GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N$6.00 WINDHOEK - 24 August 2021 No. 7608

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 178 2021

AMENDMENT OF REGULATIONS RELATING TO MEDICINES AND RELATED SUBSTANCES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under section 44(1) of the Medicines and Related Substances Control Act 2003 (Act No. 13 of 2003), after consultation with the Namibia Medicines Regulatory Council and in consultation with the Minister responsible for Finance, I have amended the Regulations Relating to Medicines and Related Substances as set out in the Schedule.

DR. K. SHANGULA
MINISTER OF HEALTH AND SOCIAL SERVICES Windhoek, 6 August 2021

SCHEDULE

Definition

1. In these regulations "the Regulations" means the Regulations Relating to Medicines and Related Substances published under Government Notices No. 178 of 25 July 2008 as amended by Government Notice Nos. 228 of 27 February 2015, 316 of 31 December 2015, 66 of l April 2019, 202 of 22 July 2019 and 219 of 1 September 2020.

Substitution of Annexure XXXVIII of Regulations

2. Annexure XXXVIII to the Regulations after the following Annexure:

"**ANNEXURE XXXVIII**

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

FEES

(Regulation 47)

1.	In respect of an application for registration of a Category A medicine -		
(a)	screening fee		N$1 250-00
(b)	application fee for medicines manufactured in its entirety outside of Namibia:		
	(i)	full assessment	N$6 250-00
	(ii)	Zazibona*	N$7 500-00
	(iii)	WHO pre-qualification collaborative registration procedure	N$7 500-00
	(iv)	based on registration with authorities the Council aligns with	N$7 500-00
(c)	expedited application review fee for medicines manufactured in its entirety outside of Namibia, in addition to the applicable application fee set out in subparagraph (b):		
	(i)	full assessment	N$15 000-00
	(ii)	Zazibona*	N$7 500-00
	(iii)	WHO pre-qualification collaborative registration procedure	N$7 500-00
	(iv)	based on registration with authorities the Council aligns with	N$7 500-00
(d)	application fee for medicines manufactured in its entirety in Namibia:		
	(i)	full assessment	N$5 000-00
	(ii)	Zazibona*	N$7 500-00
	(iii)	WHO pre-qualification collaborative registration procedure	N$7 500-00
	(iv)	based on registration with authorities the Council aligns with	N$ 7 500-00
(e)	expedited application review fee for medicines manufactured in its entirety in Namibia, in addition to the applicable application fee set out in subparagraph (d):		
	(i)	full assessment	N$10 000-00
	(ii)	Zazibona*	N$3 500-00

	(iii)	WHO pre-qualification collaborative registration procedure	N$5 000-00
	(iv)	based on registration with authorities the Council aligns with	N$5 000-00
(f)	annual fee, in respect of the retention of the registration of a medicine, payable after the expiry of 12 months after the date on which the registration of the medicine has been approved by the Council which fee is payable on or before the last working day of March each year:		
	(i)	for a medicine entirely manufactured in Namibia	N$ 750-00
	(ii)	for a medicine imported into Namibia	N$1 300-00
(g)	for a line extension of a medicine*		N$3 125-00
(h)	post-registration amendment submissions (whether approved or not):		
	(i)	request to amend patient information leaflet and professional information for an innovator product which is subject to review of clinical data	N$1 800-00
	(ii)	request to amend patient information leaflet and professional information for a generic product which is not subject to review of clinical data	N$1 800-00
	(iii)	request for addition of API* or FPP* manufacture	N$1 800-00
	(vi)	request for extension of retest or shelf-life (stability data)	N$1 800-00
	(v)	request for change in scheduling status	N$1 800-00 per amendment
	(vi)	changes to the formulation (composition)	N$1 800-00 per product
	(vii)	any other post registration amendment that requires Council approval	N$1 500-00
(i)	transfer of a certificate of registration (whether approved or not)		N$ 850-00
2.	In respect of an application for registration of a Category C medicine -		
(a)	screening fee		N$1 250-00
(b)	application fee for medicines manufactured in its entirety outside of Namibia:		
	(i)	full assessment	N$3 125-00
	(ii)	based on registration with authorities the Council aligns with	N$5000-00
(c)	expedited application review fee for medicines manufactured in its entirety outside of Namibia, in addition to the applicable application fee set out in subparagraph (b):		
	(i)	full assessment	N$7 500-00
	(ii)	based on registration with authorities the Council aligns with	N$5000-00

(d)	application fee for medicines manufactured in its entirety in Namibia:		
	(i)	full assessment	N$2 500-00
	(ii)	based on registration with authorities the Council aligns with	N$3 500-00
(e)	expedited application review fee for medicines manufactured in its entirety in Namibia, in addition to the applicable application fee set out in subparagraph (d):		
	(i)	full assessment	N$3 500-00
	(ii)	based on registration with authorities the Council aligns with	N$2 500-00
(f)	annual fee, in respect of the retention of the registration of a medicine, payable after the expiry of 12 months after the date on which the registration of the medicine has been approved by the Council which fee is payable on or before the last working day of March each year:		
	(i)	for a medicine entirely manufactured in Namibia	N$350-00
	(ii)	for a medicine imported into Namibia	N$625-00
(g)	for a line extension of a medicine*		N$1 875-00
(h)	any post-registration amendment submission that requires Council approval (whether approved or not)		N$1 500-00
(i)	transfer of a certificate of registration (whether approved or not)		N$150-00
3.	In respect of any licence issued in terms of section 31 of the Act		N$1 250-00
4.	In respect of an application in terms of section 31(5)(c) of the Act		N$2 500-00
5.	Permit to import Schedule 3 or 4 (Psychotropics/Narcotics) products		N$50-00 per permit
6.	In respect of advertising (whether approved or not)		N$200-00 per page
7.	In respect of any duplicate of the following documents issued in terms of the Act:		
(a)	licence issued in terms of section 31 of the Act		N$500-00
(b)	import permit for Schedule 3 or 4 (Psychotropics/Narcotics)		N$25-00 per permit
(c)	certificate of registration		N$ 500-00
8.	In respect of an authorisation granted for the use or sale of an unregistered medicine:		
(a)	registered outside Namibia but not registered in Namibia for the indication applied for		N$4 000-00
(b)	not registered elsewhere for the indication applied for		N$6 000-00

(c)	not registered at all, but forming part of a clinical trial	N$6 000-00
(d)	registered in Namibia, but forming part of a clinical trial for purposes of other indications	N$2 000-00
(e)	prescribed for a specific patient (human or animal)	N$ 50-00
9.	In respect of an application for the registration of premises used for the manufacturing of medicines	N$1 250-00
10.	For the performance of an inspection to determine whether premises comply with WHO current good manufacturing practices:	
(a)	in respect of the premises of a manufacturer of medicines in Namibia	N$10 000-00 per block
(b)	in respect of the premises of a manufacturer of medicines outside Namibia	N$50 000-00 per block
(c)	in respect of desk review	N$25 000-00 per site
(d)	in respect of remote inspection	N$40 000-00 per block
(e)	for the performance of an expedited inspection to determine whether premises comply with WHO current good manufacturing practices:	
	(i) in respect of the premises of a manufacturer of medicines in Namibia	N$20 000-00 per block
	(ii) in respect of the premises of a manufacturer of medicines outside Namibia	N$100 000-00 per block
11.	Fees relating to appeals against any decisions of Council	N$20 000-00

* Note:

For the purposes of this Annexure:

“API” means active pharmaceutical ingredient;

“FPP” means finish pharmaceutical product;

“line extension of a medicine” means any additional strength to the pharmaceutical form, excluding novel dosage forms or delivery systems;

“application fees, expedited application review fees and post-registration amendement fee related to the FPP for a line extension of a medicine shall be half the fee of the initial FPP strentgh”; and

“Zazibona” means the Southern African Development Community (SADC) collaborative procedure for joint assessment of medicines.”.