferum, Catha edulis, cocoa leaf, papaver setigerum and other narcotics.**				
(i)	Licence for manufacture of raw materials to be used to manufacture drugs.	60,000,000/=	45,000,000/=	60,000,000/=	45,000,000/=
(ii)	Licence to manufacture external or oral preparations.	30,000,000/=	24,000,000/=	30,000,000/=	24,000,000/=
(iii)	Licence to manufacture external preparations and oral preparations.	30,000,000/=	30,000,000/=	30,000,000/=	30,000,000/=
(iv)	Approval of primary or secondary packaging to be used in (i), (ii) and (iii).	60,000,000/=	45,000,000/=	60,000,000/=	45,000,000/=

2. Fees for application to amend conditions of manufacturing licence

(a)	Application to amend the conditions of manufacturing licence with site inspection for manufacturers in paragraph (a) categories (i),(ii) and (iii).	250,000/-
(b)	Application to amend the conditions of a manufacturing licence with site inspection for manufacturers paragraph (a), categories (iv) and (v).	150,000/-
(c)	Application to amend the conditions of a manufacturing licence for all categories in paragraph (a), without site inspection.	100,000/-

PART 6—FEES FOR IMPORTATION AND EXPORTATION OF DRUGS AND SURGICAL INSTRUMENTS AND APPLIANCES.

	Description	Fees
(a)	Application for a general import or export permit	300,000/=
(b)	Application for limited import or export permit	100,000/=
(c)	Verification of imported commercial consignments, donations and grants to commercial organizations and Government Ministries, departments, projects, programmes and institutions.	2.0% of FOB Price
(d)	Verification of bulk products of commercial consignments of drugs, where the drugs are imported under paragraph 3, for primary packaging as part of the local manufacturing process.	1% of FOB Price
(e)	Verification of bulk products of commercial consignments of drugs, where the drugs are imported under paragraph 3, for secondary packaging as part of the local manufacturing process.	1.5% of FOB Price
(f)	Verification fees for a consignment imported by a licensed person for wholesale or retail from a country which is not a member of the EAC where the consignment comprises the following drugs – **Drug composition** — **Dosage form of drug** i. Albendazole 400mg Tablets/ Suspension 100mg/5ml — Tablet/ Suspension ii. Amoxicillin trihydrate equivalent to Amoxicillin 125mg/5ml — Suspension iii. Amoxicillin trihydrate equivalent to Amoxicillin 250mg — Capsule iv. Ampicillin 125mg + Cloxacillin 125mg/5ml — Suspension v. Ampicillin 250mg + Cloxacillin 250mg — Capsule vi. Artemether / Lumefantrine 20/120mg — Tablet vii. Artemether/ Lumefantrine 15/90 Dry Suspension — Dry Suspension viii. Ascorbic acid (Vitamin C) 100mg — Tablet ix. Cetirizine Hydrochloride 10mg Tablets/Syrup 1mg/ml — Tablets/ Syrup x. Chloramphenicol Palmitate 125mg/5ml — Suspension	12% of FOB price

	xi. Ciprofloxacin 500mg	Tablet	
	xii. Ciprofloxacin 0.2%	Intravenous infusion	
	xiii. Cloxacillin 125mg/5ml	Suspension	
	xiv. Cloxacillin Sodium equivalent to Cloxacillin 250mg.	Capsule.	
	xv Dextrose 5%	IV fluids	
	xvi Dextrose 50% (D50)	Intravenous infusion	
	xvii Diclofenac Sodium 50mg	Tablet	
	xviii Doxycycline 100mg	Capsule	
	xix Erythromycin 125mg/5ml (as Estolate and Ethyl Succinate).	Suspension	
	xx Erythromycin 250mg	Tablet	
	xxi Hartmann's Ringer Lactate	IV fluids	
	xxii Ibuprofen 200mg Tablets / Suspension 100mg/5ml	Tablet/ Suspension	
	xxiii Loperamide 2mg	Capsule	
	xxiv Magnesium Trisilicate 250mg + Dried Aluminium Hydroxide 120mg/Gel	Tablet.	
	xxv Mannitol 20%	Intravenous infusion	
	xxvi Metronidazole 0.5%	Intravenous infusion	
	xxvii Metronidazole 200mg Tablets / Suspension 100mg/5ml	Tablet/ Suspension	
	xxviii. Sodium Chloride 0.9%	IV fluids	
	xxix. Omeprazole 20mg	Capsule	
	xxx. ORS - Each sachet contains: Glucose Andhyrous 13.5gm + Trisodium Citrate Dihydrate 2.9gm + Sodium Chloride 2.6gm + Potassium Chloride 1.5gm	Sachet-plain Sachet-orange flavour	
	xxxi. ORS + Zinc Sulphate Monhydarate 20mg Tablets 2 sachets ORS+ 10 Zinc Tablets.	Tablets/ Powder	
	xxxii. Paracetamol 500mg Tablets/Suspension 120mg/5ml	Tablet/Suspension	
	xxxiii. Quinine Sulphate 300mg Tablets/Syrup 100mg /5ml	Tablet/ Syrup	

	xxxiv. Sulfamethoxazole 200mg + Trimethoprim 40mg/5ml Suspension xxxv. Surgical Spirit Solution xxxvi Trimethoprim 80mg + Sulfamethoxazole 400mg Tablet xxxvii Zinc Sulfate monohydrate BP (54.90 mg) equivalent to 20mg elemental Zinc/Solution Supplement 10mg/5ml" Tablets/ Syrup	
(g)	Verification of bulk products of commercial consignment of drugs, where the consignment comprises of the drugs specified in paragraph 6, for primary packaging as part of the local manufacturing process.	6% of FOB Price
(h)	Verification of bulk products of commercial consignment of drugs, where the consignment comprises of the drugs specified in paragraph 6, for secondary packaging as part of the local manufacturing process.	10% of FOB Price
(i)	Verification fees for importation of donations of up to US $ 1000, to non-profit making charities and NGOs	100,000/=
(j)	Verification fees for importation of donations of US $ 1001-5000, to non-profit making charities and? NGOs	200,000/=
(k)	Verification fees for importation of donations of over US $ 5000 to non-profit charities and NGOs	300,000/=
(l)	Verification of imported consignments of unregistered drugs from authorized and approved sources.	3.0% of FOB price
(m)	Verification of imported consignments for – (a) donation for disasters, outbreaks; (b) vaccines; (c) anti-cancer drugs; and (d) pharmaceutical raw materials.	Nil
(n)	Verification of importation of surgical instruments and appliances excluding the item in paragraph 19.	2.0% of FOB price
(o)	Verification of a consignment of drugs imported without prior authorization by the Authority, where the consignment arrives at the port of entry before the product is registered; or before amendments to registration are applied for or are approved.	4.0% of FOB price
(p)	Application for annual export permit, for export of raw materials from cannabis, papaver somniferum, Catha edulis, coca leaf, papaver setigerum and other narcotics.	US $50,000

(q)	Verification of unregistered drugs imported from countries with stringent drug regulatory agencies where there are registered alternatives for the drug in Uganda.	12% of FOB
(r)	Verification fees for exportation of drugs and or surgical instruments and surgical appliances.	500,000/=
(s)	Verification of a consignment of examination and surgical gloves imported for wholesale or retail, from a country which is not a member of the EAC.	12% of FOB

PART 7—FEES FOR ANALYSIS OF SAMPLES IN LABORATORY

1. Routine analysis of samples

	Description	Fees per batch
(a)	Application for routine drug analysis in the laboratory of the Authority after registration, per batch	$ 300
(b)	Fees for re-analysis of sample at the request of owner, manufacturer or importer	$10,000

2. Laboratory examination of drugs and surgical instrument and appliance samples at client request.

	Item	Fees per batch
(a)	**Pharmaceutical analysis of drugs**	
(i)	Assay for single ingredient products	US $ 1000
(ii)	Assay for fixed dose combination (maximum of two Active pharmaceutical ingredients).	US $2,000
(iii)	Sterility + Endotoxins tests	US $1,500
(b)	**Other products**	
(i)	Condom testing per batch	US $ 350
(ii)	Glove testing per batch	US $ 250
(iii)	Surgical Instruments physical /chemical test	US $ 1,000
(iv)	Fees for analysis of medical Face masks per sample.	US $ 3,500
(v)	Analysis of mosquito nets per batch	US $ 200
(vi)	Analysis of more than three batches of pre market samples of locally manufactured products.	100,000/- per batch
(vii)	Fee for a detailed certificate of analysis at the request of the manufacturer or importer.	US $ 100
(viii)	Analysis by the Authority in laboratories not owned by the Authority	Cost of testing + 10% surcharge

3. Analysis of sample of cannabis, papaver somniferum, Catha edulis, coca leaf, papaver setigerum and other narcotics.

No.	Item	Fees per batch
(a)	Complete analysis	US $ 10,000
(b)	Microbial analysis	US $3,000
(c)	Analysis for pesticides and aflatoxins	US $5,500
(d)	Analysis for potency and other physical tests such as heavy metals, loss on drying (LOD).	US $3,000

4. Analysis of samples for foreign herbal products

No.	Item	Fees per batch
(a)	Analysis of chemical contaminants	US $ 1,050
(b)	Microbial analysis	US $700
(c)	Adulterants	US $1000

PART 8—FEES FOR INSPECTION OF FOREIGN MANUFACTURING PLANTS FOR GOOD MANUFACTURING PRACTICES.

1. Inspection of site for manufacturing drugs including imported herbal drugs, medical gloves, condoms and surgical instruments and appliances.

No.	Item	Fees for a facility within EAC	Fees for a facility within Africa, outside the EAC	Fees for a facility outside of Africa
(a)	Inspection of manufacturing site with all processes at one site for a maximum of 5 product lines for finished pharmaceutical product including biologicals.	US$5,000	US$6,000	US$ 8,000
(b)	Inspection of any additional finished pharmaceutical product line.	$1,000 per line	$1,500 per line	US$ 2,000 per line
(c)	Fast track GMP inspections	300% of the inspection fee	300% of the inspection fee	300% of the inspection fee

2. Inspection of sites where the manufacturing process is carried out at other sites within the country where the main site is located.

No.	Item	Fees for a facility within the EAC	Fees for a facility within Africa, outside the EAC	Fees for a facility outside of Africa
(a)	Inspection of warehousing of raw materials up to finished bulk product	US$1,500	US$2,000	US$3,000
(b)	Inspection of sites for final packaging, quality control and final release	$1,000	US$ 1,500	US$2,000
(c)	Inspection of sites for quality control and final release	US$1500	US$2000	US$3,000
(d)	GMP documents evaluation (desk audits)	US $ 5000 per manufacturing site	US $ 6000 per manufacturing site	US $ 7000 per manufacturing site

PART 9—FEES FOR CLINICAL TRIALS FOR HUMAN DRUGS AND VACCINES

No.	Stage of clinical trial	Fees for clinical trials for drugs except for locally manufactured herbal drugs	Fees for locally manufactured herbal drugs
(1)	Application to undertake clinical trial for a registered drug	US $ 2500	1,000,000/=
(2)	Application to undertake clinical trial for unregistered drug.	US $ 4000	1,000,000/=
(3)	Application to amend application for clinical trial.	US $ 200	100,000/=

PART 10—FEES FOR CLINICAL/ FIELD TRIALS FOR VETERINARY DRUGS AND VACCINES

1. Clinical trials or field trials for imported veterinary drugs and vaccines.

	Item	Fees
(1)	Application to conduct ectoparasiticides field trials	US $ 1000
(2)	Application for to conduct clinical trial for registered drug and or vaccine	US $ 1000
(3)	Application for to conduct clinical trial for unregistered drug and or vaccine	US $ 2000
(4)	Amendment of application	US $ 200

2. Clinical trials or field trials for local veterinary drugs and vaccines.

	Item	Fees for clinical trials or field trials for drugs except for locally manufactured herbal drugs	Fees for locally manufactured herbal drugs
(1)	Application to conduct ectoparasiticides field trials	US $ 1000	1,000,000/=
(2)	Application to conduct clinical trial for registered drug	1,500,000/=	1,000,000/=
(3)	Application to conduct clinical trial for unregistered drug	3,000,000/=	1,000,000/=
(4)	Amendment of application	300,000/=	100,000/=

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

No.	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 licensed seller	100,000/-
(3)	Application for change of pharmacist or person in –charge during the licensing period	100,000/-
(4)	Application for change in professional auxiliary staff	50,000/-
(5)	Application for change of person in charge for a licenced seller 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 (DRUGS AND SURGICAL INSTRUMENTS)

No.	Screening of promotional materials:	Fees for promotional materials, per language, excluding herbal related promotional materials.	Fees for herbal related promotional materials, per language
(1)	Written materials	200,000/=	100,000/=
(2)	Audios, videos and scripts	200,000/=	100,000/=
(3)	Posters or bill boards on any medium, including the internet	200,000/=	100,000/=
(4)	Posters on vehicles	200,000/=	100,000/=
(5)	T- shirts	200,000/=	100,000/=
(6)	Other materials including caps, wall clocks, watches, umbrellas and bags.	200,000/=	100,000/=

PART 14—FEES FOR DESTRUCTION OF DRUGS

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

HON. DR. ACENG JANE RUTH OCERO
Minister of Health.