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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

NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under Section 142 of the National Medicines Regulatory Authority Act, No.5 of 2015 read with Sections 3 and 118 of the aforesaid Act.

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

Colombo,
29th August, 2018.

Regulations

The Ceiling on Prices Regulations No.2 of 2016 published in the *Gazette Extraordinary* No.1989/61 of October 21, 2016 as amended by regulations published in *Gazette Extraordinary* No. 2049/ 31 of December 14, 2017 are hereby amended as follows: -

(1) by the repeal of regulation 3 thereof and the substitution therefor of the following:--

"3. The Maximum Retail Price (hereinafter referred to as the "MRP") limits in respect of the Scheduled drugs shall also be applicable to all brand names, generic names, dosage forms and strengths of the Scheduled drugs."

(2) immediately after regulation 5, by the insertion of the following which shall have effect as regulation 5A: -

"5A. A manufacturer, importer, trader, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in the possession of a Scheduled drugs as specified in Column II of Part II of the Schedule hereto for the purpose of sale of such medicine on and after the date on which this regulation comes in to operation shall not be sold above the MRP as specified in Column V of the said Schedules."

(3) immediately after the renumbered regulation 5A thereof, by the insertion of the following regulation:-

"5B. Where any dosage form or strength of the Scheduled drugs are not specified in such Schedule, the maximum price limit for the dosage form or strength not so specified shall be the maximum retail price limit as shall be fixed by the National Medicines Regulatory Authority.".

(4) by the insertion of the following regulation immediately after regulation 10 thereof: -

"11. For the purpose of these regulations –

"Medical Practitioner" shall have the same meaning as in the Medical Ordinance (Chapter 105);

"Private medical institution" shall have the same meaning assigned to it by the Private Medical Institutions (Registration) Act, No.21 of 2006.

(5) immediately after the caption "Schedule", by the insertion of the following:

"Part I"

(6) by the insertion of the following Part, immediately after Part I of the Schedule:-

"Part II"

SCHEDULE

PART II

MAXIMUM RETAIL PRICES OF THIRTEEN SELECTED MEDICINE

Column *I*	**Column *II***	**Column *III***	**Column *IV***	**Column *V***
	Generic Name	***Route of Administration/ dosage form***	***Strength***	**MRP (SLR)**
1	CEFTAZIDIME	INJECTION	500mg	480.00
	CEFTAZIDIME	INJECTION	1g	800.00
2	CEFTRIAXONE	INJECTION	250 mg	240.00
	CEFTRIAXONE	INJECTION	500 mg	450.00
	CEFTRIAXONE	INJECTION	1 g	700.00
3	CEFOTAXIME	INJECTION	500 mg	225.00
	CEFOTAXIME	INJECTION	1 g	375.00

Column *I*	**Column *II***	**Column *III***	**Column *IV***	**Column *V***
	Generic Name	***Route of Administration/ dosage form***	***Strength***	**MRP (SLR)**
4	FLUCONAZOLE	CAPSULE/TABLET	50 mg	25.00
	FLUCONAZOLE	CAPSULE/TABLET	150 mg	45.00
5	INSULIN SOLUBLE HUMAN	INJECTION	100 IU/1ml (10 ml vial)	1,200.00
	INSULIN SOLUBLE HUMAN	INJECTION	100 IU/1ml (3 ml cartridge)	600.00
	INSULIN ISOPHANE HUMAN	INJECTION	100 IU/1ml (10 ml vial)	1,200.00
	INSULIN ISOPHANE HUMAN	INJECTION	100 IU/1ml (3 ml cartridge)	600.00
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)	INJECTION	100 IU/1ml (10 ml vial)	1,200.00
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)	INJECTION	100 IU/1ml (3 ml cartridge)	600.00
6	GLIMEPIRIDE	TABLET	1 mg	7.15
	GLIMEPIRIDE	TABLET	2 mg	10.15
	GLIMEPIRIDE	TABLET	3 mg	17.00
	GLIMEPIRIDE	TABLET	4 mg	18.50
7	SITAGLIPTIN	TABLET	25 mg	15.00
	SITAGLIPTIN	TABLET	50 mg	28.50
	SITAGLIPTIN	TABLET	100 mg	48.50
8	TAMSULOSIN	CAPSULE/TABLET	0.40 mg	21.00
9	MONTELUKAST	TABLET	4 mg	12.00
	MONTELUKAST	TABLET	5 mg	15.00
	MONTELUKAST	TABLET	10 mg	21.00

Column *I*	Column *II*	Column *III*	Column *IV*	Column *V*
	Generic Name	***Route of Administration/ dosage form***	***Strength***	**MRP (SLR)**
10	PREGABALIN	CAPSULE/TABLET	50 mg	12.25
	PREGABALIN	CAPSULE/TABLET	75 mg	15.50
	PREGABALIN	CAPSULE/TABLET	100 mg	19.25
	PREGABALIN	CAPSULE/TABLET	150 mg	24.00
	PREGABALIN	CAPSULE/TABLET	300 mg	39.50
11	TOPIRAMATE	CAPSULE/TABLET	25 mg	20.00
	TOPIRAMATE	CAPSULE/TABLET	50 mg	32.00
	TOPIRAMATE	CAPSULE/TABLET	100 mg	52.00
12	LAMOTRIGINE	TABLET	25 mg	12.00
	LAMOTRIGINE	TABLET	50 mg	21.00
	LAMOTRIGINE	TABLET	100 mg	35.00
13	ATORVASTATIN	TABLET	5 mg	6.75
	ATORVASTATIN	TABLET	40 mg	26.00

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L.D.-B 9/2016

NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under section 142 of the National Medicines Regulatory Authority Act, No.5 of 2015 read with sections 3 and 118 of the aforesaid Act.

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

Colombo,
29th August, 2018.

Regulations

1. These Regulations may be cited as the Medicines (Tender Pricing) Regulations of 2018.

2. There shall be a maximum price limit to determine the maximum tender prices (hereinafter referred to as the "MTP") of the drugs specified in the Schedule hereto (hereinafter referred to as the "Scheduled drugs").

3. The MTP limits in respect of the scheduled drugs shall also be applicable to all brand names, generic names, dosage forms and strengths of the Scheduled drugs.

4. No manufacturer, importer, trader, distributor, or any other person shall place bid for any procurement or quote for any other emergency purchase of any scheduled drugs as specified in Column II of the Schedule, for a price above the maximum tender price as specified in Column V thereof on and after the date on which these regulations come in to operation.

5. No governmental or semi-governmental institution shall accept any tender or make any emergency purchase of any scheduled drugs as specified in Column II of the Schedule, for a price above the maximum tender price as specified in Column V thereof from the date on which these regulations come in to operation.

6. For the purpose of procurement or emergency purchase, where any dosage form or strength of the Scheduled drugs are not specified in such Schedule, the maximum price limit for such dosage forms or strengths shall be fixed by the National Medicines Regulatory Authority.

7. Notwithstanding the provisions of the preceding regulations, the maximum tender price of each such unit of the Scheduled drugs as specified in the Schedule shall be effective on and after the date of operation of these regulations until revised.

8. Any person or institution who or which contravenes the provisions of these regulations commits an offence under the National Medicines Regulatory Authority Act, No.5 of 2015, and shall be triable under Part IV of the said Act.

SCHEDULE

MAXIMUM TENDER PRICES OF TEN SELECTED MEDICINE

Column I	**Column II**	**Column III**	**Column IV**	**Column V**
	Generic Name	***Route of Administration/ dosage form***	***Strength***	**MTP (SLR)**
1	TRASTUZUMAB	INJECTION	150 mg	32,390.00
	TRASTUZUMAB	INJECTION	440 mg	95,000.00
2	BEVACIZUMAB	INJECTION	100 mg/4ml	35,000.00
3	RITUXIMAB	INJECTION	100 mg/10 ml	11,000.00
	RITUXIMAB	INJECTION	500 mg/50 ml	55,000.00
4	MYCOPHENOLATE MOFETIL	CAPSULE/TABLET	500 mg	15.00
5	PEGASPARAGINASE (PEGASPARGASE)	INJECTION	3750 IU	140,000.00

Column I	Column II	Column III	Column IV	Column V
	Generic Name	***Route of Administration/ dosage form***	***Strength***	**MTP (SLR)**
6	PEMETREXED DISODIUM	INJECTION	100 mg	3,120.00
	PEMETREXED DISODIUM	INJECTION	500 mg	15,600.00
7	BORTEZOMIB	INJECTION	2 mg	14,500.00
8	PEGINTERFERON ALFA 2a	INJECTION	180 mcg	27,700.00
9	ABIRATERONE ACETATE	Tablet	250 mg	275.00
10	PEGFILGRASTIM	INJECTION	6 mg/ 0.6 ml, 6 mg/1 ml	22,000.00

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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 section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015 read with sections 3 and 118 of the aforesaid Act.

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

Colombo,
29th August, 2018.

Regulations

1. These regulations may be cited as the Medical Devices (Pricing) Regulations, of 2018.

2. No manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of a private medical institution or a person who is in possession of a medical device shall sell, offer for sale or charge for any medical device set out in the Schedule hereto, described by any brand name, approved name, models, sizes or pack sizes, above the Maximum Retail Price (MRP) stipulated therein.

3. A manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of a private medical institution or a person who is in possession of a medical device set out in the Schedule hereto, currently sells the said medical device at a price less than the maximum retail price set out in the Schedule hereto, is required to maintain the existing price without any price increase.

4. Every person or institution referred to in regulation 2, who sells or offer for sale or charges for any medical device which is described by its brand name, approved name, models, sizes or pack sizes set out in the Schedule hereto, shall issue a receipt clearly indicating the brand name or the approved name, pack size and the price of such medical device as a separate item.

5. The relevant Maximum Retail Price as set out in the Schedule, of each unit of item in the stock of such medical device manufactured or available for sale shall be printed or marked in their respective commercial package or label as expeditiously as practicable, prior to the expiry of a period of forty five days from the date of publication of these regulations.

6. Any manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of private medical institution or a person who is in possession of such medical devices who contravenes the provisions of these regulations commits an offence and shall be triable under Part IV of the National Medicines Regulatory Authority Act, No. 5 of 2015.

7. It shall be the duty of every manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of private medical institution and a person who is in possession of such medical devices to display at every retail outlet the Maximum Retail Price of the medical devices set out in the Schedule hereto.

8. Where the MRP of any brand name, model, size or pack size of such medical devices are not specified in the Schedule, such MRP shall be fixed by the National Medicines Regulatory Authority.

9. In these regulations –

"Medical Practitioner" shall have the same meaning as in the Medical Ordinance (Chapter 105);

"Private Medical Institution" shall have the same meaning as in the Private Medical Institutions (Registration) Act, No. 21 of 2006.

SCHEDULE

MAXIMUM RETAIL PRICES OF TWO SELECTED MEDICAL DEVICES

Column *I*	**Column *II***	**Column *III***
	Approved Name	***MRP (SLR)***
1	BLOOD GLUCOSE MONITERING SYSTEM	2,750.00 Per Unit
2	TEST STRIPS FOR BLOOD GLUCOSE MONITERING SYSTEM	50.00 Per Strip

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