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

2025 No. 67

The National Drug Policy and Authority (Fees) Regulations, 2025

(Under section 61 of the National Drug Policy and Authority Act, Cap. 198)

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 61 of the National Drug Policy and Authority Act, and on the advice of the National Drug Authority, these Regulations are made this 9th day of September, 2025.

1. Citation and commencement

(1) These Regulations may be cited as the National Drug Policy and Authority (Fees) Regulations 2025.

(2) These Regulations shall come into force on 1st October, 2025.

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. 5 of 2022**

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

SCHEDULE

Regulation 2

FEES

PART 1 – FEES FOR REGISTRATION AND NOTIFICATION OF DRUGS AND SURGICAL INSTRUMENTS AND APPLIANCES, RETENTION ON THE REGISTER AND AMENDMENT OF APPLICATIONS

ITEM		FEES
1.	**First registration of drugs (except herbal drugs) and surgical instruments and appliances**	
(a)	Application for registration of imported drugs	US $ 2,000
(b)	Application for registration of locally manufactured drugs by large scale manufacturer	US $ 200
(c)	Application for registration of locally manufactured drugs by small scale manufacturer	Shs 150,000/=
(d)	Application for registration of imported drugs and preparations which are repackaged in Uganda	US$ 300
(e)	Application for registration of imported surgical instruments and appliances	US$ 1,500
(f)	Application for registration of locally manufactured surgical instruments and appliances	US$ 200
(g)	Amendment of an application for registration made under subparagraph (a) to (f)	10% of the applicable fee
2.	**Annual retention of registration of drugs (except herbal drugs) and surgical instruments and appliances on Register**	
(a)	Retention of imported drugs on the Register	US$ 500
(b)	Retention of locally manufactured drugs by a large-scale manufacturer on the Register	US$ 100
(c)	Retention of locally manufactured drugs by a small-scale manufacturer on the Register	US $ 100
(d)	Reinstatement of drugs on Register	USD$ 500 for each year of suspension

(e)	Retention of imported surgical instruments and appliances on the Register	US$ 200
(f)	Retention of locally manufactured surgical instruments and appliances on the Register	US$ 100

3.	**Amendment of application for registration of drugs (except herbal drugs) and surgical instruments**	
(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)	Notification of amendment of application for 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)	Notification of amendment of application for imported drugs	US$ 50
(g)	Major amendment of application for registration of imported surgical instruments and appliances	US$ 500
(h)	Minor amendment of application for registration of imported surgical instruments and appliances	US$ 200
(i)	Notification of amendment of application for registration of imported surgical instruments and appliances	US$ 50
4.	**Fast tracking applications for registration for drugs (except herbal drugs)**	
(a)	Fast tracking registration of imported drugs	US $ 10,000
(b)	Fast tracking major amendment of application for imported drugs	US$ 2,100
(c)	Fast tracking minor amendment of application for imported drugs	US$ 1,200
(d)	Fast tracking registration of locally manufactured drugs	Shs 6,000,000

5.	**Notification of local herbal drugs and registration of imported herbal drugs**	
(a)	Application for notification of local herbal drugs.	50,000/=
(b)	Application for registration of imported herbal drugs.	US $500
(c)	Application for amendment of notification of locally manufactured herbal drugs	Shs 100,000
(d)	Major amendment of application for registration of imported herbal drugs	USD$350
(e)	Minor amendment of application for registration of imported herbal drugs	USD$ 200
(f)	Notification of changes to registration of imported herbal drugs	US$ 50
(g)	Fast tracking application under subparagraphs (d), (e) and (f)	USD$ 500
(h)	Retention of imported herbal drugs on the Register	USD$ 250

PART 2—FEES FOR LICENSED SELLERS

ITEM	Application for a licence			Application for renewal of licence		
	Kampala Capital City	Areas outside Kampala		Kampala Capital City	Areas outside Kampala	
		City/Municipality	Area outside Municipality/City		City/Municipality	Area outside Municipality/City
(a) Approval of proposed location of premises	100,000	100,000	50,000	N/A	N/A	N/A
(b) Inspection for suitability of premises	135,000/=	90,000/=	67,500/=	75,000/=	52,500/=	45,000/=
(c) Application for licence	120,000/=	75,000/=	45,000/=	120,000/=	75,000/=	45,000/=
(d) Fast tracking applications made under paragraphs (a), (b) and (c)	300% of the applicable fee					

PART 3—FEES FOR RETAIL PHARMACIES

1. Within Kampala Capital City

ITEM	Application for licence		Application for renewal of licence	
	Central division	Other divisions	Central division	Other divisions
(a) Approval of proposed location of premises	1,000,000	700,000	N/A	N/A
(b) Inspection for suitability of premises	3,180,000/=	1,935,000/=	1,980,000/=	1,260,000/=
(c) Application for licence	1,800,000/=	900,000/=	1,800,000/=	1,125,000/=
(d) Fast tracking applications made under subparagraphs (a), (b) and (c)	300% of the applicable fee			

2. Outside Kampala Capital City

ITEM	New Application for licence		Application for renewal of licence	
	Municipal/ City	Area outside Municipality/ City	Municipal/ City	Area outside Municipality/ City
(a) Approval of proposed location of premises	700,000	300,000	N/A	N/A
(b) Inspection for suitability of premises	828,000/=	828,000/=	468,000/=	468,000/=
(c) Application for licence	360,000/=	360,000/=	360,000/=	360,000/=

(d) Fast tracking applications made under subparagraphs (a), (b) and (c)	300% of the applicable fee

PART 4—FEES FOR WHOLESALE PHARMACIES AND WHOLE-SALE FOR SURGICAL INSTRUMENTS AND APPLIANCES

1. Within Kampala Capital City

Item	Application for licence		Application for renewal of licence	
	Central division	Other divisions	Central division	Other divisions
(a) Approval of proposed location of premises for wholesale pharmacies	1,000,000/=	700,000/=	N/A	N/A
(b) Inspection for suitability of premises for wholesale pharmacies	3,210,000/=	1,957,500/=	1,710,000/=	1,057,500/=
(c) Application for licence for wholesale pharmacy	2,550,000/=	1,350,000/=	2,550,000/=	1,350,000/=
(d) Inspection for suitability of premises for wholesale for surgical instruments and appliances	2,385,000/=	1,451,250/=	1,485,000/=	945,000/=
(e) Application for licence for surgical instruments and appliances	1,350,000/=	675,000/=	1,350,000/=	843,750/=

(f) Fast tracking applications made under subparagraph (a) to (e)	300% of the applicable fee

2. Outside Kampala Capital City

Item	Application for a licence		Application for renewal of licence	
	Municipality/ City	Area outside Municipality/ City	Municipality/ City	Areas outside Municipality/ City
(a) Approval of proposed location of premises	700,000	500,000	N/A	N/A
(b) Inspection for suitability of premises for pharmacies	846,000/=	846,000/=	486,000/=	486,000/=
(c) Application for licence	750,000/=	750,000/=	750,000/=	750,000/=
(d) Inspection for suitability of premises for surgical instruments and appliances	621,000/=	621,000/=	351,000/=	351,000/=

(e) Application for licence for surgical instruments and appliances	270,000/=	270,000/=	270,000/=	270,000/=
(f) Fast tracking application made under subparagraphs (a) to (e)	300% of the applicable fee			

PART 5—FEES FOR LOCAL MANUFACTURE OF DRUGS

A. Fees for licences for local manufacture of drugs and certificate for suitability of premises (except herbal drugs)

Category of licence	Fees for new licence		Fees for renewal of licence	
	Application for licence	Application for certificate for suitability of premises	Application of renewal	Application for certificate for suitability of premises
1. Fees for complete manufacture of non-sterile pharmaceutical products				
(a) -Licence to manufacture general pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(b) Licence to manufacture penicillin pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=

(c) Licence to manufacture cephalosporin pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(d) Licence to manufacture cytotoxic pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(e) Licence to manufacture ectoparasiticides pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(f) Licence to manufacture hormonal pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(g) Licence to manufacture non-sterile active pharmaceutical ingredients	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(h) Licence to manufacture excipients	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(i) Licence to manufacture radiopharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(j) Licence to manufacture medical gases	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
2. Fees for complete manufacture of sterile pharmaceutical products				
(a) Licence to manufacture general pharmaceutical products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=

(b) Licence to manufacture penicillin pharmaceutical products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(c) Licence to manufacture cephalosporin pharmaceutical products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(d) Licence to manufacture cytotoxic pharmaceutical products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(e) Licence to manufacture ectoparasiticides pharmaceutical products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(f) Licence to manufacture blood products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(g) Licence to manufacture hormonal pharmaceutical products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(h) Licence to manufacture sterile active pharmaceutical ingredients	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(i) Licence to manufacture sterile excipients	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(j) Licence to manufacture radiopharmaceutical product	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=

3. Fees for the manufacture of bulk sterile and non-sterile pharmaceutical products				
(a) Licence to manufacture active pharmaceutical ingredient	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(b) Licence to manufacture bulk products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(c) Licence to conduct quality control testing activities for bulk sterile and non-sterile pharmaceutical products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
4. Fees for the manufacture of biological products and vaccine products				
(a) Licence to manufacture biological products or vaccine products	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(b) Licence to carry out primary packaging of biological products or vaccine products	3,100,000/=	2,800,000/=	2,800,000/=	2,800,000/=
(c) Licence to carry out secondary packaging of biological products or vaccine products	2,800,000/=	2,500,000/=	2,500,000/=	2,500,000/=
(d) Licence to manufacture bulk biological products and vaccines	4,200,000/=	4,200,000/=	3,600,000/=	3,600,000/=
(e) Licence to conduct quality control testing activities for biological products and vaccine products	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=

B. Fees for the manufacture of herbal drugs				
Category of licence	**Fees for new licence**		**Fees for renewal of licence**	
	Application for licence	**Application for certificate for suitability of premises**	**Application for renewal**	**Application for certificate for suitability of premises**
(a) Licence to manufacture external preparations or oral liquid preparation	900,000/=	900,000/=	900,000/=	900,000/=
(b) Licence to manufacture external preparations and oral preparations	900,000/=	900,000/=	900,000/=	900,000/=

C. Fees for the manufacture of herbals that comprise class B, Group I derivatives				
Category of licence	**Fees for new licence**		**Fees for renewal of licence**	
	Application for licence	**Application for certificate for suitability of premises**	**Application for renewal**	**Application for certificate for suitability of premises**
(a) Licence to manufacture external preparations or oral liquid preparations	2,520,000/=	2,100,000/=	2,100,000/=	2,100,000/=
(b) Licence to manufacture external preparations and oral preparations	2,880,000/=	2,400,000/=	2,400,000/=	2,400,000/=

D. Fees for the manufacture of class A drugs from cannabis, papaver somniferum, Catha edulis, cocoa leaf, papaver setigerum and other narcotics				
Category of licence	**Fees for new licence**		**Fees for renewal of licence**	
	Application for licence	**Application for certificate for suitability of premises**	**Application for renewal**	**Application for certificate for suitability of premises**
(a) Licence to manufacture of raw materials to be used to manufacture drugs	60,000,000/=	45,000,000/=	60,000,000/=	45,000,000/=

(b) Licence to manufacture external or oral preparations	30,000,000/=	24,000,000/=	30,000,000/=	24,000,000/=
(c) Licence to manufacture external preparations and oral preparations	30,000,000/=	30,000,000/=	30,000,000/=	30,000,000/=
(d) Approval of primary or secondary packaging to be used for manufacturing under (a), (b) and (c).	60,000,000/=	45,000,000/=	60,000,000/=	45,000,000/=
E. Fees for fast tracking and amending applications under A, B, C and D				
(a) Fast tracking application	300% of applicable fees			
(b) Application for amendment of conditions of manufacturing licence (with site inspection)	250,000/=			
(c) Application for amendment of conditions of manufacturing licence (without site inspection)	100,000/=			

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

	Description	Fees
(a)	Application for general import or export permit	300,000/=
(b)	Application for limited import or export permit	100,000/=
(c)	Verification of consignment of donations and grants imported for projects and programmes of commercial organisations and Government Ministries, departments and institutions.	3.0% of FOB price
(d)	Verification of consignment of bulk products of drugs, where the drugs are imported under paragraph (c), for primary packaging as part of the local manufacturing process	2% of FOB price
(e)	Verification of consignment of bulk products of drugs, where the drugs are imported under paragraph (c), for secondary packaging as part of the local manufacturing process	2.5% of FOB price
(f)	Verification of consignment of imported drugs from a country which is not a Partner State of the East African Community where the consignment comprises of the following drugs with the specified dosage form– (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	17% of FOB price

	(xi)	Ciprofloxacin 500mg	Tablet	
	(xii)	Ciprofloxacin 0.2% infusion	Intravenous	
	(xiii)	Cloxacillin 125mg/5ml	Suspension	
	(xiv)	Cloxacillin Sodium equivalent to Cloxacillin 250mg.	Capsule.	
	(xv)	Dextrose 5%	IV fluids	
	(xvi)	Dextrose 50% (D50) infusion	Intravenous	
	(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% infusion	Intravenous	
	(xxvi)	Metronidazole 0.5% infusion	Intravenous	
	(xxvii)	Metronidazole 200mg Suspension 100mg/5ml	Tablets / 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 Supplement 10mg/5ml	Solution Tablets/ Syrup	

(g)	Verification of consignment of bulk products of drugs, where the consignment comprises of the drugs specified in paragraph (f), for primary packaging as part of the local manufacturing process	10% of FOB price
(h)	Verification of consignment of bulk products of registered drugs, where the consignments comprise of the drugs specified in paragraph (f), for secondary packaging as part of the local manufacturing process	12% of FOB price
(i)	Verification of donations of up to US $ 1000, imported for a non-profit making charity or an NGO	100,000/=
(j)	Verification of donations of US $ 1001 to US $ 5000, imported for a non-profit making charity or an NGO	200,000/=
(k)	Verification of donations of over US $ 5000 imported for a non-profit charity an NGO	300,000/=
(l)	Verification of consignment of unregistered drugs imported from authorized and approved sources	4.0% of FOB price
(m)	Verification of consignment of bulk products of registered drugs for primary packaging as part of the local manufacturing process	2% of FOB price
(n)	Verification of consignment of unregistered drugs for primary packaging as part of the local manufacturing process	12% of FOB price
(o)	Verification of consignment of unregistered drugs for primary packaging as part of the local manufacturing process	15% of FOB price
(p)	Verification of consignment – (i) imported for donation for disasters or outbreaks; (ii) of imported vaccines; (iii) of imported anti-cancer drugs; and (iv) of imported pharmaceutical raw materials	Nil
(q)	Verification of consignment of imported surgical instruments and appliances excluding the item in paragraph (v)	3.0% of FOB price

(r)	Verification of consignment of drug or surgical instruments and appliances, where a consignment arrives at a port of entry without a verification certificate	12% of FOB price
(s)	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

(t)	Verification of unregistered drugs imported from countries with stringent drug regulatory agencies where there are registered alternatives for the drug in Uganda	25% of FOB price
(u)	Verification of drugs and surgical instruments and surgical appliances for exportation	500,000/=
(v)	Verification of consignment of – (i) examination and surgical gloves; (ii) syringes (2ml, 3ml, 4ml and 5ml); and (iii) needles (2ml, 3ml, 4ml and 5ml), imported from a country which is not a Partner State of the East African Community	20% of FOB price
(w)	Fast tracking applications made under this Part	300% of applicable fee

PART 7—FEES FOR EXAMINATION OF DRUGS

1. **Examination of drugs by the Authority in the course of performance of its functions (except cannabis and imported herbal drugs)**

	Test	Fees per batch
(a)	Drug analysis after registration	$ 300
(b)	Re-analysis of sample at the request of owner, manufacturer, importer or any other person	$10,000
(c)	Analysis by the Authority in laboratory not owned by the Authority	Cost for testing + 10% of the cost

2. **Examination of cannabis, papaver, somniferum, Catha edulis, coca leaf, papaver setigerum and other narcotics by the Authority in the course of performance of its functions**

No.	Test	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 and loss on drying (LOD).	US $3,000

3. **Examination of imported herbal drugs by the Authority in the course of performance of its functions**

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

4. **Examination of drugs at request of owner, importer, manufacturer or any other person**

Test	Fees (USD)
A. Pharmaceutical analysis tests	
1. Assay test (per active ingredient)	1000
2. Assay for multiple ingredients (for every additional analyte) where quantitation is in a single run.	500
3. Dissolution test for immediate release dosage forms (per analyte) by HPLC-UV	1500
4. Dissolution test for immediate release dosage forms (per analyte) by ultra violet	1000
5. Dissolution test for modified release dosage forms per analyte	2000
6. Disintegration test	200

7. Analysis for related substances and impurity per substance with CRS	2000
8. Analysis for related substances and impurity per substance without CRS	1000
9. Analysis for content uniformity	1000
10. Analysis for weight variation	1000
11. Analysis for finger printing	1000
12. Identification	400
13. Mass spectrometric analysis per analyte	1500
14. Analyte characterization	1000
15. Investigative analysis	10,000
B. Pharmaceutical microbiology tests	
1. Enumeration	500
2. Objectionable microorganisms	1000
3. Sterility	1000
4. Preservative efficacy	1000
5. Microbial assay per analyte	1000
6. Bacterial endotoxin test (BET)	500
7. Visible particles	100
8. Subvisible particles	250
C. Physical chemical tests	
1. pH	100
2. Conductivity	100
3. Salinity	100
D. Other services	
1. Testing of samples of local drug products (three batches) for purposes of registration; single ingredient -	
(a) where the Authority provides the inputs	5,700,000/=
(b) where manufacturer provides the inputs	1,900,000/=
2. Testing of samples of local drug products for purposes of registration; for every additional ingredient	1,900,000/=

3. Testing of samples of imported drug products (three batches) for purposes of registration; single ingredient	22,800,000/=
4. Testing of samples of imported drug products for purposes of registration; for every additional ingredient	5,700,000/=
5. Testing of batch or sample of imported drug products; on request of importer or directive of the Authority	USD$ 1,500
6. Re-testing of batch or sample of drug products at request of owner, importer, manufacturer or any other person	USD$ 6,000
7. Test for product classification	USD$ 100
E. Fast tracking of any service under this Part	300% of applicable fee

PART 8 – FEES FOR EXAMINATION OF SURGICAL INSTRUMENT AND APPLIANCES

1. Examination of surgical instruments and appliances by the Authority in the course of performance of its functions

	Item	Fees per batch
(a)	Condoms (per batch)	US $ 350
(b)	Gloves (per batch)	US $ 250
(c)	Surgical instruments	US $ 1,000
(d)	Medical face masks (per sample)	US $ 3,500
(e)	Mosquito nets (per batch)	US $ 200
(f)	Other locally manufactured surgical instrument and appliances (per batch)	100,000/=
(g)	Analysis by the Authority in laboratory not owned by the Authority	Cost for testing + 10% of the cost

2. Examination of surgical instruments and appliances at request of owner, importer, manufacturer or any other person

Product	Test	Amount (USD)
Condoms	(a) For holes	250
	(b) For visible defects	50
	(c) For bursting pressure and volume	250
	(d) For packaging integrity	100
	(e) For length	50
	(f) For width	50
	(g) For thickness	50
	(h) For total lubricant quantity	100
	(i) For water tightness	250
Medical gloves	(a) For width	50
	(b) For thickness	50
Syringes, needles, cannulas, catheters and infusion sets	(a) For needle point test	200
	(b) For bond between needle tube & hub	200
	(c) For cleanliness of the needle tube	100
	(d) For defects in needle tube	100
	(e) For flow rate regulator	100
	(f) For flow rate through needle	100
	(g) For freedom from air	150
	(h) For freedom from liquid leakage	150
	(i) For efficiency of filters	100
	(j) For vent fittings	50
	(k) For injection site	100
	(l) For balloon fatigue	250
	(m) For balloon rated burst pressure	250
	(n) For corrosion resistance	300
	(o) Syringe re-use prevention feature	200

Rapid diagnostic test kits	(a) For sensitivity	550
	(b) For specificity	200
	(c) For package seal integrity	100
	(d) For tensile strength	200
Surgical sutures	(a) For needle attachment	200
	(b) For length	100
	(c) For thickness	100
	(d) For sterility	1000
Medical masks	(a) For splash resistance	200
	(b) For bacterial cleanliness (sterility)	500
IUDs	For dimensions	150
Copper bearing	(a) For tensile strength	125
	(b) For barium sulfate content	150
	(c) For sterility	1000
	(d) For identification	50
	(e) For memory test	50
Surgical adhesive plaster and bandage	(a) For zinc oxide content	700
	(b) For tensile strength	125
	(c) For sterility	1000
	(d) For peel test/ peeling force	125
	(e) For weight of adhesive mass	100
	(f) For adhesive property –adhesive strength	100
Absorbent cotton and gauze	(a) For quality and safety tests	120
	(b) For sterility	1000
Plaster of Paris	(a) For determination of mass	125
	(b) For setting time	100
	(c) For casting breaking strength	200
	(d) For determination of calcium sulphate	700

Surgical blades	(a) For sharpness	125
	(b) For defects	50
	(c) For sterility	1000
	(d) For blade handle fitment	50
Dental and orthopedic implants	All tests	1000
Ultrasound gel and lubricating	(a) Physical examination	100
	(b) For ph.	100
	(c) For identification	100
	(d) For enumeration	500
	(e) For viscosity	100
Blood bags	(a) For resistance to stretch	120
	(b) For leakages	200
	(c) For permeability	200
Any other surgical equipment and appliances	For safety and performance	200
Fast tracking of examination for surgical instruments and appliances		300% of the applicable fees

PART 9—FEES FOR INSPECTION OF LOCAL MANUFACTURING PLANTS FOR GOOD MANUFACTURING PRACTICES (GMP)

A. Inspection of manufacturing activities for finished pharmaceutical products and active pharmaceutical ingredients

No.	Item	Fees
a.	**Inspection of facility for complete manufacturing process**	
1.	Inspection of a facility with all the processes for the manufacture of general pharmaceutical products (including sterile and non-sterile general products); with a maximum of 5 general pharmaceutical product lines	UGX 1,500,000
2.	Inspection of a facility with all the processes for the manufacture of herbal products; with a maximum of 5 herbal product lines	UGX 1,500,000

3.	Inspection of a facility with all the processes for the manufacture of penicillin products; with a maximum of 5 penicillin product lines	UGX 1,500,000
4.	Inspection of a facility with all the processes for the manufacture of cephalosporin products; with a maximum of 5 cephalosporin product lines	UGX 1,500,000
5.	Inspection of a facility with all the processes for the manufacture of cytotoxic products; with a maximum of 5 cytotoxic product lines	UGX 1,500,000
6.	Inspection of a facility with all the processes for the manufacture of hormonal products; with a maximum of 5 hormonal product lines	UGX 1,500,000
7.	Inspection of a facility with all the processes for the manufacture of ectoparasiticide products; with a maximum of 5 ectoparasiticide product lines	UGX 1,500,000
8.	Inspection of a facility with all the processes for the manufacture of blood products; with a maximum of 5 blood product lines	UGX 1,500,000
9.	Inspection of a facility with all the processes for the manufacture of active pharmaceutical ingredients (chemicals); with a maximum of 4 active pharmaceutical ingredients	UGX 2,500,000
10.	Inspection of a facility with all the processes for the manufacture of biological products; with a maximum of 4 biological product lines	UGX 2,500,000
11.	Inspection of facility for the manufacture of excipients; with a maximum of 5 excipient production lines	UGX 2,500,000
12.	Inspection of any additional product line at a facility, for inspections under paragraph 11	UGX 500,000 per additional line
b.	**Inspection of facility where different intermediate manufacturing activities are done at different sites located within Uganda**	
1.	Inspection of a facility for the manufacture of intermediate or bulk product; with a maximum of 5 intermediate or bulk product lines	UGX 1,200,000
2.	Inspection of any additional product line for an inspection under paragraph 1	UGX 500,000 per line

3.	Inspection of a facility for primary packaging activities	UGX 1,200,000
4.	Inspection of facility for secondary packaging activities	UGX 1,000,000
5.	Inspection of facilities for quality control testing	UGX 1,000,000

B. **Inspection of manufacturing activities for biological products**

No.	Item	Fees for a facility within Uganda
a.	**Inspection of facility for complete manufacturing process**	
1.	Inspection of a facility with all the processes for the manufacturing of bulk products; with a maximum of 4 bulk product lines	UGX 5,000,000
2.	Inspection of any additional product line for an inspection under paragraph 1	UGX 1,000,000 per line
b. Inspection of facility for intermediate manufacturing activities		
1.	Inspection of a facility for the manufacture of bulk products; with a maximum of 4 production lines	UGX 3,500,000
2.	Inspection of any additional product line for an inspection under paragraph 1	UGX 500,000 per line
3.	Inspection of facility for secondary packaging activities	UGX 2,500,000
4.	Inspection of facility for quality control testing	UGX 2,500,000

Inspection of manufacturing activities for vaccine products

No.	Item	Fees for a facility within Uganda
a.	**Inspection of complete manufacturing process**	
1.	Inspection of a facility for the manufacture of one vaccine product	UGX 5,000,000
21	Inspection of facility for the manufacture of more than one vaccine	UGX 1,000,000 per vaccine product
b.	**Inspection of facility for intermediate manufacturing activities**	
1.	Inspection of a facility for the manufacture of one vaccine product	UGX 3,500,000

2.	Inspection of a facility for the manufacture of more than one vaccine product.	UGX 500,000 per product
3.	Inspection of facility for secondary and primary packaging activities	UGX 2,500,000
4.	Inspection of facility for quality control testing	UGX 2,500,000

PART 10 - FEES FOR INSPECTION OF FOREIGN MANUFACTURING PLANTS FOR GOOD MANUFACTURING PRACTICES (GMP)

A. Inspection of manufacturing activities for general and special requirement pharmaceutical products (general, beta-lactam, hormones, cytotoxic, blood and herbal products

No.	Item	Fees for inspection of facility within a Partner State of the East African Community	Fees for inspection of facility within the rest of Africa	Fees for inspection of facility outside Africa
1.	**Inspection of facility for complete manufacturing process**			
(a)	Inspection of a facility with all the processes for the manufacture of finished pharmaceutical products (including sterile and non-sterile general products); with a maximum of 5 pharmaceutical product lines	US$5,000	US$6,000	US$ 8,000
(b)	Inspection of a facility with all the processes for the manufacture of finished herbal products; with a maximum of 5 herbal product lines	US$3,000	US$4,000	US$ 6,000

(c)	Inspection of a facility with all the processes for the manufacture of finished penicillin products; with a maximum of 5 penicillin product lines	US$5,000	US$6,000	US$ 8,000
(d)	Inspection of a facility with all the processes for the manufacture of finished cephalosporin products; with a maximum of 5 cephalosporin product lines	US$5,000	US$6,000	US$ 8,000
(e)	Inspection of a facility with all the processes for the manufacture of finished cytotoxic products; with a maximum of 5 cytotoxic product lines	US$5,000	US$6,000	US$ 8,000
(f)	Inspection of a facility with all the processes for the manufacture of finished hormonal products; with a maximum of 5 hormonal product lines	US$5,000	US$6,000	US$ 8,000
(g)	Inspection of a facility with all the processes for the manufacture of finished ectoparasiticide products; with a maximum of 5 ectoparasiticide product lines	US$5,000	US$6,000	US$ 8,000
(h)	Inspection of a facility with all the processes for the manufacture of finished blood products; with a maximum of 5 blood product lines	US$5,000	US$6,000	US$ 8,000

(i)	Inspection of a facility with all the processes for the manufacture of active pharmaceutical ingredients (chemicals); with a maximum of 4 active pharmaceutical ingredients product lines	US$5,000	US$6,000	US$ 8,000
(j)	Inspection of a facility with all the processes for the manufacture of biological products; with a maximum of 4 biological product lines	US$5,000	US$6,000	US$ 8,000
(k)	Inspection of any additional product line at a facility, for inspections under paragraphs (a), (c), (d), (e), (f), (i) (j)	$1,000 per line	$1,500 per line	US$ 2,000 per line
(l)	Inspection of any additional product line at a facility, for inspections under paragraph (b)	$500 per line	$1000 per line	$1,500 per line
(m)	Inspection of any additional product line for product in paragraphs (a), (c), (d), (e), (f), (i) (j)where the product line is located in another country	$1,000 per line	$1,500 per line	US$ 2,000 per line
2.	**Inspection of facility where the manufacturing process is conducted; for a facility located in a different country**			
(a)	Inspection of facility for the manufacture of intermediate or bulk products; with a maximum of 5 intermediate or bulk product lines at the facility	US$4,000	US$5,000	US$ 7,000
(b)	Inspection of any additional intermediate or bulk product line	US$ 1000 per line	USD 1500 per line	USD 2000 per line
(c)	Inspection of packaging activities	US$ 4,000	US$ 5,000	US$ 7,000

(d)	Inspection of facility for quality control testing	US$4,000	US$5,000	US$ 7,000
(e)	Fast tracking inspections	300% of applicable inspection fee		

Inspection of facilities for manufacturing biological products

No.	Item	Fees for inspection of facility within a Partner State of the East African Community	Fees for inspection of facility within the rest of Africa	Fees for inspection of facility outside Africa
1.	**Inspection for complete manufacture of finished products (formulation, final product filling and packaging)**			
(a)	Inspection of facility for fill and finish manufacturing activities (including formulation of primary and secondary packaging activities); with a maximum of 4 lines for fill and finish manufacturing activities	US$5,000	US$6,000	US$ 8,000
(b)	Inspection of any line at a facility, additional to the line under paragraph (a)	$1,000 per line	$1,500 per line	US$ 2,000 per line
2.	**Inspection for intermediate manufacturing activities done at different sites located in the same country**			
(a)	Inspection of facility for all formulation manufacturing activities; with a maximum of 4 lines for formulation manufacturing activities	US$4,000	US$5,000	US$ 7,000
(b)	Inspection of formulation manufacturing activity line, additional to the line under paragraph (a)	$1,000 per line	$1,500 per line	US$ 2,000 per line

(c)	Inspection of facility for secondary packaging activities	US$4,000	US$5,000	US$ 7,000
(d)	Inspection of facility for quality control testing	US$4,000	US$5,000	US$ 7,000
3.	**Inspection of intermediate manufacturing activities done in different countries**			
(a)	Inspection of facility for all formulation manufacturing activities; with a maximum of 4 lines for formulation manufacturing activities	US$5,000	US$6,000	US$ 8,000
(b)	Inspection of formulation manufacturing activity line, additional to the line under paragraph (a)	$1,000 per line	$1,500 per line	US$ 2,000 per line
(c)	Inspection of facility for secondary packaging activities	US$5,000	US$6,000	US$ 8,000
(d)	Inspection of facility for quality control testing	US$5,000	US$6,000	US$ 8,000
(e)	Fast track inspections	300% of applicable inspection fee		

C. **Inspection of facilities for manufacturing vaccine products**

No.	Item	Fees for inspection of facility within a Partner State of the East African Community	Fees for inspection of facility within the rest of Africa	Fees for inspection of facility outside Africa
1.	**Inspection of complete manufacture of finished products (including final product filling and packaging)**			
(a)	Inspection of facility for manufacturing processes, for one vaccine	US$ 6,000	US$ 8,000	US$ 10,000

(b)	Inspection of facility for manufacturing processes, for more than one vaccine	$2,000 per additional product	$3,000 per additional product	US$ 4,000 per additional product
2.	**Inspection of intermediate manufacturing activities done at different sites located in the same country**			
(a)	Inspection of facility for manufacturing	US$4,000	US$5,000	US$ 7,000
(b)	Inspection of facility for manufacturing activities for any additional vaccine	$1,000 per vaccine product	$1,500 per vaccine product	US$ 2,000 per vaccine product
(c)	Inspection of facility for packaging activities (primary and secondary packaging)	US$4,000	US$5,000	US$ 7,000
(d)	Inspection of facilities for quality control testing	US$4,000	US$5,000	US$ 7,000
(e)	Inspection of batch release activities	US$ 3,000	US$ 3,000	US$ 3,000
3.	**Inspection of intermediate manufacturing activities conducted in different countries**			
(a)	Inspection of facility for manufacturing activities at one site for 1 vaccine product	US$ 6,000	US$ 8,000	US$ 10,000
(b)	Inspection of manufacturing activity line, additional to product line in paragraph (a)	$1,000 per product antigen	$1,500 per product antigen	US$ 2,000 per product antigen
(c)	Inspection of facility for primary and secondary packaging activities (per product line)	US$5,000	US$6,000	US$ 8,000
(d)	Inspection of facility for quality control testing	US$5,000	US$6,000	US$ 8,000
(e)	Fast tracking inspections	300% of the inspection fee		

D. Inspection of the manufacturing activities of surgical instruments and appliances

No.	Item	Fees for a facility within Uganda
(a)	Inspection of complete manufacturing activities for surgical instruments and appliances per manufacturing block	UGX 3,500,000
(b)	Inspection of intermediate manufacturing activities for surgical instruments and appliances.	UGX 3,500,000
(c)	Inspection of primary packaging activities for surgical instruments and appliances	UGX 3,500,000
(d)	Inspection of secondary packaging activities or Assembly of kits/procedure packs for surgical instruments and appliances	UGX 3,500,000
(e)	Fast tracking for inspection	300% of the applicable fee

PART 11—FEES FOR CLINICAL TRIALS FOR HUMAN DRUGS AND VACCINES (EXCEPT HERBAL DRUGS)

No.	Stage of clinical trial	Fees
(1)	Application to conduct clinical trial for a registered drug	US $ 5000
(2)	Application to conduct clinical trial for unregistered drug	US $ 8000
(3)	Application to conduct adaptive clinical trial	US $ 10000
(4)	Application to conduct clinical trial for locally manufactured drugs	UG SHS 10,000,000/=

(5)	Application for major amendment of clinical trial protocol	US $ 700
(6)	Application for minor amendment of clinical trial protocol	US $ 300
(7)	Notification of amendment to clinical trial protocol	US $ 50
(8)	Application for major amendment of protocol for adaptive clinical trial	US $ 2000
(9)	Annual renewal of clinical trial certificate	US $ 500
(10)	Extension of period of clinical trial	US $ 1000
(11)	Fast tracking applications	200% of applicable fees

PART 12— FEES FOR CLINICAL TRIALS FOR HUMAN HERBAL DRUGS AND VACCINES

1. Clinical trials for imported human herbal drugs and vaccines.

	Item	Fees
(1)	Application to conduct clinical trials for registered herbal drugs and vaccines	US $ 5,000
(2)	Application to conduct adaptive clinical trial	US $ 10,000
(3)	Application to conduct clinical trials for unregistered herbal drugs and vaccines	US $ 8,000
(4)	Application for major amendment of clinical trial protocol	US $ 700
(5)	Application for minor amendment of clinical trial protocol	US $ 300
(6)	Notification of amendment of clinical trial protocol	US $ 50
(7)	Application for major amendment of protocol for adoptive clinical trial	US $ 2000
(8)	Annual renewal of clinical trial certificate	US $ 500
(9)	Extension of period of clinical trial	US $ 1000
(10)	Fast tracking applications for clinical trials for imported human herbal drugs and vaccines	200% of applicable fees

Clinical trials for local herbal drugs and vaccines.

No.	Stage of clinical trial	Fees
(1)	Application to conduct clinical trial for a registered drug	1,000,000/=
(2)	Application to conduct clinical trial for unregistered drug	1,000,000/=
(3)	Application to conduct adaptive clinical trial	15,000,000/=
(4)	Application to conduct clinical trial for locally manufactured herbal drugs	10,000,000/=
(5)	Application for major amendment of clinical trial protocol	100,000/=
(6)	Application for minor amendment of clinical trial protocol	100,000/=
(7)	Notification of amendment to clinical trial protocol	100,000/=
(8)	Application for major amendment of protocol for adaptive clinical trial	100,000/=
(9)	Fast tracking applications for clinical trials for local herbal drugs and vaccines	200% of the applicable fees

PART 13—FEES FOR FIELD TRIALS FOR VETERINARY DRUGS AND VACCINES

1. Field trials for imported veterinary drugs and vaccines

	Item	Fees
(1)	Application to conduct ectoparasiticides field trial	US $ 1000
(2)	Application to conduct field trial for registered drugs and vaccines	US $ 1000
(3)	Application to conduct field trial for unregistered drugs and vaccines	US $ 2000
(4)	Amendment of application	US $ 200

2. Field trials for local veterinary drugs and vaccines (except local herbal drugs and vaccines)

	Item	Fees
(1)	Application to conduct ectoparasiticides field trials	US $ 1,000
(2)	Application to conduct field trials for registered local herbal drugs and vaccines	1,500,000/=
(3)	Application to conduct field trials for unregistered local herbal drugs and vaccines	3,000,000/=
(4)	Amendment of application	300,000/=

3. Field trials for local herbal veterinary drugs and vaccines

	Item	Fees for field trials and clinical trials for drugs
(1)	Application to conduct ectoparasiticides field trials	1,000,000/=
(2)	Application to conduct field trial for registered local herbal drugs and vaccines	1,000,000/=
(3)	Application to conduct field trial for unregistered local herbal drugs and vaccines	1,000,000/=
(4)	Amendment of application	100,000/=

PART 14—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 licensed seller during licensing period	50,000/=
(6)	Application for replacement of licences and certificates	100,000/=

PART 15—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 16 — FEES FOR VETTING PROMOTIONAL MATERIALS FOR DRUGS AND SURGICAL INSTRUMENTS AND APPLIANCES

No.	Promotional material	Fees per language, (excluding fees for vetting herbal related promotional materials.	Fees per language (for vetting herbal related promotional materials)
(1)	Application for vetting of written materials	100,000/=	50,000/=
(2)	Application for vetting of audios, videos and scripts	100,000/=	50,000/=
(3)	Application for vetting of posters and bill boards on any medium, including the internet	100,000/=	50,000/=

(4)	Application for vetting of posters on vehicles	100,000/=	50,000/=
(5)	Application for vetting of t- shirts	100,000/=	50,000/=
(6)	Application for vetting of other materials including caps, wall clocks, watches, umbrellas and bags.	100,000/=	50,000/=
(7)	Amendment of application	100,000/=	50,000/=
(8)	Fast track applications for vetting	300/% of the applicable fee	

PART 17—FEES FOR DESTRUCTION OF DRUGS

(a) Supervision of the destruction of drugs where the weight of the drugs is more than 100kgs	100,000/= per hour
(b) Supervision of the destruction of drugs where the weight of the drugs is less than 100kgs.	3,000/= per kg

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