

ZAMBIA MEDICINES REGULATORY AUTHORITY

SCHEDULE OF FEES AS PER SI No. 38

PRESCRIBED FEES

PART I

FEES PAYABLE BY AREA

No	Description of Fees	Fee units	Amount 30Ngwee/feeunit
(1) Hospital, Pharmacy and Retail			
<i>Towns with City or Municipal Councils</i>			
a	Application for grant of certificate of registration	15,833	4,750.00
b	Re-inspection of premises to operate a retail pharmacy	12,000	3,600.00
c	Annual Returns or no change returns for retail pharmacy	8,000	2,400.00
d	Application for change of premises for Retail Pharmacy	15,833	4,750.00
e	Application for change of premises for Retail Pharmacy		
	(i) within the hospital	2,900	870.00
	(ii) new premises	15,833	4,750.00
<i>Towns with District councils and other areas</i>			
a	Application for grant of certificate of registration	7,917	2,375.00
b	Re-inspection of premises to operate a retail pharmacy	6,000	1,800.00
c	Annual Returns or no change returns for retail pharmacy	5,567	1,670.00
d	Application for change of premises for Retail Pharmacy	7,917	2,375.00
e	Application for change of premises for Retail Pharmacy		
	(i) within the hospital	1,450	435.00
	(ii) new premises	7,917	2,375.00

(2) Dispensing Certificate

Towns with City or Municipal Councils

a	Application for issue of dispensing certificate	4,000	1,200.00
b	Re-inspection of a facility with a dispensing certificate	2,500	750.00
c	Renewal for the dispensing certificate	2,500	750.00
d	Application for change of premises for dispensing certificate	4,000	1,200.00

Towns with District councils and other areas

a	Application for issue of dispensing certificate	2,000	600.00
b	Re-inspection of a facility with a dispensing certificate	1,167	350.00
c	Renewal for the dispensing certificate	1,167	350.00
d	Application for change of premises for dispensing certificate	2,000	600.00

(3) Agro-Veterinary Shop

Towns with City or Municipal Councils

a	Application for issue of an Agro – veterinary Shop Permit Class I	15,833	4,750.00
b	Re-inspection fee for grant of an Agro – veterinary Shop Permit Class I	12,000	3,600.00
c	Renewal of the Agro – Veterinary Shop Permit- Class I	12,000	3,600.00
d	Change of premises of the Agro – Veterinary Shop Permit- Class I	15,833	4,750.00

Towns with District councils and other areas

a	Application for issue of an Agro – veterinary Shop Permit Class I	7,917	2,370.00
b	Re-inspection fee for grant of an Agro – veterinary Shop Permit Class I	6,000	1,800.00
c	Renewal of the Agro – Veterinary Shop Permit- Class I	6,000	1,800.00
d	Change of premises of the Agro – Veterinary Shop Permit- Class I	7,917	2,370.00

Agro-Veterinary Shop

Towns with City or Municipal Councils

a	Application for issuance of Agro-Veterinary Shop Permit-Class 2	6,833	2,050.00
b	Re-inspection fee for grant of an Agro – veterinary Shop Permit Class2	4,000	1,200.00
c	Renewal of the Agro – Veterinary Shop Permit- Class 2	4,000	1,200.00
d	Change of premises of the Agro – Veterinary Shop Permit- Class 2	6,833	2,050.00

Towns with District councils and other areas

a	Application for issuance of Agro-Veterinary Shop Permit-Class 2	3,500	1,050.00
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b	Re-inspection fee for grant of an Agro – veterinary Shop Permit Class2	2,000	600.00
c	Renewal for Agro-Veterinary Shop Permit-Class 3	2,000	600.00
d	Change of premises of the Agro – Veterinary Shop Permit- Class 2	3,500	1,050.00

Agro-Veterinary Shop

Towns with City or Municipal Councils

a	Application for issuance of Agro-Veterinary Shop Permit-Class 3	4,000	1,200.00
b	Re-inspection	2,500	750.00
c	Renewal for Agro-Veterinary Shop Permit-Class 3	4,000	1,200.00
d	Application for change of premises	4,000	1,200.00

Towns with District councils and other areas

a	Application for issuance of Agro-Veterinary Shop Permit-Class 3	2,000	600.00
b	Re-inspection	1,167	350.00
c	Renewal for Agro-Veterinary Shop Permit-Class 3	2,000	600.00
d	Application for change of premises	2,000	600.00

(4) Health Shop

Towns with City or Municipal Councils

a	Application for issue of health shop permit	6,833	2,050.00
b	Re-inspection of premises to operate a health shop	4,000	1,200.00
c	Renewal for the health shop permit	4,000	1,200.00
d	Application for change of premises for health shop	6,833	2,050.00

Towns with District councils and other areas

a	Application for issue of health shop permit	3,500	1,050.00
b	Re-inspection of premises to operate a health shop	2,000	600.00
c	Renewal for the health shop permit	2,000	600.00
d	Application for change of premises for health shop	3,500	1,050.00

(5) Pharmaceutical License – Wholesale

Towns with City or Municipal Councils

a	Application for grant of pharmaceutical license - wholesale	15,367	4,610.00
b	Re-inspection of premises for pharmaceutical license – Wholesale	11,533	3,460.00
c	Renewal for pharmaceutical license – wholesale	11,533	3,460.00
d	Application for change of premises for wholesale	15,367	4,610.00

Towns with District councils and other areas

a	Application for grant of pharmaceutical license - wholesale	7,700	2,310.00
b	Re-inspection of premises for pharmaceutical license – Wholesale	5,867	1,760.00
c	Renewal for pharmaceutical license – wholesale	5,867	1,760.00
d	Application for change of premises for wholesale	7,700	2,310.00

PART II

FEE PAYABLE IRRESPECTIVE OF AREA

1. Pharmaceutical Licence

(a) Complete Manufacture

(i)	Application for grant of pharmaceutical license	64,533	19,360.00
(ii)	Re-inspection of premises for pharmaceutical license – manufacture of medicine	47,867	14,360.00
(iii)	Re-locating to new premises	64,533	19,360.00
(iv)	Inspection of Additional production line	25,400	7,620.00
(v)	Inspection of Additional production block	47,867	14,360.00
(vi)	Renewal for pharmaceutical license – manufacture	47,867	14,360.00

(b) Primary Repackage of Medicine

(i)	Application for grant of pharmaceutical license	35,400	10,620.00
(ii)	Re-inspection of premises for pharmaceutical license – repackage of medicine	24,400	7,320.00
(iii)	Re-locating to new premises	35,400	10,620.00
(iv)	Inspection of Additional /Modification of production line	12,200	3,660.00
(v)	Inspection of Additional /Modification of production block	25,400	7,620.00
(vi)	Renewal for pharmaceutical license – repackage of medicine	25,400	7,620.00

(c) Secondary Repackage of Medicine

(i)	Application for grant of pharmaceutical license	17,700	5,310.00
(ii)	Re-inspection of premises for pharmaceutical license – repackage of medicine	12,200	3,660.00
(iii)	Inspection of Additional /Modification of production line	7,000	2,100.00

(iv).	Inspection of Additional /Modification of production block	12,200	3,660.00
(v)	Renewal for pharmaceutical license – repackage of medicine	12,200	3,660.00
(d) Local Manufacture of Natural Remedies			
(i)	Application for grant of pharmaceutical license	35,400	10,620.00
(ii)	Re-inspection of premises for pharmaceutical license – repackage of medicine	24,400	7,320.00
(iii)	Inspection of Additional /Modification of production line	25,400	7,620.00
(iv).	Inspection of Additional /Modification of production block	25,400	7,620.00
(v)	Renewal for pharmaceutical license – repackage of medicine	25,400	7,620.00
(vi)	Re-location or export permit	25,400	7,620.00

2. Import and Export Permit

a	Importation of medicines for personal use	333	100.00
b	Importation of medicines in small quantities	2,500	750.00
c	Fees for importation of raw materials and packaging materials	333	100.00
d	Fees for import or export permit	333	100.00

3. Marketing Authorisation of Locally Manufactured or packaged medicines or allied substances)

a	Locally Manufactured Medicines		
(i)	Human Medicines	16,667	5,000.00
(ii)	Veterinary Medicines	16,667	5,000.00
b	Locally Packaged Medicines		
(i)	Human Medicines	36,667	13,328.00
(ii)	Veterinary Medicines	25,867	7,760.00
c	Allied Substances	5,000	1,500.00
d	Evaluating Additional Information for an Application of a Locally Manufactured Product supplied with Inadequate Technical Information (quality safety or efficacy)	5,667	1,700.00
e	Annual Retention Fees for Locally Manufactured Medicines and Allied Substances		
(i)	Human Medicines	8,333	2,500.00
(ii)	Veterinary Medicines	8,333	2,500.00
(iii)	Allied Substances	3,333	1,000.00
f	Renewal of Marketing Authorisation for locally manufactured Medicines or Allied Substances		
(i)	Human Medicines	11,667	3,500.00
(ii)	Veterinary Medicines	10,000	3,000.00
(iii)	Allied Substances	4,000	1,200.00
g	Amendment Fees for Medicines and Allied Locally Manufactured Products		
(i)	Minor amendment	1,333	400.00
(ii)	Major amendment	6,500	1,950.00

4. Advertising and Promotion of Medicines and Allied Substances

a	Advertising medicines to the general public	16,667	5,000.00
b	Promotional medicines to the health care professional fees	3,333	1,000.00
c	Exhibition of medicines at a public event fees	6,667	2,000.00

5. Clinical Trials Involving a Locally Manufactured Investigational Product

a	Clinical Trial Certificate involving Investigational Products without Marketing Authorisation		
(i)	Human	48,333	14,500.00
(ii)	Veterinary	34,333	10,300.00
b	Clinical Trial Certificate involving Investigational Products with Marketing Authorisation		
(i)	Human	46,667	14,000.00
(ii)	Veterinary	32,667	9,800.00

Good Clinical Practice Inspection for Local Sites

(i)	GCP inspection local sites	50,000	15,000.00
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7. Other fees

a	Preclearance Fees for Quality Assurance (QA) of imports for commercial consignments, Government ministries departments, Programs projects and similar institutions		1.5% of FOB invoice value
b	Preclearance Fees for Quality Assurance (QA) of imports for unregistered medicines and Allied substance for commercial consignments, Government Ministries Departments, Programs projects and Similar institutions		5% of FOB invoice value
c	Preclearance Fees for Quality Assurance (QA) of imports for Donations		1% of FOB invoice value
d	Preclearance Fees for Quality Assurance (QA) of imports for Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates		1% of FOB invoice value
e	Amendment to licences, certificates and permits	1,500	450.00
f	Loss of licences, certificates and permits	1,500	450.00
g	Transfer of licences, certificates and permits	1,500	450.00
h	Issue of Certificate of a Pharmaceutical Product(CPP)	333	100.00
i	Application for import of Narcotic drugs and psychotropic substances	333	100.00
j	Inspection of premises for issue of a GMP certificate (local Manufacture)	20,000	6,000.00
k	Inspection and supervision for disposal of expired products	3,333	1,000.00
l	Fast track fees		Double the applicable MA applicable fee
m	Restoration of Marketing Authorisation Medicines		
(i)	Medicines	20,000	6,000.00
(ii)	Allied Substances	4,000	1,200.00
n	Inspection of Register	167	50.00
o	Late submission of application for renewal of marketing authorisation in respect of locally manufactured medicines and allied substances	33 per day application is late	10.00

**PART III
FEES PAYABLE IN US DOLLARS**

1. Application for Marketing Authorisation of Human Medicines Imported as Finished Products

a	Generics		US\$ 2,000.00
b	New Chemical Entities		US\$ 2,800.00
c	Biologicals		US\$ 2,800.00
d	Abridged Applications		US\$ 1,700.00

2. Application for Marketing Authorisation of Veterinary Medicines Imported as Finished Products

a	Generics		US\$ 1,750.00
b	New Chemical Entities		US\$ 2,100.00
c	Biologicals		US\$ 2,100.00
d	Abridged applications		US\$ 1,550.00

3. Application for Marketing Authorisation Allied Substances Imported as Finished Products

a	Allied Substances		US\$ 500
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4. Evaluating Additional Information for an Application Imported as Finished Products

a	Inadequate Technical Information (quality safety or efficacy)		US\$400.00
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5. Annual Retention Fees for Medicines or Allied Substances Imported as Finished Products

a	Human Medicines Generics		US\$ 800.00
b	Human Medicines NCEs		US\$ 800.00
c	Biologicals		US\$ 800.00
d	Veterinary Medicines		US\$ 700.00
e	Allied Substances		US\$ 200.00

6. Renewal of Marketing Authorisation for Medicines or Allied Substances Imported as Finished Products

a	Human Medicines Generics		US\$ 1,200.00
b	Human Medicines NCEs		US\$ 1,200.00
c	Biologicals		US\$ 1,200.00

d	Veterinary Medicines		US\$ 1,000.00
e	Allied Substances		US\$ 350.00
f	Late submission of application for renewal of marketing authorisation in respect of imported medicines or allied substances		5.00

7. Amendment Fees for Medicines and Allied Substances Imported as Finished Products

a	Minor amendment		US\$ 100.00
b	Major amendment		US\$ 500.00

8. Good Manufacturing Practices Inspection for Foreign-Based Manufacturers in Support of Applications for Marketing

122.	Full site: Southern Africa		US\$ 3,500.00
123.	Full site: Rest of Africa		US\$ 5,000.00
124.	Full site: Far East/Asia		US\$ 6,500.00
125.	Full site: Europe, America and Australia		US\$ 7,500.00
126.	Additional production line		US\$ 1,500.00
127.	Fees for GMP documents evaluation (desk Audits) per manufacturing site		US\$ 3,500.00

9. Good Manufacturing Practices Inspection for Foreign-Based Manufacturers in Support of Applications for Marketing

a	Each additional site such as warehousing for raw materials, final packaging, quality control and final release		US\$ 1,500.00
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10. Clinical Trials Involving Imported Investigational Products

a	Human Clinical Trial Certificate involving Investigational Products without Marketing Authorisation		US\$ 3,000.00
b	Human Clinical Trial Certificate involving Investigational Products with Marketing Authorisation		US\$ 2,500.00
c	Veterinary Clinical Trial Certificate involving Investigational Products without Marketing Authorisation		US\$ 2,100.00
d	Veterinary Clinical Trial Certificate involving Investigational Products with Marketing Authorisation		US\$ 2,000.00
e	Amendment of clinical trial certificate involving an imported investigational product		
(i)	Minor amendment		100.00
(ii)	Major amendment		500.00

11. Good Clinical Practice Inspection Foreign based Bioequivalence Sites (Part VI, Section 52)

a	Full site: Southern Africa		US\$ 3,500.00
b	Full site: Rest of Africa		US\$ 5,000.00
c	Full site: Far East/Asia		US\$ 6,500.00
d	Full site: Europe, America and Australia		US\$ 7,500.00