



PHARMACY, MEDICINES & POISONS BOARD

CIRCULAR No. 01-FIN/2014 FEES STRUCTURE

The fees structure outlined in the tables below has been passed by the Pharmacy, Medicines and Poisons Board (PMPB) and is effective from 1st July 2014

1. FEES FOR REGISTRATION FOR DRUGS, RENEWAL, RETENTION, AND AMMENDMENT

REGISTRATION/RENEWAL/RETENTION/NOTIFICATION/AMMENDMENTS	Fees in US\$ and MK where indicated
A. REGISTRATION OF PRODUCTS	
(i) Human/Veterinary products	US \$1000
(ii) Imported Human Nutritional Supplements	US \$500
(iii) Imported Vet Nutritional Supplements	US \$500
(iv) Locally manufactured medicine registration (LSM)	MK150,000
(v) Registration Traditional (Herbal) Medicines	US \$500
(vi) Registration Traditional (Herbal) Medicines	MK50,000
(vi) Registration of locally repacked foreign product	US \$300
B. ANNUAL RETENTION FEES OF PRODUCTS	
(i) Human/Veterinary products	US \$500
(ii) Traditional (Herbal) Medicines (foreign)	US \$300
(iii) Imported Human Nutritional Supplement	US \$200
(iv) Imported Vet Nutritional Supplement	US \$200
(vi) Traditional (Herbal) Medicines	MK30,000
(v) Locally manufactured medicine retention (LSM)	MK75,000
<p>Note: Products not retained for Previous years will have to pay for TWO YEARS before re-instatement on the Register.</p>	
C. FEES FOR AMENDMENTS	
(i) AMENDMENT OF HUMAN/VET PRODUCTS	
Major Amendments; i.e Indications, formulation, Strength, Manufacturing site & Manufacturer	US \$300
Minor Amendments; i.e Flavour, Colour or Artwork	US \$100
Notification; i.e Change of Pack Size	US \$50

(ii) AMENDMENT OF HERBAL PRODUCTS	
Major Amendments; i.e Indications, formulation, Strength, Manufacturing site & Manufacturer	US \$150
Minor Amendments; i.e Flavour, Colour or Artwork	US \$75
Notification; i.e Change of Pack Size	US \$40
(iii) AMENDMENT OF LOCALLY MANUFACTURED PRODUCTS	
Major Amendments; i.e Indications, formulation, Strength, Manufacturing site & Manufacturer	MK40,000
Minor Amendments; i.e Flavour, Colour or Artwork	MK20,000
Notification; i.e Change of Pack Size	MK10,000

2. FEES FOR A PHARMACEUTICAL MANUFACTURING LICENCE

a) Fees for operating licences and certificate of suitability of premises

	Licence Category	APPLICATION AND REGISTRATION FEES	ANNUAL RETENTION FEES
		Total (MK)	Total (MK)
i)	Manufacture of external preparation OR Oral liquid preparations	250,500	150,000
ii)	Manufacture of external preparations AND/OR Oral liquid preparation	350,500	200,000
iii)	Manufacture of sterile preparations AND/OR other types of dosage forms	500,500	250,000
iv)	Primary packaging	150,500	100,000
v)	Secondary packaging	100,500	75,000

b) Re-inspection fees for the above categories (after failure to comply with PMPB standards)

i) Manufacturers in category d and e		MK100,000
ii) Manufacturers in category a, b, and c		MK120,000

c) Application to amend a manufacturing licence

i) With site inspection (for manufacturer)	MK80,000
ii) With site inspection (for packaging activities)	MK50,000
iii) Without inspection	MK30,000

3. FEES FOR A WHOLESALE PHARMACY

Item	APPLICATION AND REGISTRATION FEES		ANNUAL RETENTION FEES	
	Urban	Rural	Urban	Rural
a). Inspection				
b). Suitability of premises				
c). Operating Licence				
Total Fees payable	MK350,500	MK200,500	MK200,000	MK150,000

4. FEES FOR A RETAIL PHARMACY

Item for fees payment	APPLICATION AND REGISTRATION FEES		ANNUAL RETENTION FEES
	Urban	Rural	URBAN / RURAL
a). Inspection			
b). Suitability of premises			
c). Operating Licence			
Total Fees payable	MK150,500	MK120,500	MK100,000

5. FEES FOR A MEDICINE STORE

ITEM	APPLICATION AND REGISTRATION FEES			ANNUAL RETENTION FEES		
	City	Municipal	Rural	City	Municipal	Rural
a). Inspection						
b). Suitability of premises						
c). Operating Licence						
Total Fees payable	MK55,500	MK45,500	MK35,500	MK40,000	MK30,000	MK20,000

6. FEES FOR DISPENSING LICENCES

ITEM	APPLICATION AND REGISTRATION FEES			ANNUAL RETENTION FEES		
	City	Municipal	Rural	City	Municipal	Rural
a). Clinic/Hospital WITH Admission Facilities	MK100,500	MK50,500	MK30,500	MK75,000	MK50,000	MK50,000
b). Clinic/Hospital WITHOUT Admission Facilitates	MK50,500	MK40,500	MK30,500	MK35,000	MK30,000	MK30,000
Total Fees payable	MK50,500	MK40,500	MK30,500	MK40,000	MK30,000	MK20,000

7. FEES FOR REGISTRATION AND RETENTION OF PHARMACY PERSONNEL

	Nature of task	Fees payable in MK
a).	Pharmacist Local Registration (plus internship)	25,500
b).	Pharmacist Local Annual Retention Fees	15,000
c).	Pharmacist Foreign Registration	US \$750
d).	Pharmacist Foreign Annual Retention Fees	US \$400
e).	Pharmacy Technician Local Registration	12,500
f).	Pharmacy Technician Local Annual Retention Fees	7,500
g).	Pharmacy Technician Foreign Registration	US \$ 500
h).	Pharmacy Technician Foreign Annual Retention Fees	US \$ 200
i).	Pharmacy Assistant Local Registration	10,500
j).	Pharmacy Assistant Local Annual Retention Fees	5,000

8. FEES FOR IMPORTATION OF DRUGS

	Description	Fees
a).	Annual Import or Export Permit	MK300,000
b).	Provisional Import or Export Permit (<i>Per consignment</i>)	MK100,000
c).	Verification fees for commercial consignments and donations to commercial organizations and Government Ministries, Departments, Projects, Programmes and Institutions	1.0%
d).	Verification for unregistered drugs from authorized and approved sources	5.0%
e).	(a) Verification fees for donations to non-profit making charitable NGOs (0 to \$1,000=)	MK25,000
	(b) Verification fees for donations to non-profit making charitable NGOs (\$1,001= to \$5,000)	MK50,000
	(c) Verification fees for donations to non-profit making charitable NGOs (over \$5000)	75,000
f).	Verification for consignments for disasters, outbreaks, vaccines, raw materials	Exempted
g).	<i>Fine for a consignment of drugs imported without prior authorization by PMPB and/or arrives at the port of entry before the product is registered or amendments are applied for and approved*</i>	US \$1,000

**Such consignments shall only be inspected for release on condition that the amendments have been approved and the fine has been paid.*

9. FEES FOR ANALYSIS OF SAMPLES IN A LABORATORY

	Description	Fees
a).	Routine drug analysis of one batch in the PMPB Lab	US \$300
b).	Male Latex Condoms per batch	US \$50
c).	Long Lasting Insecticide Treated Nets (LLINs), per batch of size up to 30,000 nets and every 30,000 nets	US \$200
d).	Samples analyzed at laboratories outside PMPB	Cost + 10% service charge
e).	Re-analysis of a sample at owner's or importer's request	US \$800
f).	Detailed Certificate of Analysis at the request of the owner/importer	US \$350
g).	Analysis for gloves	US \$150
h).	Analysis for more than three batches	US\$ 50 per batch
i).	Import/Export Analysis of Medicine	0.3% of invoice total value

10. FEES FOR cGMP INSPECTION FOR FOREIGN PLANTS

a) On site GMP inspection per manufacturing site

	Processes at the site	Within SADC or COMESA	Within the rest of Africa	Outside Africa (Asia/Europe/America/New Zealand/Australia)
	Site with all processes at one site for 5 product lines	US \$3,000	US \$4,000	US \$5,000
ii).	Any additional production line	\$1,000 per line		
iii).	For products moving through several sites, additional Sites in the same country as main site:			
	Warehousing of raw materials up to finished bulk product	US \$1,500	US \$2,000	US \$3,000
iv)	Final packaging, quality control and final release	US \$1,000	US \$1,500	US \$2,000
v)	Quality control and final release	US \$500	US \$750	US \$1,000

11. FEES FOR CLINICAL TRIALS (HUMAN AND VETERINARY)

	Stage of Clinical Trial	Product	Fees in US\$
a).	Regardless of Phase	Registered or Unregistered (Application and Registration)	US\$4,000
b).	Regardless of Phase	Annual Renewal	US\$1,500
c).	Amendments to Clinical Trial Application		US\$200
d).	Fees for Field Trial (Veterinary)		
	All phases		US\$1,000

12. FEES FOR PMPB PUBLICATIONS

	Nature of publication	Fees in MK
a)	Set of Statutes and Statutory Instruments	25,000
b).	Dangerous Drug Register (DDA) Register	5,000
c).	List of licensed drug outlets/wholesalers/manufacturers	25,000
d).	GMP Audit Checklist or Set of PMPB Guidelines	15,000
e).	Drug Register (Human)	15,000
f).	Drug Register (Veterinary)	15,000
g).	Pharmacist Register Book	2,000
h).	PMPB Act	1,500
i).	PMPB Regulation	2,000
J).	List of Registered Medicines	5,000
k).	Code of Ethics	1,000
l).	Guidelines to Licensing	1,000

13. FEES FOR VETTING DRUG PROMOTIONAL MATERIALS

	Nature of task	Fees in MK
a).	Screening of Promotional materials per language:	
	(i) Written materials	25,000
	(ii) Audio/video + written Scripts	50,000
	(iii) Posters/Bill boards on any medium including internet	50,000
	(iv) Posters on Vehicles	20,000
	(v) T-shirts	10,000
	(vi) Other materials e.g. caps, wall clocks, watches, umbrellas, bags etc	10,000
b).	Organising a launch / a symposium	50,000
c).	Participating in exhibitions	25,000
d).	Miscellaneous:	75,000
	(i) Roadside shows	
	(ii) Sponsorship of functions	

14. OTHER MISCELLANEOUS SERVICES

	Nature of task	Fees in MK
a).		
	(i) Supervision of Specialised Task of Drug Destruction	40,000
	(ii) Narcotics Licences	15,000

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