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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2049/31 - 2017 දෙසැම්බර් මස 14 වැනි බ්‍රහස්පතින්දා - 2017.12.14  
No. 2049/31 - THURSDAY, DECEMBER 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 Section 142 read with Section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

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

Colombo,  
12<sup>th</sup> December, 2017.

**REGULATIONS**

The National Medicines Regulatory Authority (Ceiling on Prices) Regulations No. 2 of 2016 published in the *Gazette Extraordinary* No. 1989/61 of October 21, 2016 is hereby amended as follows :-

(1) by the substitution for regulation 1 thereof, of the following :-

“1. These regulations may be cited as the Ceiling on Prices Regulations, No. 6 of 2017 and shall come into operation on 14.12.2017 ”;



(2) by the substitution for regulation 4 thereof, of the following :-

“4. On and after the relevant date, no manufacturer, importer, trader, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of any Scheduled drug set out in column II of the Schedule hereto, for the purpose of sale shall sell such drug above the Maximum Retail Price (MRP) stipulated in the corresponding entry in column V thereof.”;

(3) by the substitution for regulation 5 thereof, of the following :-

“5. A manufacturer, importer, trader, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of a Scheduled drug for the purpose of sale currently sells such drug at a price less than the MRP stipulated in the Schedule may increase the existing price by only five *per centum* (5%) and shall maintain at such revised price.”;

(4) by the substitution for regulation 6 thereof, of the following :-

“6. The relevant MRP as set out in the Schedule hereto or the current retail price, whichever is less, of each unit of item in the stock of Scheduled drugs manufactured or available in the market, medical institution including a private medical institution, pharmacy or person who or which is in possession of such drug for the purpose of sale on the relevant date shall be printed or marked on its commercial package or label as expeditiously as practicable, so however, before the expiry of a period of Forty-five days from the relevant date.”;

(5) by the substitution for regulation 7 thereof, of the following :-

“7. Notwithstanding the provisions of regulation 6, the MRP of each unit shall be as set out in the Schedule on and after the relevant date. The MRP set out in the Schedule shall continue to be valid and effectual from the relevant date until revised.”;

(6) by the substitution for regulation 9 thereof, of the following :-

“9. Any manufacturer, importer, trader, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of a Scheduled drug for the purpose of sale and 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) by the substitution for regulation 10 thereof, of the following :-

“10. It shall be the duty of every manufacturer, importer, trader, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of Scheduled drugs for the purpose of sale, to display at every retail outlet the MRP of the Scheduled drugs set out in the Schedule hereto.”; and

(8) by the substitution for the Schedule thereof, of the following :-

#### SCHEDULE

#### MAXIMUM RETAIL PRICES OF 48 SELECTED MEDICINAL PRODUCT FORMULATIONS

<i>Column I</i>	<i>Column II Generic Name</i>	<i>Column III Route of Administration/ Dosage forms</i>	<i>Column IV Strength</i>	<i>Column V Ceiling Maximum Price (SLR)</i>
1	ALBENDAZOLE	Tablet/ capsule	400mg	31.50
2	AMOXICILLIN+CLAVULANIC ACID	Oral suspension	156mg/ 5ml	301.88
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	375mg	37.17
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	625mg	63.00
	AMOXICILLIN+CLAVULANIC ACID	Injection	1.2g	662.55

<i>Column I</i>	<i>Column II Generic Name</i>	<i>Column III Route of Administration/ Dosage forms</i>	<i>Column IV Strength</i>	<i>Column V Ceiling Maximum Price (SLR)</i>
3	CLARITHROMYCIN	Tablet/ capsule	250mg	38.33
	CLARITHROMYCIN	Tablet/ capsule	500mg	77.70
	CLARITHROMYCIN	Oral suspension	125mg/5ml	457.80
4	AZITHROMYCIN	Tablet/ capsule	250mg	39.48
	AZITHROMYCIN	Tablet/ capsule	500mg	55.39
	AZITHROMYCIN	Oral suspension	200mg/ 5ml	183.75
5	CEFUROXIME	Tablet/ capsule	250mg	47.78
	CEFUROXIME	Tablet/ capsule	500mg	76.23
6	DOXYCYCLIN	Tablet/ capsule	100mg	10.61
7	ACICLOVIR	Tablet/ capsule	200mg	38.85
8	CIPROFLOXACIN	Tablet/ capsule	250mg	6.04
	CIPROFLOXACIN	Tablet/ capsule	500mg	8.93
9	LEVOFLOXACIN	Tablet/ capsule	250mg	25.41
	LEVOFLOXACIN	Tablet/ capsule	500mg	42
10	CEPHALEXIN	Tablet/ capsule	250mg	8.61
	CEPHALEXIN	Tablet/ capsule	500mg	15.75
	CEPHALEXIN	Oral suspension	125mg/5ml	278.25
11	CEFIXIME	Tablet/ capsule	100mg	24.15
	CEFIXIME	Tablet/ capsule	200mg	44.84
	CEFIXIME	Oral suspension	100mg/5ml	362.25
12	AMLODIPINE	Tablet/ capsule	5mg	16.07
	AMLODIPINE	Tablet/ capsule	10mg	22.37
13	DILTIAZEM	Tablet/ capsule	30mg	2.84
	DILTIAZEM	Tablet/ capsule	60mg	9.35
	DILTIAZEM	Tablet/ capsule	90mg	22.47

<i>Column I</i>	<i>Column II Generic Name</i>	<i>Column III Route of Administration/ Dosage forms</i>	<i>Column IV Strength</i>	<i>Column V Ceiling Maximum Price (SLR)</i>
14	LOSARTAN POTASSIUM	Tablet/ capsule	25mg	7.72
	LOSARTAN POTASSIUM	Tablet/ capsule	50mg	10.82
15	LOSARTAN + HCT	Tablet/ capsule	62.5mg	20.42
16	ENALAPRIL	Tablet/ capsule	5mg	6.30
	ENALAPRIL	Tablet/ capsule	10mg	10.61
17	ATENOLOL	Tablet/ capsule	25mg	3.15
	ATENOLOL	Tablet/ capsule	50mg	4.62
	ATENOLOL	Tablet/ capsule	100mg	13.65
18	NIFEDIPINE – sustained release	Tablet/ capsule	20mg	3.89
19	CLOPIDOGREL	Tablet/ capsule	75mg	18.38
20	ATORVASTATIN	Tablet/ capsule	10mg	11.71
	ATORVASTATIN	Tablet/ capsule	20mg	18.48
21	ROSUVASTATIN	Tablet/ capsule	5mg	22.58
	ROSUVASTATIN	Tablet/ capsule	10mg	38.85
22	TELMISARTAN	Tablet/ capsule	20mg	10.71
	TELMISARTAN	Tablet/ capsule	40mg	17.01
	TELMISARTAN	Tablet/ capsule	80mg	31.92
23	ASPIRIN	Tablet/ capsule	75mg	3.15
	ASPIRIN	Tablet/ capsule	100mg	5.57
24	METFORMIN	Tablet/ capsule	500mg	4.15
	METFORMIN-sustained release	Tablet/ capsule	500mg	8.09
	METFORMIN	Tablet/ capsule	850mg	7.77
25	GLIBENCLAMIDE	Tablet/ capsule	5mg	2.31
26	GLICLAZIDE	Tablet/ capsule	80mg	11.87
27	THYROXINE	Tablet/ capsule	50mcg	6.41
	THYROXINE	Tablet/ capsule	100mcg	9.56
28	GLIPIZIDE	Tablet/ capsule	5mg	8.30
29	IBUPROFEN	Tablet/ capsule	200mg	1.16
	IBUPROFEN	Tablet/ capsule	400mg	3.89

<i>Column I</i>	<i>Column II Generic Name</i>	<i>Column III Route of Administration/ Dosage forms</i>	<i>Column IV Strength</i>	<i>Column V Ceiling Maximum Price (SLR)</i>
30	DICLOFENAC SODIUM	Tablet/ capsule	50mg	13.65
	DICLOFENAC SODIUM	Tablet/ capsule	100mg	15.86
31	DICLOFENAC POTASSIUM	Tablet/ capsule	50mg	11.50
32	PARACETAMOL	Tablet/ capsule	500mg	1.37
33	SODIUM VALPROATE	Tablet/ capsule	200mg	9.45
34	RISPERIDONE	Tablet/ capsule	1mg	8.30
	RISPERIDONE	Tablet/ capsule	2mg	9.71
35	OLANZAPINE	Tablet/ capsule	5mg	10.50
	OLANZAPINE	Tablet/ capsule	10mg	21.84
36	CARBAMAZEPINE	Tablet/ capsule	200mg	12.60
37	ALPRAZOLAM	Tablet/ capsule	0.25mg	6.83
	ALPRAZOLAM	Tablet/ capsule	0.5mg	10.40
38	FLUOXETINE	Tablet/ capsule	20mg	11.55
39	GABAPENTIN	Tablet/ capsule	100mg	17.59
	GABAPENTIN	Tablet/ capsule	300mg	34.81
40	BECLOMETHASONE	DP capsule (inhalation)	200mcg	6.30
	BECLOMETHASONE	DP capsule (inhalation)	400mcg	7.14
	BECLOMETHASONE	Metered dose inhaler (200 doses)	100mcg	532.88
	BECLOMETHASONE	Metered dose inhaler (200 doses)	250mcg	589.05
41	SALBUTAMOL	DP capsule (inhalation)	200mcg	4.20
	SALBUTAMOL	DP capsule (inhalation)	400mcg	5.78
	SALBUTAMOL	Metered dose inhaler (200 doses)	100mcg	325.50
42	METHYL PREDNISOLONE	Tablet/ capsule	4mg	12.44
	METHYL PREDNISOLONE	Tablet/ capsule	16mg	43.05
43	OMEPRAZOLE	Tablet/ capsule	20mg	4.73
44	PANTOPRAZOLE	Tablet/ capsule	20mg	17.85
	PANTOPRAZOLE	Tablet/ capsule	40mg	29.40
45	ESOMEPRAZOLE	Tablet/ capsule	20mg	21.21
	ESOMEPRAZOLE	Tablet/ capsule	40mg	40.32

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PART I : SEC. (I) - GAZETTE EXTRAORDINARY OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA - 14.12.2017

<i>Column I</i>	<i>Column II Generic Name</i>	<i>Column III Route of Administration/ Dosage forms</i>	<i>Column IV Strength</i>	<i>Column V Ceiling Maximum Price (SLR)</i>
46	DOMPERIDONE	Tablet/ capsule	10mg	5.67
47	RABEPRAZOLE	Tablet/ capsule	10mg	11.87
	RABEPRAZOLE	Tablet/ capsule	20mg	22.63
48	ALENDRONIC ACID	Tablet/ capsule	70mg	106.47

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