GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 38 OF 2016

The Medicines and Allied Substances Act, 2013

(Act No. 3 of 2013)

The Medicines and Allied Substances (Fees) Regulations, 2016

IN EXERCISE of the powers contained in sections *nineteen, thirty-nine* and *sixty-nine* of the Medicines and Allied Substances Act, 2013, the following Regulations are made:

Title

1. These Regulations may be cited as the Medicines and Allied Substances (Fees) Regulations, 2016.

Prescribed fees

2. The fees set out in the Schedule are prescribed for the matters specified therein.

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K16.00 each.

SCHEDULE

(*Regulation* 2)

PRESCRIBED FEES

PART I

FEES PAYABLE BY AREA

No.	*Item*	*Fee Units*	
		City or Municipal Councils	*Other District Councils*
1.	**Hospital, Pharmacy and Retail**		
	(a) Application for certificate of registration	15,833	7,917
	(b) Re-inspection of premises in relation to an application for a certificate of registration	12,000	6,000
	(c) Annual returns or no change returns	8,000	5,567
	(d) Application for change of premises for retail pharmacy	15,833	7,917
	(e) Application for change of location for hospital pharmacy -		
	(i) within the hospital premises	2,900	1,450
	(ii) new premises	15,833	7,917
2.	**Dispensing Certificate**		
	(a) Application for dispensing certificate	4,000	2,000
	(b) Re-inspection of a facility in relation to an application for a dispensing certificate	2,500	1,167
	(c) Renewal of dispensing certificate	2,500	1,167
	(d) Application for change of premises for dispensing certificate	4,000	2,000
3.	**Agro-Veterinary Shop**		
	(a) Application for agro-veterinary shop permit-		
	(i) Class 1	15,833	7,917
	(ii) Class 2	6,833	3,500
	(iii) Class 3	4,000	2,000
	(b) Re-inspection of premises in relation to an application for an agro-veterinary shop permit -		
	(i) Class 1	12,000	6,000
	(ii) Class 2	4,000	2,000
	(iii) Class 3	2,500	1,167
	(c) Renewal of agro-veterinary shop permit-		
	(i) Class 1	12,000	6,000
	(ii) Class 2	4,000	2,000
	(iii) Class 3	4,000	2,000
	(d) Application for change of premises for agro-veterinary shop-		
	(i) Class 1	15,833	7,917
	(ii) Class 2	6,833	3,500
	(iii) Class 3	4,000	2,000

4.	**Health Shop**		
	(a) Application for health shop permit	6,833	3,500
	(b) Re-inspection of premises in relation to an application for a health shop	4,000	2,000
	(c) Renewal of health shop permit	4,000	2,000
	(d) Application for change of premises for health shop	6,833	3,500
5.	**Pharmaceutical Licence (wholesale)**		
	(a) Application for pharmaceutical licence	15,367	7,700
	(b) Re-inspection of premises in relation to an application for a pharmaceutical licence	11,533	5,867
	(c) Renewal for pharmaceutical licence	11,533	5,867
	(d) Application for change of premises	15,367	7,700

PART II

FEES PAYABLE IRRESPECTIVE OF AREA

No.	*Item*	*Fee Units*
1.	**Pharmaceutical Licence**	
	(a) **Complete Manufacture**	
	(i) Application for pharmaceutical license	64,533
	(ii)Re-inspection of premises in relation to an application for a pharmaceutical licence	47,867
	(iii) Re-locating to new premises	64,533
	(iv) Inspection of additional production line	25,400
	(v) Inspection of additional production block	47,867
	(vi) Renewal of pharmaceutical licence	47,867
	(b) **Primary Repackage of Medicine**	
	(i)Application for pharmaceutical licence35,400	
	(ii) Re-inspection of premises in relation to an application for a pharmaceutical license	24,400
	(iii) Re-locating to new premises	35,400
	(iv) Inspection of additional/modification of production line	12,200
	(v) Inspection of additional/modification of production block	25,400
	(vi) Renewal of pharmaceutical license	25,400
	(c) **Secondary Repackage of Medicine**	
	(i) Application for pharmaceutical licence	17,700
	(ii) Re-inspection of premises in relation to an application for a pharmaceutical licence	12,200
	(iii) Inspection of additional/modification of production line	7,000
	(iv) Inspection of additional/modification of production block	12,200
	(v) Renewal of pharmaceutical license	12,200
	(d) **Local Manufacture of Natural Remedies**	
	(i) Application for pharmaceutical licence	35,400

	(ii) Re-inspection of premises in relation to an application for a	24,400
	(iii) Inspection of additional or modification of production line pharmaceutical license	25,400
	(iv) Inspection of additional or modification of production block	25,400
	(v) Renewal of pharmaceutical license	25,400
	(vi) Re-location to new premises	25,400
2.	**Import and Export Permits**	
	(a) Importation of medicines for personal use	333
	(b) Importation of medicines in small quantities	2,500
	(c) Fees for importation of raw materials (APIs and Excipients)	333
	(d) Fees for import or export permit	333
3.	**Marketing Authorisation for locally manufactured or packaged medicines or allied substances**	
	(a) Locally Manufactured Medicines -	
	(i) human	16,667
	(ii) veterinary	16,667
	(b) Locally Packaged Medicines -	
	(i) human	36,667
	(ii) veterinary	25,867
	(c) Allied Substances	5,000
	(d) Evaluation of additional information where supplied with application for marketing authorisation - inadequate technical information (quality safety or efficacy)	5,667
	(e) Annual retention fees	
	(i) human medicines	8,333
	(ii) veterinary medicines	8,333
	(iii) allied substances	3,333
	(f) Renewal of marketing authorisation	
	(i) human medicines	11,667
	(ii) veterinary medicines	10,000
	(iii) allied substances	4,000
	(g) Amendment of marketing authorisation:	
	(i) minor amendment	1,333
	(ii) major amendment	6,500
4.	**Advertising and Promotion of Medicines and Allied Substances**	
	(a) Advertising medicines to the general public	16,667
	(b) Promotional medicines to the health care professional fees	3,333
	(c) Exhibition of medicines at a public event fees	6,667
5.	**Clinical Trials involving a Locally Manufactured Investigational Product**	
	(a) Clinical trial certificate involving investigational products without marketing authorization -	
	(i) human	48,333

	(ii) veterinary	34,333
	(b) Clinical trial certificate involving investigational products with marketing authorisation	
	(i) human	46,667
	(ii)veterinary	32,667
	(c) Amendment of clinical trial certificate for a locally manufactured investigational product -	
	(i) minor amendment	1,333
	(ii) major amendment	6,500
6.	**Good Clinical Practice Inspection for Local Sites**	
	GCP inspection fee per site local sites	50,000
7.	**Other Fees**	
	(a) Pre-clearance fees for quality assurance of imports for commercial consignments, Government ministries, departments, programmes, projects and similar institutions	1.5% of FOB invoice value
	(b) Pre-clearance fees for quality assurance 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) Pre-clearance fees for quality assurance of imports for donations	1% of FOB invoice value
	(d) Pre-clearance fees for quality assurance of imports for active pharmaceutical ingredients (API), bulk finished products and intermediates	1% of FOB invoice value
	(e) Amendment to licences, certificates and permits	167
	(f) Duplicate licences, certificates and permits	167
	(g) Transfer of licences, certificates and permits	167
	(h) Issue of certificate of a pharmaceutical product(CPP)	333
	(i) Application for import of Narcotic drugs and psychotropic substances	333
	(j) Inspection of premises for issue of a GMP certificate (local manufacture)	20,000
	(k) Inspection and supervision for disposal of expired products	3,333
	(l) Fast track fees	Double the applicable application fee
	(m) Restoration of marketing authorisation medicines	
	(i) medicines	20,000
	(ii) allied substances	4,000
	(n) Inspection of register	167
	(o) Late submission of application for renewal of marketing authorization in respect of locally manufactured medicines or allied substances	33 for each day application is late

PART III

FEES PAYABLE IN US DOLLARS

No.	*Item*	*Amount (US$)*
1.	**Application for Marketing Authorisation of Human Medicines imported as finished products**	
	(a) Generics	2,000.00
	(b) New Chemical Entities	2,800.00
	(c) Biologicals	2,800.00
	(d) Abridged Applications	1,700.00
2.	**Application for Marketing Authorisation of Veterinary Medicines imported as finished products**	
	(a) Generics1,750.00	
	(b) New Chemical Entities	2,100.00
	(c) Biologicals	2,100.00
	(d) Abridged applications	1,550.00
3.	**Application for Marketing Authorisation Allied Substances imported as finished products**	
	(a) Allied Substances	500
4.	**Evaluation of additional information for an application of medicines and allied substances imported as finished products**	
	(a) Inadequate Technical Information (quality safety or efficacy)	400.00
5.	**Annual Retention Fees for Medicines or Allied Substances imported as finished products**	
	(a) Human Medicines Generics	800.00
	(b) Human Medicines NCEs	800.00
	(c) Biologicals	800.00
	(d) Veterinary Medicines	700.00
	(e) Allied Substances	200.00
6.	**Renewal of Marketing Authorisation for Medicines or Allied Substances imported as finished products**	
	(a) Human Medicines Generics	1,200.00
	(b) Human Medicines NCEs	1,200.00
	(c) Biologicals	1,200.00
	(d) Veterinary Medicines	1,000.00
	(e) Allied Substances	350.00
	(f) Late submission of application for renewal of marketing authorization in respect of imported medicines or allied substance	5.00 for each day application is late
7.	**Amendment of Marketing Authorisation for Medicines and Allied Substances imported as finished products**	
	(a) Minor amendment	100.00
	(b) Major amendment	500.00

8.	**Good Manufacturing Practices Inspection for Foreign-Based Manufacturers in Support of Applications for Marketing Authorisation per manufacturing site up to five production lines where all the manufacturing process is carried on one site**	
	(a) Full site: Southern Africa	3,500.00
	(b) Full site: Rest of Africa	5,000.00
	(c) Full site: Far East or Asia	6,500.00
	(d) Full site: Europe, America and Australia	7,500.00
	(e) Additional production line	1,500.00
	(f) Fees for GMP documents evaluation (Desk Audits) per manufacturing site	3,500.00
9.	**Good Manufacturing Practices Inspection for Foreign-Based Manufacturers in Support of Applications for Marketing Authorisation per manufacturing where the manufacturing process carried out in more than one site in the Country where the main site is located**	
	(a) Each additional site such as warehousing for raw materials, final packaging, quality control and final release	1,500.00
10.	**Clinical Trials involving Imported Investigational Products**	
	(a) Human clinical trial certificate involving investigational products without marketing authorisation	3,000.00
	(b) Human clinical trial certificate involving investigational products with marketing authorisation	2,000.00
	(c) Veterinary clinical trial certificate involving investigational products without marketing authorisation	2,100.00
	(d) Veterinary clinical trial certificate involving investigational products with marketing authorisation	2,000.00
	(e) Amendment of clinical trial certificate involving an imported investigational product	
	(i) minor amendment	100
	(ii) major amendment	50
11.	**Good Clinical Practice Inspection Foreign-based Bioequivalence Sites**	
	(a) Full site – per site per inspection: Southern Africa	3,500.00
	(b) Full site – per site per inspection: Rest of Africa	5,000.00
	(c) Full site – per site per inspection: Far East or Asia	6,500.00
	(d) Full site – per site per inspection: Europe, America and Australia	7,500.00

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Minister of Health

LUSAKA
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