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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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No. 2452/39 - THURSDAY, SEPTEMBER 04, 2025

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B. 9/2016 (IV)

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

REGULATIONS made by the Minister of Health and Mass Media 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. Nalinda Jayatissa,
Minister of Health and Mass Media.

Colombo,
3rd September, 2025.

Regulations

The Registration and Licensing of Medicines (fees) Regulations, No. 02 of 2017 published in *Gazette* Extraordinary No. 2023/30 of June 14, 2017 as amended by regulations published in *Gazette* Extraordinary No.2052/33 of January 05, 2018 are hereby further amended as follows:-

(1) by the insertion immediately after regulation 2 thereof, of the following:-

1A- PG 7239 - 404 (09/2025)

This Gazette Extraordinary can be downloaded from www.documents.gov.lk

"2A. The applicable fees for the services provided by the National Medicines Regulatory Authority, listed in Column III of the Schedule hereto in United States Dollars (USD), may be paid in Sri Lankan Rupees (LKR) equivalent to the United States Dollar (USD) amount at the prevailing exchange rate published by the National Medicines Regulatory Authority in its official website based on the exchange rate of the Central Bank of Sri Lanka.";

(2) by the repeal of the Schedule thereof, and the substitution therefor, of the following:-

SCHEDULE

(i) Processing fee for applications for registrations of medicines

Column I	***Column II*** ***Type***		***Column III*** ***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** Application for Initial decision on Molecule (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 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
4	New Product (Any new product of an already registered medicine in Sri Lanka.)	**(Foreign)**	$ 750
		(Local) Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal products.	$ 200

Schedule (*Contd.*)

Column I	***Column II*** ***Type***		***Column III*** ***Fee (USD)***
5	Therapeutic Biological and Biotechnological Products		$ 2,000
6	Medicines required for rare diseases and medicines required in small quantities (List of products in this category published in the NMRA Official Website.)		Free of Charge
7	Application for renewal of registration after five years	**(Foreign)**	$ 750
		(Local) Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product.	$ 200

ii Processing fee for applications for licenses and others

Column 1	***Column II*** ***Type***		***Column III*** ***Fee* (USD)**
1	Application for Sample Import License		$ 50
2	Application for Manufacturing Premises (MP) approval - Foreign		$ 2000
3	Renewal application for Manufacturing Premises (MP) approval - Foreign		$ 500
4	Application for Licenses for licensed Importer of Medicines		$ 600
5	Renewal for Licenses for licensed Importer of Medicines		$ 200

Schedule (*Contd.*)

Column 1	***Column II*** ***Type***		***Column III*** ***Fee* (USD)**
6	Application fee for appointment of New Market Authorization Holder		$ 500
	Application fee for Wholesale License		$ 120
	Application fee for Retail License		$ 90
	Application fee for Transport License for therapeutic goods		$ 20
7	Application fee for preliminary approval of a local manufacturing plant	Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product	$ 50
8	Application fee for renewal of a local manufacturing Plant approval	Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product	$ 50

Schedule (*Contd.*)

(iii) Fee for Additional Data Evaluation

Column I		***Column II*** ***Type***	***Column III*** ***Fee (USD)***
1	Additional data Evaluation for medicine registration.	**(Foreign)**	$ 500
		(Local) Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product .	$ 100
2	Additional data evaluation for Medicines required for rare diseases and medicines required in Small quantities (List of products in this category is published in the NMRA Official Website).		Free of charge
3	Additional data for Manufacturing Plant (MP) Evaluation – Foreign		$ 500
4	Variations that require review (except for medicines required for rare diseases and medicines required in small quantities)	Notification	Free of Charge
		Minor Variations	$ 100
		Major Variations	$ 250
5	Any variation for medicines required for rare diseases and medicines required in small quantities		Free of Charge

(iv) Processing fees for Clinical Trials

Column 1	***Column II*** ***Type***	***Column III*** ***Fee* (USD)**
1	Industry Sponsored	$ 1,000
2	Academic with International Sponsorship	$ 250
3	Local Investigator Sponsored	Free of charge

Schedule (*Contd.*)

Column 1	***Column II*** ***Type***		***Column III*** ***Fee* (USD)**
4	Amendments that require review	Industry Sponsored	$ 250
		Academic with International Sponsorship	$ 50
		Local Investigator Sponsored	Free of charge

(v) Fees for Certificates of Registration

Column 1	***Column II*** ***Type***		***Column III*** ***Fee* (USD)**
1	Full registration (issued for five years)	**(Foreign)**	$ 400
		(Local) Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product.	$ 100
		Medicines required for rare diseases and medicines required in Small quantities	Free of Charge
2	Provisional Registration (issued for a maximum period of two years)	**(Foreign)**	$ 200

Schedule (*Contd.*)

Column 1	***Column II*** ***Type***		***Column III*** ***Fee* (USD)**
		(Local) Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product	$ 50
		Medicines required for rare diseases and medicines required in Small quantities	Free of Charge
3	Approval for a foreign manufacturing premises		$ 250
4	GMP Certificate for foreign manufacturing premises (on request)		$ 250
5	Duplicate Copy of Certificate of Registration		$ 250
6	Amendment of Certificate of Registration/ Approval		$ 100

(vi) Fees for Licenses

Column 1	***Column II*** **Type**		***Column III*** **Fee (USD)**
1	Sample Import License		$ 50
2	Import License	for 1 year	$ 100
		for 2 years	$ 200
3	License for licensed Importer of Medicines		$ 400

Schedule (*Contd.*)

Column 1	***Column II*** **Type**		***Column III*** **Fee (USD)**
4	Manufacturing License **(Local)**	Category A- (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- Dosage forms applicable on skin other than anti-infective or steroidal product.	$ 50
5	License for licensed local manufacture of medicine	Category A – (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	$ 300
		Category B – Dosage forms applicable on skin other than anti-infective or steroidal product	$ 200
6	Duplicate copy of the License		$ 250
7	Amendment of the License		$ 100

(vii) Fees for other approvals

Column 1	***Column II*** **Type**	***Column III*** ***Fee*** **(USD)**
1	Application for Formulation Approval (local Manufacturing)	$ 25
2	Application for Formulation Approval (local Manufacturing) of medicines required for rare diseases and medicines required in small quantities .	Free of Charge
3	Application for Approval of Repackaging Sites	$ 50

Schedule (*Contd.*)

Column 1	***Column II*** **Type**		***Column III*** ***Fee*** **(USD)**
4	(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
5	Any Clarification Letter		$ 10
6	GMP certificate for a local manufacturing site		$ 100
7	Certificate of Pharmaceutical Product (COPP)		$ 50
8	Free Sale Certificate		$ 50
9	Appointment of New marketing Authorization Holder (Agency Transfer)	From Manufacturer	$ 1000
		From Each new marketing authorization holder	$ 500

(viii) Fees for Analysis

Column 1	***Column II*** ***Type***		***Column III*** ***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 tests other than items 1, 2, 3, 4 and 5 in Column 1	$ 1000

Schedule (*Contd.*)

Column 1	***Column II*** ***Type***		***Column III*** ***Fee* (USD)**
8	Single test	tests other than items 1, 2, 3, 4 and 5 in Column 1	$ 175

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

Column 1	***Column II*** ***Type***	***Column III*** ***Fee* (USD)**
1	Wholesale License	$ 60
2	Retail License	$ 45
3	Transport License	$ 10
4	Duplicate of License	$ 50
5	Amendment of License	$ 30
6	TELE Pharmacy (Home Delivery) License (Period of one year)	$ 100

(x) Fee for Pharmacy and Good Distribution Practice Inspection (GDP)

Column 1	***Column II***	***Column III*** **Fee (USD)**
1	Good Distribution Practice Inspection	$ 100
2	Pharmacovigilance Inspection	$ 100

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

Column 1		***Column II*** ***Type***	***Column III*** ***Fee* (USD)**
1	A Manufacturing site	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.	$ 300

Schedule (*Contd.*)

Column 1		***Column II*** ***Type***	***Column III*** ***Fee* (USD)**
		Category B- Dosage forms applicable on skin other than anti-infective or steroidal product.	$ 100
2	A Repackaging site		$ 100

(xii) Fee for Good Manufacturing Practice Inspection (GMP) – Foreign

Column 1	***Column II*** ***Country***	***Column III*** ***Fee* (USD)**
1	SAARC Countries	$ 15,000
2	Other Countries	$ 20,000
3	Follow up inspection (All countries)	$ 5,000

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

(xiii) Fee for advertisement

Column 1	***Column II*** ***Advertisement***	***Column III*** ***Fee* (USD)**
1	Processing fee for the application of an Advertisement (All categories)	$ 700
2	Approval of Advertisement (All categories)	$ 300

* (separate applications shall be submitted for each advertisement as per the guideline)

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