ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2023/30 - 2017 ජූනි මස 14 වැනි බදාදා - 2017.06.14
No. 2023/30 - WEDNESDAY, JUNE 14, 2017

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B 9/2016.

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015.

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under paragraph (u) of Subsection (2) of Section 142 read together with Sections 59 and 63 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE,
Minister of Health, Nutrition and Indigenous Medicine.

Colombo,
13th of June, 2017.

REGULATIONS

1. These regulations may be cited as the Registration and Licensing of Medicines (fees) Regulations, No. 02 of 2017 and shall come into operation from 14.06.2017.

2. Applications for registration and licensing of a medicine under sections 59 and 63 of the National Medicines Regulatory Authority Act, No. 5 of 2015 shall be accompanied by the processing fees, and any other relevant fees subsequently as set out in the Schedule hereto.

3. Schedule XI of Drug Regulations No. 38 of 1984 published in *Gazette Extraordinary*,No. 378/3 of 02nd December, 1985 as last amended by *Gazette Extraordinary* No. 1601/15 of 12th May, 2009 is hereby rescinded.

SCHEDULE

(i) Processing fee

	Type		Fee (USD)
(a)	New Molecule Entity (A chemical moiety which has not been previously registered in Sri Lanka, including a new salt, an ester or complex of a previously approved Chemical moiety)	**Part 1 -** Initial decision on application (process or decline)	500.00
		Part 2 - Evaluation (if accepted)	1,500.00
(b)	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)		1,000.00
(c)	New Product (any new product of a already registered medicine in Sri Lanka.)		(Foreign) 750.00
			(Local) 500.00
(d)	New Combination Product (A new combination product is a formulation of two or more medicines in a single dosage form which has not been previously registered in Sri Lanka.)		1,500.00
(e)	Therapeutic Biological and Biotechnological Products	**Part 1 -** Initial decision on application (process or decline)	1,000.00
		Part 2 - Evaluation (if accepted)	2,000.00
(f)	Application for registration renewal after 5 years		(Foreign) 750.00
			(Local) 500.00
(g)	Application for Manufacturing Plant (MP) approval		(Foreign) 2,000.00

(ii) Fee for Additional Data Evaluation

Type of Evaluation	Fee (USD)
Additional data Evaluation	500.00
Additional data for Manufacturing Plant (MP) Evaluation	500.00

SCHEDULE *(Continued)*

(iii) Processing fees for Clinical Trials

Type of Application	Fee (USD)
Industry Sponsored	1,000.00
Local Investigator Sponsored	Free of charge
Academic with International Sponsorship	250.00
Amendments that require review	250.00

(iv) Fees for Certificates

Type of Registration Certificate	Fee (USD)
Certificate of Registration for 5 years Foreign Manufacturer	400.00
Certificate of Registration for 5 years Local Manufacturer	200.00
Provisional Registration for 1 year for Foreign Manufacturer (will be for a maximum of 2 years)	200.00
Provisional Registration for 1 year for Local Manufacturer (will be for a maximum of 2 years)	100.00
Duplicate Copy of Registration Certificate	250.00
Amendment of Registration Certificate	100.00

(v) Fees for License

Types of Licenses	Fee (USD)
Sample Import License	100.00
Import License	100.00
Manufacturing License	100.00
Amendment of License	100.00

(vi) Fees for other approvals

Type	Fee (USD)
Formulation Approval of local manufacturer	Free of charge
Approval for Repackaging	50.00
Submission fee for waiver of registration	100.00
WHO GMP certificate	100.00
Certificate Of Pharmaceutical Product (COPP)	50.00
Free Sale Certificate	50.00
Agency Transfer per each party	1,000.00

SCHEDULE *(Continued)*

(vii) Fees for analysis of Medicines

Category	Analysis		Fee (USD)
a	Biological test		250.00
b	Microbiological test		250.00
c	Assay Test (Chemical, Microbiological, Biological)		250.00
d	Limit test (HPLC)		250.00
e	Dissolution test		250.00
f	Three tests or less than three tests	(I) If all three tests are in categories (a), (b), (c), (d) & (e) specified above	750.00
		(II) Otherwise	500.00
g	Four tests or more than four tests	(I) If three or more than three tests are in the categories (a), (b), (c) (d) & (e) specified above	1,500.00
		(II) Otherwise	1,000.00
h	Single test	Test other than the categories (a), (b, (c), (d) & (e) specified above	175.00

(viii) Fees for License to Deal in Medicines in Retail Pharmacies, Wholesale Establishments and Transporting of Medicines.

Type of License	Fee (USD)
Wholesale License	250.00
Retail License	100.00
Transport License	30.00
Amendment of License	30.00

(ix) Fee for Good Manufacturing Practice Inspection (GMP) - Local

Type	Fee (USD)
Large Scale Manufacturing sites	300.00
Small Scale Manufacturing sites	200.00
Repackaging sites	200.00

(x) Fee for Good Manufacturing Practice Inspection (GMP) - Foreign

Country	Fee (USD)
SAARC Countries	15,000.00
Other Countries	20,000.00

* Air tickets, Visa fees and transport cost within that country should be born by the Applicant.

SCHEDULE *(Continued)*

(xi) Fee for sample import license for clinical trials.- (USD) 100.00

(xii) Fee for advertisement

Advertisement	Fee (USD)
Processing fee for Advertisement (All categories)	1,000.00

*(Separate applications should be submitted for each advertisement).

6-1021/1

L.D.B 9/2016.

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015.

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under paragraph (u) of Subsection (2) of Section 142 read together with Sections 83 and 86 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE,
Minister of Health, Nutrition and Indigenous Medicine.

Colombo,
13th of June, 2017.

REGULATIONS

1. These regulations may be cited as the Registration and Licensing of Medical Devices (fees) Regulations, No. 03 of 2017 and shall come into operation with effect from 14.06.2017.

2. Applications for registration and licensing of any medical device under Sections 83 and 86 of the National Medicines Regulatory Authority Act, No. 5 of 2015 shall be accompanied by the processing fees, and any other relevant fees subsequently as set out in the Schedule hereto.

3. Schedule II of Devices Regulations No. 38 of 1984 published in *Gazette Extraordinary* No. 378/3 of 2nd December, 1985 as last amended by *Gazette Extraordinary* No. 1601/15 of 12th May, 2009 is hereby rescinded.

SCHEDULE

(i) Processing fee

Type	Fee (USD)
New Application	(Foreign) 1,000.00
	(Local) 750.00
Application for Registration renewal after 5 years	(Foreign) 750.00
	(Local) 500.00
Application for Manufacturing Plant (MP) approval	(Foreign) 1,000.00

(ii) Fee for Additional Data Evaluation

Type	Fee (USD)
Additional data Evaluation	500.00
Additional data for Manufacturing Plant (MP) Evaluation	300.00

(iii) Processing fee for Clinical Trials.

Type of Application	Fee (USD)
Industry Sponsored	1,000.00
Local Investigator Sponsored	Free of charge
Academic with International Sponsorship	250.00
Amendments that require review	250.00

(iv) Fee for Certificates

Type of Registration Certificates	Fee (USD)
Certificate of Registration for 5 years for Foreign Manufacturer	400.00
Certificate of Registration for 5 years for Local Manufacturer	200.00
Provisional Registration; for 1 year for Foreign Manufacturer (will be for a maximum of 2 years)	200.00
Provisional Registration; for 1 year for Local Manufacturer (will be for a maximum of 2 years)	100.00
Duplicate Copy of Registration Certificate	250.00
Amendment of Registration Certificate	100.00

SCHEDULE *(Continued)*

(v) Fee for Licenses

Types of Licenses	Fee (USD)
Sample Import License	100.00
Import License	100.00
Manufacturing License	100.00
Amendment of License	100.00

(vi) Fee for other approvals for Medical Devices

Type of Approval	Fee (USD)
Formulation Approval of local manufacturer	Free of charge
Approval for Repackaging	50.00
Submission fee for waiver of registration	100.00
WHO GMP Certificate	100.00
Free Sale Certificate	50.00
Agency Transfer per each party	1,000.00

(vii) Fees for analysis of Medical Devices

Category	Analysis		Fee (USD)
a	Biological test		250.00
b	Microbiological test		250.00
c	Assay Test (Chemical, Microbiological, Biological)		250.00
d	Limit test (HPLC)		250.00
e	Three tests or less than three tests	(I) If all three tests are in categories (a), (b), (c) & (d) specified above	750.00
		(II) Otherwise	500.00
f	Four tests or more than four tests	(I) If three or more than three tests are in the categories (a), (b), (c) & (d) specified above	1,500.00
		(II) Otherwise	1,000.00
g	Single test	Test other than the categories (a), (b, (c), & (d) specified above	175.00

(viii) Fee for Good Manufacturing Practice Inspection (GMP) - Local

Type	Fee (USD)
Large Scale Manufacturing sites	300.00
Small Scale Manufacturing sites	200.00
Repackaging sites	200.00

SCHEDULE *(Continued)*

(ix) Fee for Good Manufacturing Practice Inspection (GMP) - Foreign

Country	Fee (USD)
SAARC Countries	15,000.00
Other Countries	20,000.00

* Air Tickets, Visa fees and transport cost within that country should be born by the Applicant.

(x) Fee for sample import license for clinical trials - (USD) 100.00

(xi) Fee for advertisement

Advertisement	Fee (USD)
Processing fee for Advertisement (All categories)	1,000.00

* (Separate applications should be submitted for each advertisement).

06-1021/2

L.D.B 9/2016.

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under paragraph (u) of subsection (2) of section 142 read together with sections 102 and 105 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE,
Minister of Health, Nutrition and Indigenous Medicine.

Colombo,
13th of June, 2017.

REGULATIONS

1. These regulations may be cited as the Registration and Licensing of Borderline Products (fees) Regulations, No. 04 of 2017 and shall come into operation with effect from 14.06.2017.

2. Applications for registration and licensing of any borderline product under Sections 102 and 105 of the National Medicines Regulatory Authority Act, No. 5 of 2015 shall be accompanied by the processing fees, and any other relevant fees subsequently as setout in the Schedule hereto.

SCHEDULE

(i) Processing fee

Type		Fee (USD)
New Application	**Part 1-** Initial decision on application (process or decline)	500.00
	Part-2 Evaluation (if accepted)	1,000.00
Application for Registration renewal after 5 years	Foreign Product	750.00
	Local Product	500.00
Application for Manufacturing Plant (MP) approval	Foreign Manufacturing Plant	1,000.00

(ii) Fees for additional Data Evaluation

Type	Fee (USD)
Additional data Evaluation	500.00
Additional data for Manufacturing Plant (MP) Evaluation	300.00

(iii) Processing fees for clinical trials

Type	Fee (USD)
Industry Sponsored	1,000.00
Local Investigator Sponsored	Free of charge
Academic with International Sponsorship	250.00
Amendments that require review	250.00

(iv) Fees for Certificates

Type of Registration Certificates	Fee (USD)
Certificate of Registration for 5 years for Foreign Manufacturer	400.00
Certificate of Registration for 5 years for Local Manufacturer	200.00
Provisional Registration; for 1 year for Foreign Manufacturer (will be for a maximum of 2 years)	200.00

SCHEDULE *(Continued)*

Type of Registration Certificates	Fee (USD)
Provisional Registration; for 1 year for Local Manufacturer (will be for a maximum of 2 years)	100.00
Duplicate Copy of Registration Certificate	250.00
Amendment of Registration Certificate	100.00

(v) Fees for Licenses

Types of Licenses	Fee(USD)
Sample Import License	100.00
Import License	100.00
Manufacturing License	100.00
Amendment of License	100.00

(vi) Fees for other approvals for Borderline Products

Type of Approval	Fee (USD)
Formulation Approval of local manufacturer	50.00
Approval for Repackaging	50.00
Submission fee for waiver of registration	100.00
WHO GMP certificate	100.00
Certificate of Pharmaceutical Product (COPP)	50.00
Free Sale Certificate	50.00
Agency Transfer per each party	1,000.00

(vii) Fees for Good Manufacturing Practice Inspection (GMP) - Local

Type	Borderline Products Fee (USD)
Large Scale Manufacturing sites	300.00
Small Scale Manufacturing sites	200.00
Repackaging sites	200.00

SCHEDULE *(Continued)*

(viii) Fees for Good Manufacturing Practice Inspection (GMP) - Foreign

Country	Fee (USD)
SAARC Countries	15,000.00
Other Countries	20,000.00

* Air tickets, Visa fees and transport cost within that country should be born by the Applicant.

(ix) Fee for sample Import License for Clinical Trials - (USD) 100.00

(x) Fee for advertisement

Advertisement	Fee (USD)
Processing fee for Advertisement (All categories)	1,000.00

* (Separate applications should be submitted for each advertisement).

06-1021/3

PRINTED AT THE DEPARTMENT OF GOVERNMENT PRINTING, SRI LANKA.