MCAZ Medicines Control Authority of Zimbabwe

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B/279/35/20/2023

CIRCULAR NO.20 OF 2023

25th August 2023

TO: Holders of licences or permits issued by MCAZ

RE: FEE SCHEDULE

The Authority draws attention to its Licence or Permit Holders of the Fee Schedule below which is effective with immediate effect -

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				USD	
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)	1,900	
		(ii)	pharmacy (in any other urban location)	1,000	
		(iii)	Pharmacy (under a rural district council)	600	
		(iv)	dispensing medical practitioner or veterinary surgeon	500	
		(v)	industrial clinic	250	
		(vi)	dispensary at a local authority clinic	50	
		(vii)	dispensary at a public health institution	50	
		(viii)	any other clinic	150	
	(b)		a pharmaceutical manufacturer's premises—		

Item				USD	
		(i)	a sterile pharmaceutical manufacturing unit	6,000	
		(ii)	a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	5,000	
		(iii)	a pharmaceutical manufacturer's premises with up to 3 dosage forms	4,500	
	(c)		a restricted pharmaceutical manufacturing premises	3,500	
	(d)		a person other than a pharmacist or nurse	120	
	(e)		a nurse	75	
	(f)		a pharmacist	100	
	(g)		A local authority nurse	30	
2.			Application for the renewal of a licence for—		
	(a)		a person other than a pharmacist or nurse	80	
	(b)		a nurse	60	
	(c)		a local authority nurse	30	
	(d)		a pharmacist	50	
	(e)		a premises other than a pharmaceutical manufacturer's premises		
		(i)	pharmacy (in the Central Business District of a city)	500	
		(ii)	pharmacy (in any other urban location)	400	
		(iii)	Pharmacy under a rural district council	250	
		(iv)	dispensing medical practitioner/veterinary surgeon	250	
		(iv)	industrial clinic	180	
		(vi)	dispensary at a local authority clinic	50	
		(vii)	dispensary at a public health institution	50	
		(viii)	other clinics	100	
	(f)		a pharmaceutical manufacturer's premises-		
		(i)	a sterile pharmaceutical manufacturing unit	4,000	

Item				USD	
		(ii)	a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	3,500	
		(iii)	a pharmaceutical manufacturer's premises with up to 3 dosage forms	3,000	
	(g)		a restricted pharmaceutical manufacturing premises	2,500	
3.			Inspection of premises —		
	(a)		Pharmaceutical manufacturer's premises	1,000	
	(b)		Other premises	200	
	(c)		Other premises, expedited inspection	400 plus costs of the re-inspection	
4.			Application for the temporary renewal of a licence in terms of section 60(7) of the Act	200	
5.			Application for the issue of a permit for —		
	(a)		a wholesale dealer	3,500	
	(b)		a restricted wholesale dealer	500	
	(c)		a sales representative	120	
6.			Application for the renewal of a permit for—		
	(a)		a wholesale dealer	1,750	
	(b)		a restricted wholesale dealer	250	
	(c)		a sales representative	100	
7.			Application for a registration of a medicine—		
	(a)		in the case of a medicine imported into Zimbabwe as a finished product for-		
		(i)	a new chemical entity including dosage form or delivery system (human)	3,000	
		(ii)	a new chemical entity including dosage form or delivery system (veterinary)	2,000	
		(iii)	a generic medicine (human)	2,500	

Item				USD	
		(iv)	a generic medicine (veterinary)	1,500	
		(v)	a line extension of a medicine (human)	1,500	
		(vi)	a line extension of a medicine (veterinary)	1,000	
		(vii)	orphan medicine	750	
		(viii)	a previously registered medicine	750	
		(ix)	resubmission of an application	600	
	(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	1,500	
		(ii)	New chemical entity	1,500	
		(iii)	Veterinary medicine	900	
		(iv)	a previously registered medicine	750	
		(v)	resubmission of an application	600	
	(c)		in any other case —		
		(i)	human medicine	900	
		(ii)	veterinary medicine	600	
		(iii)	a previously registered medicine	750	
		(iv)	resubmission of an application	600	
	(d)		in the case of expedited review of-		
		(i)	a new chemical	4,500	
		(ii)	a generic medicine	4,000	
		(iii)	a line of extension of a medicine	3,000	
8			Retention of a registered medicine, annually		
	(a)		in the case of a medicine for human use imported into Zimbabwe as a finished product	500	
	(b)		in the case of a veterinary medicine imported into Zimbabwe as a finished product	300	
	(c)		in the case of a medicine imported into Zimbabwe and which is relabelled and		

Item				USD	
			repackaged before being sold as a finished product —		
		(i)	human medicine	300	
		(ii)	veterinary medicine	200	
	(d)		In any other case—		
		(i)	human medicine	200	
		(ii)	veterinary medicine	150	
9			Retention of the right to sell an unregistered specified medicine annually-		
	(a)		in the case of a medicine for human imported into Zimbabwe as a finished product	500	
	(b)		In the case of a veterinary medicine or orphan medicine imported into Zimbabwe as a finished product	300	
	(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	300	
		(ii)	veterinary medicine	200	
	(d)		In any other case—		
		(i)	human medicine	200	
		(ii)	veterinary medicine	150	
10.			Application to export or import an unregistered medicine in terms of section 75 of the Act —		
	(a)		individual prescription	10	
	(b)		institutions- per medicine —		
		(i)	Hospitals	50	
		(ii)	non-government organisations (NGOs)	50	
		(iii)	other (wholesale dealers, etc)	100	
	(c)		clinical trials - per medicine —		
		(i)	foreign sponsored	10	

Item				USD	
		(ii)	locally sponsored	10	
	(d)		Authorisation to import an unregistered veterinary product where -		
		(i)	no registered alternative is available and no application for registration has been submitted	300	
		(ii)	no application for registration has been submitted	500	
11			Any amendment to the original application for the registration of medicine-		
	(a)		in the case of a medicine imported into Zimbabwe as a finished product		
		(i)	indications	400	
		(ii)	category for distribution	400	
		(iii)	formulation	300	
		(iv)	stability data	300	
		(v)	change of additional manufacturer	300	
		(vi)	batch data	300	
		(vii)	bioavailability/bioequivalence	300	
		(viii)	any other	250	
	(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	300	
		(ii)	category for distribution	300	
		(iii)	formulation	200	
		(vi)	stability data	200	
		(v)	change of or additional manufacturer	200	
		(vi)	batch data	200	
		(vii)	bioavailability/bioequivalence	200	
		(viii)	promotional material	100	
		(ix)	any other	175	
	(c)		any other case—		

Item				USD	
		(i)	indications	200	
		(ii)	category for distribution	200	
		(iii)	formulation	75	
		(iv)	stability data	75	
		(v)	change of or additional manufacturer	75	
		(vi)	batch data	75	
		(vii)	bioavailability/bioequivalence	75	
		(viii)	promotional material	50	
		(ix)	any other	65	
12.			Application to conduct a clinical trial of a medicine—		
	(a)		Funded by a local sponsor—		
		(i)	human medicine	2,000	
		(ii)	veterinary medicine	1,000	
		(iii)	sub-study	1,000	
		(iv)	operational research study	1,000	
		(v)	observational study	200	
		(vi)	any other case	100	
	(b)		funded by a foreign sponsor-		
		(i)	human medicine phase I study	5,000	
		(ii)	human medicine phase II study	4,000	
		(iii)	human medicine phase III or phase IV study	3,000	
		(iv)	veterinary medicine	1,000	
		(v)	in any other case	500	
		(vi)	operational	1,000	
		(vii)	bioavailability/bioequivalence	500	
		(viii)	observational	200	
		(ix)	in any other case	200	
	(c)		Any amendment to original application funded by a local sponsor—		

Item				USD	
		(i)	Initial	50	
		(ii)	Subsequent	50	
	(d)		Any amendment to original application funded by a foreign sponsor-		
		(i)	initial	100	
		(ii)	subsequent	100	
	(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	50	
14.			Application to export psychotropic substances	50	
15.			Application for authorisation to procure, possess, administer or distribute medicine	50	
16			Application for a permit to supply veterinary medicines (VMGD)	200	
17.			Application for any duplicate copy of a current licence or permit	30	
18.			Application for a duplicate copy of a certificate of registration of a medicine—		
	(a)		in the case of a medicine imported into Zimbabwe as a finished product	100	
	(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	50	
	(c)		in any other case	50	
19.			Application for a copy of a certificate of registration—		
	(a)		in the case of a medicine imported into Zimbabwe as a finished product	50	
	(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	30	
	(c)		in any other case	20	

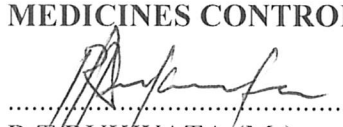
Item				USD	
20.			Application to manufacture a medicine on contract for export or otherwise—		
	(a)		in the case of a foreign principal	1,500	
	(b)		in the case of a local principal	500	
21.			Approval of advertisements —		
	(a)		in the case of an initial submission	50	
	(b)		in the case of a resubmission of an advertisement	40	
22.			Any amendment to the original application and additional information for—		
	(a)		licence or permit	30	
	(b)		authorisation to import an unregistered medicine	30	
23.			Application for the issue of a certificate of free sale (COFs)	80	
24.			Application for the issue of a certificate of a pharmaceutical product (CPP)	150	
25.			Fee for conducting hearings	500	
26.			Application for issue of a WHO-type GMP certificate	150	
27.			Application for a licence to acquire, possess and administer Part IV drugs	50	
28.			Application for renewal of a licence to acquire, possess and administer Part IV drugs	50	
29.			Application for a licence to import dangerous drugs	75	
30.			Application for a licence to export dangerous drugs	75	
31.			Application for a precursor import permit	50	
32.			Application for precursor export permit	50	
33.			Application for extension of a precursor import or export permit	50	

Item				USD	
34.			Consignment verification	1 percent of the Cost, Insurance and Freight (CIF) value	
35.			Application for an import permit	50	
36.			Application for an export permit	40	
37.			Consignment verification	1 percent of the Cost, Insurance and Freight (CIF) value	

Notes

1. The fees specified herein shall not apply to any person or institution exempted by the Authority.
2. Laboratory fees levied in terms of section 73A of the Act shall be charged by the Authority on a cost recovery basis.
3. GMP inspection costs shall be charged by the Authority on a cost recovery basis.
4. Inspection fees for new premises are part of the application fee.
5. Restricted pharmaceutical manufacturing premises where only repackaging and labelling is done.
6. 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).
7. 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).
8. Incomplete applications will attract an amendment fee as stipulated in items 11 and 22.
9. 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.

Yours faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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DIRECTOR-GENERAL