MCAZ Medicines Control Authority of Zimbabwe

106 Baines Avenue
Tel: +263-4-736981-7
708255/792165, 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/35/04/2022

CIRCULAR 4 of 2022

Date: 3 February 2022

To: Holders of licences or permits issued by MCAZ

RE: FEE SCHEDULE

The Authority draws its attention to its Licence or Permit Holders of the Fee Schedule below effective 2022 -

FEES

In this schedule —

" finished product", in relation to a medicine , means a medicine which is wholly manufactured outside Zimbabwe and is imported into Zimbabwe and ready for sale without having to be relabelled or repackaged;

"line extension of a medicine" means any additional strength or pharmaceutical forms excluding novel dosage forms or delivery systems;

"orphan medicine" means a medicine, which is used in low volumes and is intended for the treatment of conditions of low morbidity as determined from time to time by the Authority.

Item				ZWL$	
1.			Application for the issue of a licence for—		
	(a)		Premises, other than a pharmaceutical manufacturer's premises—		
		(i)	pharmacy (in the Central Business District of a city)	285,000	
		(ii)	pharmacy (in any other urban location)	150,000	
		(iii)	Pharmacy under a rural district council	90,000	
		(iv)	dispensing medical practitioner or veterinary surgeon	75, 000	
		(v)	industrial clinic	30,000	
		(vi)	dispensary at a local authority clinic	7,500	

Item				ZWL$	
		(vii)	dispensary at public health institution	7,500	
		(viii)	any other clinic	22,500	
	(b)		a pharmaceutical manufacturer's premises—		
		(i)	a sterile pharmaceutical manufacturing unit	450,000	
		(ii)	a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	375,000	
		(iii)	a pharmaceutical manufacturer's premises with up to 3 dosage forms	300,000	
	(c)		a restricted pharmaceutical manufacturing premises	225,000	
	(d)		a person other than a pharmacist or nurse	18,000	
	(e)		a nurse	11,250	
	(f)		a pharmacist	7,500	
	(g)		A local authority nurse	4,500	
2.			Application for the renewal of a licence for—		
	(a)		a person other than a pharmacist or nurse	12,000	
	(b)		a nurse	9,000	
	(c)		a local authority nurse	4,500	
	(d)		a pharmacist	7,500	
	(e)		a premises other than a pharmaceutical manufacturer's premises		
		(i)	pharmacy (in the Central Business District of a city)	75,000	
		(ii)	pharmacy (in any other urban location)	60,000	
		(iii)	Pharmacy under a rural district council	37,500	
		(iv)	dispensing medical practitioner/veterinary surgeon	37,500	
		(iv)	industrial clinic	18,000	

Item				ZWL$	
		(vi)	dispensary at a local authority clinic	7,500	
		(vii)	dispensary at a public health institution	7,500	
		(viii)	other clinics	15,000	
	(f)		a pharmaceutical manufacturer's premises-		
		(i)	a sterile pharmaceutical manufacturing unit	300,000	
		(ii)	a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	225,000	
		(iii)	a pharmaceutical manufacturer's premises with up to 3 dosage forms	180,000	
	(g)		a restricted pharmaceutical manufacturing premises	150,000	
3.			Inspection of premises —		
	(a)		Pharmaceutical manufacturer's premises	150,000	
	(b)		Other premises	30,000	
	(c)		Other premises, expedited inspection	60,000 plus costs of the re-inspection	
4.			Application for the temporary renewal of a licence in terms of section 60(7) of the Act	30,000	
5.			Application for the issue of a permit for —		
	(a)		a wholesale dealer	262,500	
	(b)		a restricted wholesale dealer	37,500	
	(c)		a sales representative	18,000	
6.			Application for the renewal of a permit for—		
	(a)		a wholesale dealer	262,500	

Item				ZWL$	
	(b)		a restricted wholesale dealer	37,500	
	(c)		a sales representative	15,000	
7.			Application for a registration of a medicine—		
	(b)		in the case of a medicine imported into Zimbabwe and which is re-labelled or repacked before being sold as a finished product —		
		(i)	human medicine	187,500	
		(ii)	New chemical entity	225,500	
		(iii)	Veterinary medicine	112,500	
		(iv)	a previously registered medicine	75,000	
		(v)	resubmission of an application	67,500	
	(c)		in any other case —		
		(i)	human medicine	67,500	
		(ii)	veterinary medicine	45,000	
		(iii)	a previously registered medicine	56,250	
		(iv)	resubmission of an application	45,000	
8			Retention of a registered medicine, annually		
	(c)		in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as a finished product —		
		(i)	human medicine	33,750	
		(ii)	veterinary medicine	22,500	
	(d)		In any other case—		
		(i)	human medicine	15,000	
		(ii)	veterinary medicine	11,250	

Item				ZWL$	
9			Retention of the right to sell an unregistered specified medicine, annually		
	(c)		in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as a finished product —		
		(i)	human medicine	22,500	
		(ii)	veterinary medicine	15,000	
	(d)		In any other case—		
		(i)	human medicine	15,000	
		(ii)	veterinary medicine	11,250	
10.			Application to export or import an unregistered medicine in terms of section 75 of the Act —		
	(a)		individual prescription	1,500	
	(b)		institutions- per medicine —		
		(i)	Hospitals	7,500	
		(ii)	non-government organisations (NGOs)	7,500	
		(iii)	other (wholesale dealers, etc)	7,500	
	(c)		clinical trials - per medicine —		
		(ii)	locally sponsored	1,500	
	(d)		Authorisation to import an unregistered veterinary product where -		
		(i)	no registered alternative is available and no application for registration has been submitted	22,500	
		(ii)	no application for registration has been submitted	37,500	
11.			Any amendment to the original application for the registration of medicine —		

Item				ZWL$	
	(b)		in the case of a medicine imported into Zimbabwe and which is re-labelled or repacked before being sold as a human or veterinary medicine		
		(i)	Indications	33,750	
		(ii)	category for distribution	33,750	
		(iii)	Formulation	22,500	
		(vi)	stability data	22,500	
		(v)	change of or additional manufacturer	22,500	
		(vi)	batch data	22,500	
		(vii)	bioavailability/bioequivalence	22,500	
		(viii)	Promotional material	15,000	
		(ix)	any other	19,500	
	(c)		any other case—		
		(i)	Indications	15,000	
		(ii)	category for distribution	15,000	
		(iii)	Formulation	11,250	
		(iv)	stability data	11,250	
		(v)	change of or additional manufacturer	11,250	
		(vi)	batch data	11,250	
		(vii)	bioavailability/bioequivalence	11,250	
		(viii)	Promotional material	7,500	
		(ix)	any other	9,750	
12.			Application to conduct a clinical trial of a medicine—		
	(a)		Funded by a local sponsor—		
		(i)	human medicine	150,000	
		(ii)	Veterinary medicine	75,000	
		(ii)	sub-study	75,000	

Item				ZWL$	
		(iii)	operational research study	75,000	
		(iv)	observational study	15,000	
		(v)	any other case	7,500	
	(c)		Any amendment to original application funded by a local sponsor—		
		(i)	Initial	3,750	
		(ii)	Subsequent	3,750	
	(e)		In the case of an expedited consideration of any process listed in paragraphs (a) to (d)	Fees listed in (a) to (d) for that particular process plus 50% of the fee	
13.			Application to import psychotropic substances	3,750	
14.			Application to export psychotropic substances	3,750	
15.			Application for authorisation to procure, possess, administer or distribute medicine	3,750	
16			Application for a permit to supply veterinary medicines (VMGD)	15,000	
17.			Application for any duplicate copy of a current licence or permit	2,250	
18.			Application for a duplicate copy of a certificate of registration of a medicine—		
	(b)		in the case of a medicine imported into Zimbabwe and which is re-labelled or repacked before being sold as a human or veterinary medicine	6,000	
	(c)		in any other case	3,750	
19.			Application for a copy of a certificate of registration—		
	(b)		in the case of a medicine imported into Zimbabwe and which is re-labelled or repacked before being sold as a human or veterinary medicine	3,750	
	(c)		in any other case	1,500	

Item				ZWL$	
20.			Application to manufacture a medicine on contract for export or otherwise—		
	(b)		in the case of a local principal	7,500	
21.			Approval of advertisements —		
	(a)		in the case of an initial submission	7,500	
	(b)		in the case of a resubmission of an advertisement	6,000	
22.			Any amendment to the original application and additional information for—		
	(a)		licence or permit	2,250	
	(b)		authorisation to import an unregistered medicine	2,250	
23.			Application for the issue of a certificate of free sale (COFs)	6,000	
24.			Application for the issue of a certificate of a pharmaceutical product (CPP)	6,000	
25.			Fee for conducting hearings	75,000	
26.			Application for issue of a WHO-type GMP certificate	6,000	
27.			Application for a licence to acquire, possess and administer Part IV drugs	7 500	
28.			Application for renewal of a licence to acquire, possess and administer Part IV drugs	7 500	
29.			Application for a licence to import drugs (Dangerous Drugs)	11 250	
30.			Application for a licence to export drugs (Dangerous Drugs)	11 250	
31.			Application for an import permit (Precursors and Certain Chemical Substances)	7 500	
32.			Application for an export permit (Precursors and Certain Chemical Substances)	7 500	

Item				ZWL$	
33.			Application for extension of an import or export permit (Precursors and Certain Chemical Substances)	7 500	
34.			Application for an import permit	7 500	
35.			Application for an export permit	6 000	
36.			Consignment verification	1 percent of the Cost, Insurance and Freight (CIF) value	

Notes

1. The fees specified herein are exclusive of VAT which shall be charged upon payment of the fees.
2. The fees specified herein shall not apply to any person or institution exempted by the Authority.
3. Laboratory fees levied in terms of section 73A of the Act shall be charged by the Authority on a cost recovery basis
4. GMP inspection costs shall be charged by the Authority on a cost recovery basis
5. Inspection fees for new premises are part of the application fee.
6. Restricted pharmaceutical manufacturing premises where only repackaging and labelling is done.
7. Second and subsequent inspections carried out due to unsuccessful initial inspections will attract an inspection fee and costs of the inspection as stipulated in item 3 (c).
8. A restricted wholesale dealer is a wholesale dealer who is not in the business of wholesaling but applies for a special permit to supply products by wholesale (e.g. not for profit) in terms of items 5(b) and 6(b).
9. Incomplete applications will attract an amendment fee as stipulated in items 11 and 22.
10. The application fee item 26 applies to an application submitted within 6 months of the last inspection. Beyond 6 months the premises concerned have to pass a re-inspection prior to the issuance of a WHO-type cGMP certificate."

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R.Rukwata (Mr.)

ACTING DIRECTOR-GENERAL