Medicines and Allied Substances Control (General) (Amendment) Regulations, 2020 (No. 30)

IT is hereby notified that the Minister of Health and Child Care has, in terms of section 74, and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act [*Chapter 15:03*], made the following regulations:—

1. These regulations may be cited as the Medicines and Allied Substances Control (General) (Amendment) Regulations, 2020 (No. 30).

2. These regulations shall be effective from 1st January, 2020.

3. The Medicines and Allied Substances Control (General) Regulations, 1991, published in Statutory Instrument 150 of 1991, is amended by the deletion of the First Schedule and substitution of the following—

"FIRST SCHEDULE (*Sections 2, 16 and 100A)*

FEES

In this Schedule—

"finished product", in relation to the 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 for the treatment of conditions of low morbidity as determined from time to time by the Authority.

Item	*Fee* US$	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)	—	6 000,00
(ii) pharmacy (in any other location)	—	3 600,00
(iii) despensing medical practitioner or veterinary surgeon	—	3 000,00
(iv) industrial clinic	—	1 500,00

Item		*Fee*	
		US$	ZWL$
	(v) dispensary at a local clinic	—	300,00
	(vi) dispensary at a public health institution	—	300,00
	(vii) any other clinic	—	900,00
(b)	a pharmaceutical manufacturer's premises—		
	(i) a sterile pharmaceutical manufacturing unit	—	36 000,00
	(ii) a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	—	30 000,00
	(iii) a pharmaceutical manufacturing premises with up to 3 dosage forms	—	27 000,00
(c)	a restricted pharmaceutical manufacturing premises	—	21 000,00
(d)	a person other than a pharmacist or nurse	—	720,00
(e)	a nurse	—	450,00
(f)	a pharmacist	—	600,00
(g)	a local authority nurse	—	120,00
2.	Application for the renewal of a licence for—		
(a)	a person other than a pharmacist or nurse	—	480,00
(b)	a nurse	—	360,00
(c)	a local authority nurse	—	90,00
(d)	a pharmacist	—	300,00
(e)	a premises other than a pharmaceutical manufacturer's premises lodged at least one months before expiry of such licence—		
	(i) pharmacy	—	2 400,00
	(ii) dispensing medical practitioner/veterinary surgeon	—	1 500,00
	(iii) industrial clinic	—	1 080,00
	(iv) dispensary at a local authority clinic	—	300,00
	(v) dispensary at a public health institution	—	300,00
	(vi) other clinics	—	600,00
(f)	a pharmaceutical manufacturer's premises—		
	(i) a sterile pharmaceutical manufacturing	—	24 000,00
	(ii) a pharmaceutical manufacturer's premises with more than 3 dosage forms and not including sterile product manufacturing facilities	—	21 000,00

Item		*Fee* US$	ZWL$
	(iii) a pharmaceutical manufacturer's premises with up to 3 dosage forms	—	18 000,00
	(g) a restricted pharmaceutical manufacturing premises	—	15 000,00
	(h) premises other than a pharmaceutical manufacturer's premises lodged within the last month of expiry of such licence—		
	(i) pharmacy	—	3 000,00
	(ii) despensing medical/veterinary surgeon	—	2 100,00
	(iii) industrial clinic	—	1 200,00
	(iv) dispensary at a local authority clinic	—	300,00
	(v) dispensary at a public health institution	—	300,00
	(vi) other clinics	—	720,00
3.	Inspection of premises other than the initial inspection—		
	(a) excluding a pharmaceutical manufacturer's premises	—	1 200,00
	(b) pharmaceutical manufacturer's premises—		
	(i) of a sterile pharmaceutical manufacturer's unit	—	6 000,00
	(ii) of a pharmaceutical manufacturer's premises with more than 3 dosage forms, excluding sterile product manufacturer's facilities	—	4 500,00
	(iii) of a pharmaceutical manufacturer's premises with up to 3 dosage forms	—	3 000,00
4.	Application for the temporary renewal of a licence in terms of section 60(7) of the Act	—	200,00
5.	Application for the issue of a permit for—		
	(a) a wholesale dealer	—	21 000,00
	(b) a restricted wholesale dealer	—	3 000,00
	(c) a sales representative	—	720,00
6.	Application for the renewal of a permit for—		
	(a) a wholesale dealer	—	10 500,00
	(b) a restricted wholesale dealer	—	1 500,00
	(c) a sales representative	—	600,00

Item	*Fee* US$	ZWL$
7. Application for the 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)	3 000,00	—
(ii) a new chemical entity including dosage form or delivery system (veterinary)	2 000,00	—
(iii) a generic medicine (human)	2 500,00	—
(iv) a generic medicine (veterinary)	1 500,00	—
(v) a line extension of a medicine (human)	1 500,00	—
(vi) a line extension of a medicine (veterinary)	1 000,00	—
(vii) ophan medicine	750,00	—
(viii) a previously registered medicine	750,00	—
(ix) resubmission of an application	600,00	—
(b) in the case of a medicine imported into Zimbabwe and which is relabelled or repackaged before being sold as a finished product—		
(i) human medicine	—	9 000,00
(ii) new chemical entity	—	9 000,00
(iii) veterinary medicine	—	5 400,00
(iv) a previously registered medicine	—	4 500,00
(v) resubmission of an application	—	3 600,00
(c) in any other case—		
(i) human medicine	—	5 400,00
(ii) veterinary medicine	—	3 600,00
(iii) a previously registered medicine	—	4 500,00
(iv) resubmission of an application	—	3 600,00
(d) in the case of expedited review of—		
(i) a new chemical entity	4 500,00	—
(ii) a generic medicine	4 000,00	—
(iii) a line of extension of a medicine	3 000,00	—
8. Retention of a registered medicine, annually—		
(a) in the case of a medicine for human use imported into Zimbabwe as a finished product	500,00	—

Item	*Fee* US$	ZWL$
(b) in the case of a veterinary medicine imported into Zimbabwe as a finished product	300,00	—
(c) in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as—		
(i) human medicine	—	1 800,00
(ii) veterinary medicine	—	1 200,00
(d) in any other case—		
(i) human medicine	—	1 200,00
(ii) veterinary medicine	—	900,00
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	500,00	—
(b) in the case of a veterinary medicine or orphan medicine imported into Zimbabwe as a finished product	300,00	—
(c) in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as—		
(i) human medicine	—	1 800,00
(ii) veterinary medicine	—	1 200,00
(d) in any other case—		
(i) human medicine	—	1 200,00
(ii) veterinary medicine	—	900,00
10. Application to export or import an unregistered medicine in terms of section 75 of the Act—		
(a) individual prescription	—	30,00
(b) institutions per medicine—		
(i) hospitals	—	150,00
(ii) non-governmental organisations (NGOs)	—	60,00
(iii) other (wholesale dealers, etc.)	—	600,00
(c) clinical trials per medicine—		
(i) foreign sponsored	10,00	—
(ii) locally sponsored	—	60,00

Item	*Fee* US$	ZWL$
(d) authorisation to import an unregistered veterinary product where—		
(i) no registered alternative is available and an application for registration has been submitted	—	1 800,00
(ii) no application for registration has been submitted	—	3 000,00
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	400,00	—
(ii) category for distribution	400,00	—
(iii) formulation	300,00	—
(iv) stability data	300,00	—
(v) change of additional manufacturer	300,00	—
(vi) batch data	300,00	—
(vii) bioavailability/bioequivalence	300,00	—
(viii) any other matter	250,00	—
(b) in the case of medicine imported into Zimbabwe and which is relabelled or repacked before being sold as a human medicine or veterinary medicine—		
(i) indications	—	1 800,00
(ii) category for distribution	—	1 800,00
(iii) formulation	—	1 200,00
(iv) stability data	—	1 200,00
(v) change of or additional manufacturer	—	1 200,00
(vi) batch data	—	1 200,00
(vii) bioavailability/bioequivalence	—	1 200,00
(viii) any other	—	1 050,00
(c) any other case—		
(i) indications	—	1 200,00
(ii) category for distribution	—	1 200,00
(iii) formulation	—	900,00
(iv) stability data	—	900,00

Item	*Fee*	
	US$	ZWL$
(v) change of or additional manufacturer	—	900,00
(vi) batch data	—	900,00
(vii) bioavailability/bioequivalence	—	150,00
(viii) any other	—	750,00
12. Application to conduct a clinical trial of a medicine—		
(a) funded by a local sponsor—		
(i) human medicine	—	12 000,00
(ii) veterinary medicine	—	6 000,00
(iii) sub-study	—	6 000,00
(iv) operational research study	—	6 000,00
(v) observational study	—	1 200,00
(vi) any other case	—	600,00
(b) funded by a foreign sponsor—		
(i) human medicine phase I study	5 000,00	—
(ii) human medicine phase II study	4 000,00	—
(iii) human medicine phase III or phase IV study	3 000,00	—
(iv) veterinary medicine	1 000,00	—
(v) in any other case	500,00	—
(vi) operational	1 000,00	—
(vii) bioequivalence/bioavailability	500,00	—
(viii) observational	200,00	—
(ix) in any other case	200,00	—
(c) any amendment to original application funded by a local sponsor—		
(i) initial	—	300,00
(ii) subsequent	—	300,00
(d) any amendment to original application funded by a foreign sponsor—		
(i) initial	100,00	—
(ii) subsequent	100,00	—
13. Application to import psychotropic substances	—	300,00
14. Application to export psychotropic substances	—	300,00
15. Application for authorisation to procure, possess, administer or distribute medicine	—	300,00

Item	*Fee* US$	ZWL$
16. Application for a permit to supply veterinary medicines (VMGD)	—	1 200,00
17. Application for any duplicate copy of a current licence or permit	—	180,00
18. Application for a duplicate copy of a certificate of registration—		
(a) in the case of a medicine imported into Zimbabwe as a finished product	100,00	—
(b) in the case of a medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as a human medicine or veterinary medicine	—	300,00
(c) in any other case	—	300,00
19. Application for a copy of a certificate of registration—		
(a) in the case of a medicine imported into Zimbabwe as a finished product	50,00	—
(b) in the case of medicine imported into Zimbabwe and which is relabelled and repackaged before being sold as a human or veterinary medicine	—	180,00
(c) in any other case	—	120,00
20. Application to manufacture a medicine on contract for export or otherwise—		
(a) in the case of a foreign principal	1 500,00	—
(b) in the case of local principal	—	3 000,00
21. Approval of advertisements or promotional material—		
(a) in the case of an imported medicine	—	300,00
(b) in the case of a medicine imported which is relabelled and repackaged before being sold as a finished product	—	300,00
(c) in any other case	—	300,00
22. Any amendment to the original application and additional information for—		
(a) a licence or permit	—	180,00
(b) authorisation to import an unregistered medicine	—	180,00
23. Application for the issue of a certificate of free sale (COFs)	—	900,00

Item	*Fee* US$	ZWL$
24. Application for the issue of a certificate of pharmaceutical product (CCP)	—	900,00
25. Fee for conducting hearings	—	1 800,00
26. Application for issue of a WHO-type GMP certificate	—	900,00
27. The fees specified herein shall not apply to any person or exempted by the Authority.		
28. Laboratory fees levied in terms of section 73A of the Act shall be charged by the Authority on a cost recovery basis		
29. GMP inspection costs shall be charged by the Authority on a cost recovery basis		

Notes

1. *Inspection fees for new premises are part of the application fee.*
2. *Restricted pharmaceutical manufacturing premises where only repackaging and labelling is done.*
3. *Second and subsequent inspections carried out due to unsuccessful initial inspections will attract an inspection fee.*
4. *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).*
5. *The expedited fee in item 7 is for registration of medicines reviewed expeditiously.*
6. *An unregistered specified medicine mentioned in item 9 is commonly referred to as a listed medicine.*
7. *Incomplete applications will attract an amendment fee as stipulated in items 11 and 22.*
8. *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.".*

4. The Medicines and Allied Substances Control (General) (Amendment) Regulations, 2012 (No. 26), published in Statutory Instrument 186 of 2012, is repealed.