

C.1168

SCHEDULE 5
FEES

HUMAN MEDICINES

DESCRIPTION	(BOTSWANA PULA)
Screening (all products)	1 1600
Application for registration (New Chemical Entity) <ul style="list-style-type: none"> • Without delivery system • With a delivery system • Biological & biosimilar • vaccine 	12000 15 000 15 000 15 000
Application for registration (generic) Generic with clinical data	12 500
Evaluation of additional submitted clinical data (pre-registration)	5000
Evaluation of request to re-schedule	1000
Package insert amendment	2000
Application for registration of B listed product	10 000
Registration of medicine partly manufactured in BOTSWANA	7 500
Registration of medicine fully manufactured in BOTSWANA	5 000
Expedited application (New Chemical Entity)	50 000
Expedited application (generic)	40 000
Expedited application of line extension	15 000
Line extension (New Chemical Entity)	7 500
Line extension(generic) Generic with clinical data	7 500
Registration of an orphan medicine	1 000
Renewal of registration	5 000
Annual Fee (NEC) medicines fully manufactured in country	1 000

Annual Fee (NEC) imported	1 000
Annual Fee (generic) medicines fully manufactured in country	500
Annual Fee(generic) imported	1 000
Application for Variation (NEC & generic) <ul style="list-style-type: none"> ▪ major ▪ minor ▪ notification 	1 500 1 000 500
Re-issue of certificates	100
Certificate of Pharmaceutical Product (all products)	250

Registration of complementary medicines-

- a) In the case of a complementary medicine imported into Botswana as a finished product for—

	(BOTSWANA PULA)
Screening fee	500
Re-Screening fee	500
Complementary medicine	5 000
A line extension of complementary medicine	1 000
Renewal of registration	4 000
Annual fee	4 00
Variations	500

- b) In the case of a complementary medicine imported into Botswana for packaging, relabelling or repackaging before being sold as—

Complementary medicine	1 750
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- c) Full manufacturing in Botswana

Complementary medicine	1 000
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- d) In the case of expedited review of —

Complementary medicine	10 000
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- GMP COMPLIANCE FEES

	(USD)
SADC	3 500
REST OF AFRICA	5 000
ASIA	6 500
REST OF THE WORLD	7 000
Desk review	3 500

LICENSING FEES
(reg. 17, 18, 19, 20, 21 and 23)

- MANUFACTURING
- LOCAL MANUFACTURER

				(BOTSWANA PULA)
Application for licensing fee				
	Licensing fees – Non Sterile			
Full manufacturing				4250
Part Manufacturing				7500
	Licensing fees – Sterile			
Full manufacturing				7500
Part Manufacturing				15 000
Clinical Trial site				7 500
Re-inspection				2 500

- OTHER PHARMACEUTICAL OPERATIONS

	(BOTSWANA PULA)
DISTRIBUTOR/WHOLESALER	1 250
PHARMACY/DISPENSARY/AGRIC SHOP /VET CLINIC	750
AUTHORISED PREMISES	750
RE-INSPECTION	750
EXPEDITED LICENCE APPLICATION	10 000

- LICENSING RENEWAL

	(BOTSWANA PULA)
DISTRIBUTOR/WHOLESALE	1 250
PHARMACY/DISPENSARY/AGRIC SHOP/VET CLINIC	750
AUTHORISED PREMISES	750
RE -INSPECTION	750

- PERMITS

	(BOTSWANA PULA)
Application to import / export Narcotics, psychotropics & precursor chemicals	100 per permit
Application to vary the import or export permit of Narcotics, psychotropics & precursor chemicals	100 per permit
Application to import / export for all products excluding Narcotics, psychotropics & precursor chemicals	50 per permit
Importation fee for wholesale exempted products	0.25% of the value of the consignment
Importation fee for all other products	0.15% of the value of the consignment
Application for Transit Permit	100 per permit

- IMPORTATION OF UNREGISTERED MEDICINES

	(BOTSWANA PULA)
Individual prescription	00
Wholesale dealers per medicine	350
Hospitals/vet clinic per medicine	50
Clinical trials per medicine	150

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• APPLICATION TO CONDUCT A CLINICAL TRIAL OF A MEDICINE FUNDED

				(BOTSWANA PULA)
BY LOCAL SPONSOR				
Application to conduct a clinical trial				15 000
Application to conduct a Sub study				7 500
Application to conduct an Operational research				7 500
				(BOTSWANA PULA)
BY FOREIGN SPONSOR				
Phase I study				50 000
Phase 2 study				40 000
Phase 3/4 study				30 000
Bioequivalence/Bioavailability				5 000
AMENDMENT APPLICATION				
Local sponsor				500
Foreign sponsor				2 000

• APPLICATION FOR APPROVAL OF ADVERTISEMENT OR PROMOTIONAL MATERIAL

	(BOTSWANA PULA)
Application for approval of advertisement or promotional material per product	Print media – 500 Electronic media – 1 000

- Cosmetics

a) In the case of cosmetics imported into Botswana as finished product for—

	(BOTSWANA PULA)
Screening fee	250
Re- Screening fee	250
Cosmetics (registration)	800
A line extension of cosmetics	100
Renewal of registration	200
Annual fee	100
Variations	200
Exemption	175

b) In the case of cosmetics imported into Botswana for packaging, relabelling or repackaging before being sold as —

Cosmetics	400
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c) Full manufacturing in Botswana

Cosmetics	250
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d) In the case of expedited review of —

Cosmetics	5 000
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• LABORATORY ANALYSIS FEES

NO.	TEST PARAMETERS	(BOTSWANA PULA)
1	Physical characteristics	150
	Uniformity of mass	
2	• tablets	200
3	• capsules	250
	Identification	
4	• UV /VIS	650
5	• HPLC	4 350
6	• FTIR	1 050
7	• TLC	1 750
8	• Colour reaction	800
	Assay	
9	• UV/VIS	1 800
10	• HPLC	6 250
11	• Titration	2 250
	Dissolution	
12	• UV/VIS	1 300
13	• HPLC	7 200
	Uniformity of dosage unit	
14	Content of uniformity (cu) by UV/VIS	3 200
15	Content of uniformity (cu) by HPLC	9 000
	Uniformity of dosage unit	
16	Weight variation	250
	Related Substances / Impurities	
17	HPLC	12 100
18	TLC	5 550
19	Optical rotation	300
20	Limit test	3000
21	Moisture Content	700
22	Loss on drying	700
23	Disintegration	500
24	Friability	250

25	Hardness	150
26	Average weight	150
27	Melting point	500
28	Ph	150
29	Deliverable volume	250
30	Weight/ml	250
31	Fill volume liquid	250
32	Fill volume injectability	250
	Microbiological tests	
33	Microbial enumeration tests	2 500
34	Tests for Specified Microorganisms	3 500
35	Antibiotic Assay	2 000
36	Antimicrobial Effectiveness test (Preservative Efficacy)	3 000
37	Sterility	2 500
38	Bacterial Endotoxin (LAL)	4 500
39	Microbial enumeration tests	2 500
40	Tests for Specified Microorganisms	2 000
	Male Latex Condom tests	
	Freedom From Holes	
41	• Batch Size 35 001-150 000	1 250
42	• Batch Size 150 001-500 000	1 500
43	• Batch Size 500 000 and over	1 750
	Burst Volume and Pressure	
44	• Batch Size 35 001-150 000	1 750
45	• Batch Size 150 001-500 000	2 000
46	• Batch Size 500 000 and over	2 250
47	Lubricant quantity	1 000
48	Package Integrity test	250
49	Width	200
50	Length	200
51	Thickness	250
52	Certificate of Analysis	250

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NOTES –

UV/VIS-means Ultraviolet Visible

HPLC means High Performance Liquid Chromatography

TLC means Thin Layer Chromatography

FTIR means Fourier Transform Infrared

LAL means Limulus Amebocyte Lysate

• Registration of Veterinary medicines

	(BOTSWANA PULA)
Screening (all products)	870
New Chemical Entity	4 530
Vaccine	10 000
Generic	2 360
Generic with clinical data	4 530
Additional submitted data (pre-reg)	2 400
Rescheduling	5 400
Package insert amendment	3 500
Premix	1 000
Medicated feed	800
Line extension of New Chemical Entity	2 360
Line extension of a generic	1 275
Registration of vaccine fully manufactured in BOTSWANA	4 080
Registration of veterinary medicine partly manufactured in BOTSWANA	5 000
Registration of veterinary medicine fully manufactured in BOTSWANA	2 000
Renewal of registration	50% of registration amount
Annual Fee of vaccine fully manufactured in BOTSWANA	275
Annual Fee (NCE) medicine fully manufactured in BOTSWANA	275
Annual Fee (NCE) imported	915
Annual Fee (generic) medicines fully manufactured in BOTSWANA	130
Annual Fee (generic) imported	435
Expedited application (New Chemical Entity)	1 7060
Expedited application (Vaccine)	16 000

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Expedited application (generic)	15 190
Expedited application of line extension	7 690
Application for Variation (NCE & generic)	
• major	1 300
• minor	375
• notification	190