

GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 7 OF 2008

The Pharmaceutical Act, 2004
(Act No. 14 of 2004)

The Pharmaceutical (Fees) Regulations, 2008

IN EXERCISE of the powers contained in sections *twenty-nine, forty-eight* and *sixty-four* of the Pharmaceutical Act, 2004, the following Regulations are hereby made:

1. These Regulations may be cited as the Pharmaceutical (Fees) Regulations, 2008. Title
2. The fees set out in the Schedule to these Regulations shall be the prescribed fees for the matters mentioned therein. Prescribed fees

SCHEDULE
(Regulation 2)

PRESCRIBED FEES

PART I

Retail or Hospital Pharmacy

	<i>Fee units</i>
1. Application for registration certificate to operate a retail pharmacy	5,000
2. Application for registration certificate to operate a hospital pharmacy	2,834
3. Inspection fee relating to application to operate a retail or hospital pharmacy	4,223
4. Application for change of premises	2,500
5. Re-inspection of retail or hospital pharmacy	2,500
6. Application for renewal of a registration certificate	6,667
7. Application for renewal of hospital pharmacy registration certificate	4,445

PART II
IMPORT OR WHOLESALE DEALER'S LICENCE

	<i>Fee units</i>
1. Application for import licence	5,556
2. Application for wholesale dealer's licence	5,000
3. Inspection fees relating to an application for a wholesale dealer's licence	4,223
4. Application for renewal of import licence	5,000
5. Application for renewal of wholesale dealer's licence	7,778
6. Application for change of premises for wholesale dealing	4,445
7. Re-inspection fee for wholesale dealer	2,778

PART III
MANUFACTURER'S LICENCE

	<i>Fee units</i>
1. Application for licence to manufacture	10,000
2. Inspection fee - local manufacturer	20,000
3. Application for renewal of manufacturer's licence	10,000
4. Application for change of premises	5,000
5. Issue of licence to manufacture - 5 years	50,000
6. Application for manufacturer's licence—	
(a) to repackaging medicines	10,000
(b) inspection	11,112
(c) annual renewal	7,778
(d) re-inspection fee	5,000
(e) change of premises	4,445

PART IV
OTHER SERVICES

	<i>Fee units</i>
1. Screening fees for import authorisation	2% of invoice value in kwacha
2. Screening fees for export authorisation	278
3. Application for clinical trial certificate	2,778
4. Application for product licence of an investigational product	16,889
5. Application for issue of GMP certificate	2,223
6. Application for import of narcotics and psychotropic substances	223
7. Minor amendments to dossier or labeling	1,389
8. Major amendments to dossier	2,778
9. Issue of certificate of a pharmaceutical product (CPP)	278
10. Amendment to product licence imported	1,389
11. Amendments to licences and certificates locally manufactured and locally packaged	1,389

12. Amendments to import or export authorisation .	1% of invoice value in kwacha
13. Application for approval of advertisement, promotion, launch, etc	5,556
14. Application for fast track registration	18,334
15. Inspection for good clinical practice	29,445
16. Inspection and supervision of disposal of expired products	500per day
17. Application by an individual for importation or exportation of a medicine for personal use	278
18. Application for change of category of distribution	5,556
19. Inspection of premises for issue of a GMP certificate	2,000
20. Application by an authorised institution for the importation of small quantities of drugs for specific patient(s)	2,500
21. Application for registration for import of a medicine for supply through government public tenders. (Where the medicine is required to be maintained on the market, a fresh application fee shall be paid.)	4,223
22. Replacement of lost document, licence or certificate	1,389
23. Application for restoration of a product licence	16,667

PART V
PRODUCT REGISTRATION

	<i>Registration Fee units</i>	<i>Retention Fee units</i>
1. <i>Human medicines</i>		
Application for registration—		
(a) Imported as finished product;	21,112	14,056
(b) Packaged in Zambia	18,334	14,056
(c) Locally manufactured	4,223	2,778
(d) New chemical entities	23,334	11,278
(e) Biological including vaccines	23,334	11,278

2. <i>Veterinary medicines</i>		
(a) Imported as a finished product	12,778	10,556
(b) Packaged in Zambia	8,445	10,556
(c) Locally manufactured	2,834	2,223
3. <i>Herbal Medicinal product</i>		
(a) Imported as a finished product	21,112	14,056
(b) Herbal medicinal product packaged in Zambia	12,778	10,566
(c) Herbal medicine locally manufactured	4,223	2,778
4. <i>Allied substances</i>		
(a) Application for restoration of a product licence	16,667	14,056
(b) Registration of an allied substance	4,223	2,778

Note: 1 fee unit = K180.00

DR B. CHITUWO,
Minister of Health

LUSAKA
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