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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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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,
05th January, 2018.

Regulations

The Regulations for Registration and Licensing of Medicines (fees) Regulations, No. 2 of 2017 published in the *Gazette Extraordinary* No. 2023/30 of June 14, 2017 is hereby amended by the substitution for the Schedule thereof, of the following: -

SCHEDULE

(i) **Processing fee**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	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
		Part 2 Evaluation (if accepted)	1,500
2	New Dosage Form (Any physical form of a registered medicine in Sri Lanka other than the available registered forms)		1,000
3	New Product (Any new product of an already registered medicine in Sri Lanka.)	**(Foreign)**	750
		(Local) Category A- Manufacturers whose product range include: - (i) Medicines to be administered internally (*e.g.* oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	500
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients etc) but do not include any anti-infective or steroidal product.	200

SCHEDULE *(Contd.)*

(i) **Processing fee** *(Contd.)*

Column 1	***Column 2*** ***Type***		***Column 3*** ***Fee (USD)***
4	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
5	Therapeutic Biological and Biotechnological Products		2,000
6	Application for renewal of registration after five years	**(Foreign)**	750
		(Local) Category A- Manufacturers whose product range include :— (i) Medicines to be administered internally (*e.g.* oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	500
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients *etc*) but do not include any anti-infective or steroidal product.	200
7	Application for Manufacturing Plant (MP) approval -**Foreign**		2,000

SCHEDULE *(Contd.)*

(ii) **Fee for Additional Data Evaluation**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Additional data Evaluation	**(Foreign)**	500
		(Local) Category A- Manufacturers whose product range include: - (i) Medicines to be administered internally (*e.g.* oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	200
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients etc) but do not include any anti-infective or steroidal product.	100
2	Additional data for Manufacturing Plant (MP) Evaluation		500
3	Variations that require review		200

(iii) **Processing fees for Clinical Trials**

Column 1	***Column 2 Type***	***Column 3 Fee (USD)***
1	Industry Sponsored	1,000
2	Local Investigator Sponsored	Free of charge
3	Academic with International Sponsorship	250
4	Amendments that require review	250

SCHEDULE *(Contd.)*

(iv) Fees for Certificates of Registration

Column 1	***Column 2*** ***Type***		***Column 3*** ***Fee (USD)***
1	Certificate of Registration for five years	**(Foreign)**	400
		(Local) Category A- Manufacturers whose product range include :— (i) Medicines to be administered internally (*e.g.* oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	200
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients *etc*) but do not include any anti-infective or steroidal product.	100
2	Provisional Registration (may be issued for a maximum period of two years)	**(Foreign)**	200
		(Local) Category A- Manufacturers whose product range include: - (i) Medicines to be administered internally (e.g. oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients *etc*) but do not include any anti-infective or steroidal product.	50
3	Duplicate Copy of Certificate of Registration		250
4	Amendment of Certificate of Registration		100

SCHEDULE *(Contd.)*

(v) Fees for Licenses

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Sample Import License		100
2	Import License		100
3	Manufacturing License **(Local)**	Category A- Manufacturers whose product range include: - (i) Medicines to be administered internally (*e.g.* oral, injectable, inhalational) (ii) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (iii) Anti-infective and steroidal products to be applied locally.	100
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients etc) but do not include any anti-infective or steroidal product.)	50
4	Amendment of the License		100

(vi) Fees for other approvals

Column 1	***Column 2 Type***	***Column 3 Fee (USD)***
1	Formulation Approval for local Manufacturer	25

SCHEDULE *(Contd.)*

(vi) Fees for other approvals *(Contd.)*

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
2	Approval for Packaging/Repackaging		50
3	(i) Approval for waiver of registration for the government supplies (ii) Application for waiver of registration for the private supplies	Invoice Value (USD) 2,000 or below	50
		Invoice Value (USD) 2,000-15,000	100
		Invoice Value (USD) 15,000 or above	200
4	Any Clarification Letter		10
5	WHO GMP certificate		100
6	Certificate of Pharmaceutical Product (COPP)		50
7	Free Sale Certificate		50
8	Agency Transfer	Manufacturer	1,000
		Each new marketing authorization holder	1,000

(vii) Fees for Analysis

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Biological test		250
2	Microbiological test		250
3	Assay (Chemical, Microbiological, Biological)		250
4	Limit test (performed using Analytical Equipment- HPLC, AAS *etc.*)		250
5	Dissolution test		250
6	Three or less than three tests	(I) If all three tests comprise from items 1, 2, 3, 4 and 5 in Column 1	750
		(II) Otherwise	500
7	Four tests or more than four tests	(I) If all four tests comprise from items 1, 2, 3, 4 and 5 in Column 1	1,500
		(II) Otherwise	1,000
8	Single test	tests other than items 1, 2, 3, 4 and 5 in Column 1	175

SCHEDULE *(Contd.)*

(viii) **Fees for Licenses to deal in medicines in Retail Pharmacies, Wholesale Establishments and Transporting of Medicines.**

Column 1	***Column 2 Type***	***Column 3 Fee (USD)***
1	Wholesale License	60
2	Retail License	45
3	Transport License	30
4	Amendment of License	30

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

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	A Manufacturing site	Category A- Manufacturers whose product range include: - (iv) Medicines to be administered internally (*e.g.* oral, injectable, inhalational) (v) Medicines to be administered through other body cavities (*e.g.* ophthalmic, otological, nasal, rectal, vaginal) (vi) Anti-infective and steroidal products to be applied locally.	300
		Category B- Manufacturers whose products are limited to dosage forms applicable on skin (*e.g.* ointments, creams, liniments, emollients *etc*) but do not include any anti-infective or steroidal product.	100
2	A Packaging/Repackaging site		100

SCHEDULE *(Contd.)*

(x) **Fee for Good Manufacturing Practice Inspection (GMP) – Foreign**

Column 1	***Column 2 Country***	***Column 3 Fee (USD)***
1	SAARC Countries	15,000
2	Other Countries	20,000

* Air tickets, Visa fees should be borne by the Applicant.

(xi) Fee for sample import license for clinical trials - (USD) 100

(xii) Fee for advertisement

Column 1	***Column 2 Advertisement***	***Column 3 Fee (USD)***
1	Processing fee for an Advertisement (All categories)	1,000

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

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,
05th January, 2018.

Regulations

The Regulations for Registration and Licensing of Medical Devices (Fees) Regulations, No. 3 of 2017 published in the *Gazette Extraordinary* No. 2023/30 of June 14, 2017 is hereby amended by the substitution for the Schedule thereof, of the following: -

SCHEDULE

(i) **Processing fee**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	New Application	**(Foreign)**	1,000
		(Local) Category A- "All products other than category B"	750
		Category B- "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	250
2	Application for renewal of registration after five years	**(Foreign)**	750
		(Local) Category A - "All products other than category B"	500
		Category B - "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	200
3	Application for Manufacturing Plant (MP) approval - **(Foreign)**		1,500

(ii) **Fees for Additional Data Evaluation**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Additional data evaluation	**(Foreign)**	500
		(Local) Category A- "All products other than category B"	200
		Category B- "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	100
2	Additional data for Manufacturing Plant (MP) evaluation		300
3	Variation that require review		200

SCHEDULE *(Contd.)*

(iii) **Processing fees for Clinical Trials**

Column 1	***Column 2 Type***	***Column 3 Fee (USD)***
1	Industry Sponsored	1,000
2	Local Investigator Sponsored	Free of charge
3	Academic with International Sponsorship	250
4	Amendments that require review	250

(iv) **Fees for Certificates of Registration**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Certificate of Registration for five years	**(Foreign)**	400
		(Local) Category A- "All products other than category B"	200
		Category B- "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	100
2	Provisional Registration; (may be issued for a maximum period of two years)	**(Foreign)**	200
		(Local) Category A- "All products other than category B"	100
		Category B- "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	50
3	Duplicate Copy of Certificate of Registration		250
4	Amendment to the Certificate of Registration		100

SCHEDULE *(Contd.)*

(v) **Fees for Licenses**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Sample Import License		100
2	Import License		100
3	Manufacturing License (Local)	Category A- "All products other than category B"	100
		Category B- "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	50
4	Amendment of License		100

(vi) **Fees for other approvals**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Formulation Approval for local manufacturer		Free of charge
2	Approval for Packaging/Repackaging		50
3	(i) Approval for waiver of registration for the government supplies (ii) Application for waiver of registration for the private supplies	Invoice Value (USD) 2000 or below	50
		Invoice Value (USD) 2,000-10,000	100
		Invoice Value (USD) 10,000 -15,000	200
		Invoice Value (USD) 15,000 -20,000	500
		Invoice Value More than (USD) 20,000	750
4	Any Clarification Letter		10
5	WHO GMP Certificate		100
6	Free Sale Certificate		50
7	Agency transfer	Manufacturer	1,000
		Each new marketing authorization holder	1,000

SCHEDULE *(Contd.)*

(vii) **Fees for Analysis**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Biological test		250
2	Microbiological test		250
3	Assay (Chemical, Microbiological, Biological)		250
4	Limit test (performed using Analytical Equipment- HPLC, AAS etc.)		250
5	Three tests or less than three tests	(I) If all three tests comprise from items 1,2,3 and 4 in Column 1	750
		(II) Otherwise	500
6	Four tests or more than four tests	(I) If all four tests comprise from items 1,2,3 and 4 in Column 1	1,500
		(II) Otherwise	1,000
7	Single test	Tests other than items 1,2,3 and 4 in Column 1	175

(viii) **Fee for Good Manufacturing Practice Inspection (GMP) – Local**

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	A Manufacturing site	Category A- "All products other than category B"	300
		Category B- "Non Sterile products other than Gloves, Diapers, Sanitary Napkins and Tooth Brushes"	100
2	A Packaging/ Repackaging site		100

(ix) **Fee for Good Manufacturing Practice Inspection (GMP) – Foreign**

Column 1	***Column 2 Country***	***Column 3 Fee (USD)***
1	SAARC Countries	15,000
2	Other Countries	20,000

* Air Tickets, Visa fees should be borne by the Applicant.

SCHEDULE *(Contd.)*

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

(xi) **Fee for advertisement**

Column 1	***Column 2*** ***Advertisement***	***Column 3*** ***Fee (USD)***
1	Processing fee for an Advertisement (All categories)	1,000

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

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,
05th January, 2018.

Regulations

The Regulations for Registration and Licensing of Borderline Products (Fees) Regulations, No. 4 of 2017 published in the *Gazette Extraordinary* No. 2023/30 of June 14, 2017 is hereby amended by the substitution for the Schedule thereof, of the following: -

SCHEDULE

(i) Processing fee

Column 1	***Column 2*** ***Type***			***Column 3*** ***Fee (USD)***
1	New Application	**Part 1** Initial decision on application (process or decline)	**(Foreign)**	500
			(Local)	Free of Charge
		Part 2 Evaluation (if accepted)	**(Foreign)**	1,000
			(Local)	750

SCHEDULE *(Contd.)*

2	Application for the renewal of the registration after five years	**(Foreign)**	750
		(Local)	500
3	Application for Manufacturing Plant (MP) approval - **(Foreign)**		1,500

(ii) Fees for additional Data Evaluation

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Additional data evaluation	**(Foreign)**	500
		(Local)	200
2	Additional data for Manufacturing Plant (MP) evaluation		300
3	Variations that require review		200

(iii) Processing fees for clinical trials

Column 1	***Column 2 Type***	***Column 3 Fee (USD)***
1	Industry sponsored	1,000
2	Local investigator sponsored	Free of charge
3	Academic with international sponsorship	250
4	Amendments that require review	250

(iv) Fees for Certificates of Registration

Column 1	***Column 2 Type***		***Column 3 Fee (USD)***
1	Certificate of Registration for five years	**(Foreign)**	400
		(Local)	200
2	Provisional Registration; (may be issued for a maximum period of two years)	**(Foreign)**	200
		(Local)	100
3	Duplicate Copy of Certificate of Registration		250
4	Amendment to the Certificate of Registration		100

SCHEDULE *(Contd.)*

(v) Fees for Licenses

Column 1	***Column 2*** ***Type***	***Column 3*** ***Fee (USD)***
1	Sample Import License	100
2	Import License	100
3	Manufacturing License (Local)	100
4	Amendment of the License	100

(vi) Fees for other approvals

Column 1	***Column 2*** ***Type***		***Column 3*** ***Fee (USD)***
1	Formulation Approval for Local Manufacturer		200
2	Approval for Packaging /Repackaging		50
3	(i) Approval for waiver of registration for the government supplies	Invoice Value (USD) 2,000 or below	50
	(ii) Application for waiver of registration for the private supplies	Invoice Value (USD) 2,000-15,000	100
		Invoice Value (USD) 15,000 or above	200
4	Any Clarification Letter		10
5	WHO GMP Certificate		100
6	Certificate of Pharmaceutical Product (COPP)		50
7	Free Sale Certificate		50
8	Agency transfer	Manufacturer	1,000
		Each new marketing authorization holder	1, 000

SCHEDULE *(Contd.)*

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

Column 1	***Column 2*** ***Type***	***Column 3*** ***Fee (USD)***
1	A Manufacturing site	300
2	A Packaging /Repackaging site	100

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

Column 1	***Column 2*** ***Type***	***Column 3*** ***Fee (USD)***
1	SAARC Countries	15,000
2	Other Countries	20,000

* Air tickets, Visa fees should be borne by the Applicant.

(ix) Fees for Sample Import License for Clinical Trials - (USD) 100

(x) Fees for advertisements

Column 1	***Column 2*** ***Type***	***Column 3*** ***Fee (USD)***
1	Processing fee for an advertisement (all categories)	1,000

* (separate applications shall be submitted for each advertisement)

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