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

B279/35/09/2021

CIRCULAR NO. 9 OF 2021

5 March 2021

TO: Holders of licences or permits issued by MCAZ

FEE SCHEDULE

The Authority draws its attention to its Licence or Permit Holders of the Fee Schedule below effective 2021 -

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)	1000	
		(ii)	pharmacy (in any other urban location)	500	
		(iii)	Pharmacy under a rural district council	300	
		(iv)	dispensing medical practitioner or veterinary surgeon	250	
		(v)	industrial clinic	100	
		(vi)	dispensary at a local authority clinic	25	
		(vii)	dispensary at public health institution	25	
		(viii)	any other clinic	75	

Item				USD	
	(b)		a pharmaceutical manufacturer's premises—		
		(i)	a sterile pharmaceutical manufacturing unit	3000	
		(ii)	a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	2500	
		(iii)	a pharmaceutical manufacturer's premises with up to 3 dosage forms	2000	
	(c)		a restricted pharmaceutical manufacturing premises	1500	
	(d)		a person other than a pharmacist or nurse	60	
	(e)		a nurse	40	
	(f)		a pharmacist	30	
	(g)		A local authority nurse	10	
2.			Application for the renewal of a licence for—		
	(a)		a person other than a pharmacist or nurse	40	
	(b)		a nurse	30	
	(c)		a local authority nurse	10	
	(c)		a pharmacist	20	
	(d)		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)	250	
		(iii)	Pharmacy under a rural district council	100	
		(iv)	dispensing medical practitioner/veterinary surgeon	125	
		(iv)	industrial clinic	60	
		(vi)	dispensary at a local authority clinic	25	

Item				USD	
		(vii)	dispensary at a public health institution	25	
		(viii)	other clinics	50	
	(e)		a pharmaceutical manufacturer's premises-		
		(i)	a sterile pharmaceutical manufacturing unit	2000	
		(ii)	a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	1500	
		(iii)	a pharmaceutical manufacturer's premises with up to 3 dosage forms	1200	
	(f)		a restricted pharmaceutical manufacturing premises	1000	
3.			Inspection of premises —		
	(a)		Pharmaceutical manufacturer's premises	1000	
	(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	100	
5.			Application for the issue of a permit for —		
	(a)		a wholesale dealer	1750	
	(b)		a restricted wholesale dealer	250	
	(c)		a sales representative	60	
6.			Application for the renewal of a permit for—		
	(a)		a wholesale dealer	900	

Item				USD	
	(b)		a restricted wholesale dealer	150	
	(c)		a sales representative	50	
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 a delivery system (human)	3 000	
		(ii)	a new chemical entity including dosage form or a delivery system (veterinary)	2 000	
		(iii)	a generic medicine (human)	2 500	
		(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)	1000	
		(vii)	orphan medicine	750	
		(viii)	a previously registered medicine	750	
		(vii)	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	1000	
		(ii)	Veterinary medicine	600	
		(iii)	a previously registered medicine	500	
		(iv)	resubmission of an application	450	
	(c)		in any other case —		
		(i)	human medicine	450	
		(ii)	veterinary medicine	300	
		(ii)	a previously registered medicine	375	

Item				USD	
		(iii)	resubmission of an application	300	
	(d)		In the case of expedited review of—		
		(i)	a new chemical entity	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 repackaged before being sold as a finished product—		
		(i)	human medicine	225	
		(ii)	veterinary medicine	150	
	(d)		In any other case—		
		(i)	human medicine	100	
		(ii)	veterinary medicine	75	
9.			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	15	
		(ii)	non-government organisations (NGO's)	10	
		(iii)	other (wholesale dealers, etc)	50	
	(c)		clinical trials - per medicine —		

Item				USD	
		(i)	foreign sponsored	20	
		(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	150	
		(ii)	no application for registration has been submitted	250	
10.			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)	Promotional material	100	
		(ix)	any other matter	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	225	
		(ii)	category for distribution	225	
		(iii)	Formulation	150	
		(vi)	stability data	150	
		(v)	change of or additional manufacturer	150	

Item				USD	
		(vi)	batch data	150	
		(vii)	bioavailability/bioequivalence	150	
		(viii)	Promotional material	100	
		(ix)	any other	130	
	(c)		any other case—		
		(i)	Indications	100	
		(ii)	category for distribution	100	
		(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	
11.			Application to conduct a clinical trial of a medicine—		
	(a)		Funded by a local sponsor—		
		(i)	human medicine	1000	
		(ii)	Veterinary medicine	500	
		(ii)	sub-study	500	
		(iii)	operational research study	500	
		(iv)	observational study	100	
		(v)	any other case	50	
	(b)		funded by a foreign sponsor—		
		(i)	human medicine phase 1 study	5 000	
		(ii)	human medicine phase II study	4 000	

Item				USD	
		(iii)	human medicine phase III study or phase IV study	3 000	
		(iv)	Veterinary medicine	1 000	
		(v)	Sub-study	1000	
		(vi)	in any other case	500	
		(vii)	Operational	1 000	
		(viii)	bioequivalence/bioavailability	500	
		(ix)	Observational	200	
		(x)	in any other case	200	
	(c)		Any amendment to original application funded by a local sponsor—		
		(i)	Initial	25	
		(ii)	Subsequent	25	
	(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	
12.			Application to import psychotropic substances	25	
13.			Application to export psychotropic substances	25	
14.			Application for authorisation to procure, possess, administer or distribute medicine	25	
15			Application for a permit to supply veterinary medicines (VMGD)	100	
16.			Application for any duplicate copy of a current licence or permit	15	

Item				USD	
17.			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	40	
	(c)		in any other case	25	
18.			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	25	
	(c)		in any other case	10	
19.			Application to manufacture a medicine on contract for export or otherwise—		
	(a)		in the case of a foreign principal	250	
	(b)		in the case of a local principal	50	
20.			Approval of advertisements —		
	(a)		in the case of an initial submission	30	
	(b)		in the case of a resubmission of an advertisement	20	
21.			Any amendment to the original application and additional information for—		
	(a)		licence or permit	15	
	(b)		authorisation to import an unregistered medicine	15	

Item				USD	
22.			Application for the issue of a certificate of free sale (COF's)	40	
23.			Application for the issue of a certificate of a pharmaceutical product (CPP)	40	
24.			Fee for conducting hearings	500	
25.			Application for issue of a WHO-type GMP certificate	40	
26			Application for the approval of a complementary medicine		
		(a)	in the case of a complementary medicine imported into Zimbabwe as a finished product	600	
		(b)	in the case of a complementary medicine imported into Zimbabwe and which is relabelled or repackaged before being sold	300	
		(c)	in any other case (locally manufactured)	200	
27			Retention to sell an approved complementary medicine, annually		
		(a)	in the case of a complementary medicine imported into Zimbabwe as a finished product	150	
		(b)	in the case of a complementary medicine imported into Zimbabwe and which is relabelled or repackaged before being sold	90	
		(c)	in any other case (locally manufactured)	50	
28			Any amendment to the original application for the approval of a complementary medicine		
		(a)	in the case of a complementary medicine imported into Zimbabwe as a finished product	100	
		(b)	in the case of a complementary medicine imported into Zimbabwe and which is relabelled or repackaged before being sold	75	

Item				USD	
		(c)	in any other case (locally manufactured)	50	
29			Application for a replacement or copy of a certificate of approval		
		(a)	in the case of a complementary medicine imported into Zimbabwe as a finished product	50	
		(b)	in the case of a complementary medicine imported into Zimbabwe and which is relabelled or repackaged before being sold	30	
		(c)	in any other case (locally manufactured)	20	
30			Application for a permit to import medicines	25	
31			Application for a permit to export medicines	20	
32			Consignment verification fee for importation of medicines	1 percent of Cost Insurance and Freight (CIF) value	
33			Application for a permit to import a precursor or certain chemical substance	25	
34			Application for a permit to export a precursor or certain chemical substance	25	
35			Consignment verification fee for importation of a precursor or certain chemical substance	0.5 percent of Cost Insurance and Freight (CIF) value	
36			Application for extension of a permit to import or export a precursor or certain chemical substance	25	
37			Application for a licence to acquire, possess and administer Part IV drugs	25	

Item				USD	
38			Application for renewal of a licence to acquire, possess and administer Part IV drugs	25	
39			Application for a licence to import Part IV drugs	40	
40			Application for a licence to export Part IV drugs	40	

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. The expedited fee in item 7 is for registration of medicines reviewed expeditiously.
9. Incomplete applications will attract an amendment fee as stipulated in items 10 and 21.
10. The application fee item 25 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

.....

R.T. RUKWATA (Mr)

ACTING DIRECTOR-GENERAL