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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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No. 2336/53 - THURSDAY, JUNE 15, 2023

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PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B 9/2016 (III)

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

REGULATIONS made by the Minister of Health under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
12.06.2023.

Regulations

The Medicines (Ceiling on Prices) Regulations, 2019 published in the *Gazette Extraordinary* No. 2123/35 of May 15, 2019, as amended by regulations published in *Gazette Extraordinary* No. 2241/43 of August 19, 2021 and regulations published in *Gazette Extraordinary* No. 2271/23 of March 15, 2022 and regulations published in the *Gazette Extraordinary* No. 2277/55 of April 29, 2022 are hereby further amended as follows:



(1) by the repeal of regulation 6 thereof and the substitution therefor, of the following: -

- “6. (1) A manufacturer or importer who sells any Scheduled Medicine at a Maximum Retail Price specified in Column V of the Schedule to the Medicines (Ceiling on Prices) Regulations of 2019 published in *Gazette Extraordinary* No. 2123/35 of May 15, 2019 as last amended by regulations published in *Gazette Extraordinary* No. 2277/55 of April 29, 2022 shall not sell such medicine at a price more than the Maximum Retail Price specified in Column V of the Schedule to these regulations.
- (2) A manufacturer or importer who sells any Scheduled Medicine at a revised retail price which is less than the Maximum Retail Price specified in Column V of the Schedule to the Medicines (Ceiling on Prices) Regulations of 2019 as last amended by regulations published in *Gazette Extraordinary* No. 2277/55 of April 29, 2022, shall reduce proportionately such revised retail price by a total sixteen *per centum* (16%).
- (3) Every trader, distributor, pharmacist, medical practitioner, dentist, veterinary surgeon, medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medicines for the purpose of sale shall maintain the price of the Scheduled Medicines at the maximum retail price or revised retail price whichever is less.”.

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

“SCHEDULE

[regulation 2]

MAXIMUM RETAIL PRICES OF MEDICINES

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
1	ALBENDAZOLE	Tablet/ capsule	400mg	59.59
2	AMOXICILLIN+CLAVULANIC ACID	Oral suspension	156mg/ 5ml	571.06
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	375mg	70.32
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	625mg	119.16
	AMOXICILLIN+CLAVULANIC ACID	Injection	1.2g	1,253.33
3	CLARITHROMYCIN	Tablet/ capsule	250mg	72.50
	CLARITHROMYCIN	Tablet/ capsule	500mg	146.99
	CLARITHROMYCIN	Oral suspension	125mg/5ml	866.01

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
4	AZITHROMYCIN	Tablet/ capsule	250 mg	74.68
	AZITHROMYCIN	Tablet/ capsule	500 mg	104.78
	AZITHROMYCIN	Oral suspension	200mg/ 5ml	347.58
5	CEFUROXIME	Tablet/ capsule	250 mg	90.38
	CEFUROXIME	Tablet/ capsule	500 mg	144.19
6	DOXYCYCLIN	Tablet/ capsule	100 mg	20.08
7	ACICLOVIR	Tablet/ capsule	200 mg	73.47
8	CIPROFLOXACIN	Tablet/ capsule	250 mg	11.42
	CIPROFLOXACIN	Tablet/ capsule	500 mg	16.88
9	LEVOFLOXACIN	Tablet/ capsule	250 mg	48.06
	LEVOFLOXACIN	Tablet/ capsule	500 mg	79.45
10	CEPHALEXIN	Tablet/ capsule	250 mg	16.28
	CEPHALEXIN	Tablet/ capsule	500 mg	29.81
	CEPHALEXIN	Oral suspension	125 mg/5 ml	526.35
11	CEFIXIME	Tablet/ capsule	100 mg	45.68
	CEFIXIME	Tablet/ capsule	200 mg	84.81
	CEFIXIME	Oral suspension	100 mg/5 ml	685.25

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
12	AMLODIPINE	Tablet/ capsule	5 mg	30.39
	AMLODIPINE	Tablet/ capsule	10 mg	42.31
13	DILTIAZEM	Tablet/ capsule	30 mg	5.38
	DILTIAZEM	Tablet/ capsule	60 mg	17.69
	DILTIAZEM	Tablet/ capsule	90 mg	42.51
14	LOSARTAN POTASSIUM	Tablet/ capsule	25 mg	14.59
	LOSARTAN POTASSIUM	Tablet/ capsule	50 mg	20.46
15	LOSARTAN + Hydrochlorothiazide	Tablet/ capsule	62.5 mg	38.62
16	ENALAPRIL	Tablet/ capsule	5 mg	11.91
	ENALAPRIL	Tablet/ capsule	10 mg	20.08
17	ATENOLOL	Tablet/ capsule	25mg	5.95
	ATENOLOL	Tablet/ capsule	50 mg	8.74
	ATENOLOL	Tablet/ capsule	100 mg	25.82
18	NIFEDIPINE – sustained release	Tablet/ capsule	20 mg	7.36
19	CLOPIDOGREL	Tablet/ capsule	75 mg	34.78
20	ATORVASTATIN	Tablet/ capsule	5mg	12.76
	ATORVASTATIN	Tablet/ capsule	10 mg	22.14

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	ATORVASTATIN	Tablet/ capsule	20 mg	34.95
	ATORVASTATIN	Tablet/ capsule	40 mg	49.17
21	ROSUVASTATIN	Tablet/ capsule	5 mg	42.70
	ROSUVASTATIN	Tablet/ capsule	10 mg	73.47
22	TELMISARTAN	Tablet/ capsule	20 mg	20.25
	TELMISARTAN	Tablet/ capsule	40 mg	32.17
	TELMISARTAN	Tablet/ capsule	80mg	60.38
23	ASPIRIN	Tablet/ capsule	75 mg	5.95
	ASPIRIN	Tablet/ capsule	100 mg	10.53
24	METFORMIN	Tablet/ capsule	500 mg	7.85
	METFORMIN-sustained release	Tablet/ capsule	500 mg	15.29
	METFORMIN	Tablet/ capsule	850 mg	14.70
25	GLIBENCLAMIDE	Tablet/ capsule	5 mg	4.35
26	GLICLAZIDE	Tablet/ capsule	80mg	22.45
27	THYROXINE	Tablet/ capsule	50 mcg	12.10
	THYROXINE	Tablet/ capsule	100 mcg	18.09
28	GLIPIZIDE	Tablet/ capsule	5 mg	15.70

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
29	IBUPROFEN	Tablet/ capsule	200 mg	2.18
	IBUPROFEN	Tablet/ capsule	400mg	7.36
30	DICLOFENAC SODIUM	Tablet/ capsule	50 mg	25.82
	DICLOFENAC SODIUM	Tablet/ capsule	100 mg	29.99
31	DICLOFENAC POTASSIUM	Tablet/ capsule	50 mg	21.76
32	PARACETAMOL	Tablet/ capsule	500 mg	3.49
33	SODIUM VALPROATE	Tablet/ capsule	200 mg	17.88
34	RISPERIDONE	Tablet/ capsule	1 mg	15.70
	RISPERIDONE	Tablet/ capsule	2 mg	18.35
35	OLANZAPINE	Tablet/ capsule	5 mg	19.87
	OLANZAPINE	Tablet/ capsule	10 mg	41.29
36	CARBAMAZEPINE	Tablet/ capsule	200 mg	23.81
37	ALPRAZOLAM	Tablet/ capsule	0.25 mg	12.91
	ALPRAZOLAM	Tablet/ capsule	0.5 mg	19.67
38	FLUOXETINE	Tablet/ capsule	20 mg	21.85

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
39	GABAPENTIN	Tablet/ capsule	100 mg	33.27
	GABAPENTIN	Tablet/ capsule	300 mg	65.85
40	BECLOMETHASONE	DP capsule (inhalation)	200 mcg	11.91
	BECLOMETHASONE	DP capsule (inhalation)	400 mcg	13.50
	BECLOMETHASONE	Metered dose inhaler (200 doses)	100 mcg	1,008.03
	BECLOMETHASONE	Metered dose inhaler (200 doses)	250 mcg	1,114.29
41	SALBUTAMOL	DP capsule (inhalation)	200 mcg	7.94
	SALBUTAMOL	DP capsule (inhalation)	400 mcg	10.93
	SALBUTAMOL	Metered dose inhaler (200 doses)	100 mcg	615.75
42	METHYL PREDNISOLONE	Tablet/ capsule	4 mg	23.53
	METHYL PREDNISOLONE	Tablet/ capsule	16mg	81.44
43	OMEPRAZOLE	Tablet/ capsule	20 mg	8.94
44	PANTOPRAZOLE	Tablet/ capsule	20 mg	33.75
	PANTOPRAZOLE	Tablet/ capsule	40 mg	55.60
45	ESOMEPRAZOLE	Tablet/ capsule	20 mg	40.11

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	ESOMEPRAZOLE	Tablet/ capsule	40 mg	76.27
46	DOMPERIDONE	Tablet/ capsule	10 mg	10.73
47	RABEPRAZOLE	Tablet/ capsule	10 mg	22.45
	RABEPRAZOLE	Tablet/ capsule	20 mg	42.81
48	ALENDRONIC ACID	Tablet/ capsule	70 mg	201.40
49	CEFTAZIDIME	INJECTION	500 mg	908.01
	CEFTAZIDIME	INJECTION	1 g	1,513.36
50	CEFTRIAZONE	INJECTION	250 mg	454.00
	CEFTRIAZONE	INJECTION	500 mg	851.26
	CEFTRIAZONE	INJECTION	1 g	1,324.18
51	CEFOTAXIME	INJECTION	500 mg	425.64
	CEFOTAXIME	INJECTION	1 g	709.39
52	FLUCONAZOLE	Tablet/ capsule	50 mg	47.28
	FLUCONAZOLE	Tablet/ capsule	150 mg	85.12
53	INSULIN SOLUBLE HUMAN	INJECTION	100 IU/1ml (10 ml vial)	2,270.02

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	INSULIN SOLUBLE HUMAN	INJECTION	100 IU/1ml (3ml cartridge)	1,135.02
	INSULIN ISOPHANE HUMAN	INJECTION	100 IU/1ml (10ml vial)	2,270.02
	INSULIN ISOPHANE HUMAN	INJECTION	100 IU/1ml (3ml cartridge)	1,135.02
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)	INJECTION	100 IU/1ml (10 ml vial)	2,270.02
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)	INJECTION	100 IU/1ml (3 ml cartridge)	1,135.02
54	GLIMEPIRIDE	TABLET	1 mg	13.53
	GLIMEPIRIDE	TABLET	2 mg	19.19
	GLIMEPIRIDE	TABLET	3 mg	32.16
	GLIMEPIRIDE	TABLET	4 mg	34.99
55	SITAGLIPTIN	TABLET	25 mg	28.37
	SITAGLIPTIN	TABLET	50 mg	53.89
	SITAGLIPTIN	TABLET	100 mg	91.74
56	TAMSULOSIN	Tablet/ capsule	0.40 mg	39.72
57	MONTELUKAST	TABLET	4 mg	22.71

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	MONTELUKAST	TABLET	5 mg	28.37
	MONTELUKAST	TABLET	10 mg	39.72
58	PREGABALIN	Tablet/ capsule	50 mg	23.17
	PREGABALIN	Tablet/ capsule	75 mg	29.33
	PREGABALIN	Tablet/ capsule	100 mg	36.41
	PREGABALIN	Tablet/ capsule	150 mg	45.40
	PREGABALIN	Tablet/ capsule	300 mg	74.73
59	TOPIRAMATE	Tablet/ capsule	25 mg	37.83
	TOPIRAMATE	Tablet/ capsule	50 mg	60.53
	TOPIRAMATE	Tablet/ capsule	100 mg	98.36
60	LAMOTRIGINE	TABLET	25 mg	22.71
	LAMOTRIGINE	TABLET	50 mg	39.72
	LAMOTRIGINE	TABLET	100 mg	66.21"

(3) The provisions of these regulations shall come into effect on June 26, 2023.

EOG 06-0101