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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

LD.-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 together with Section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE (M.P.),
Minister of Health, Nutrition and
Indigenous Medicine.

Colombo,
21st October, 2016.

Regulations

1. These regulations may be cited as the National Medicines Regulatory Authority (Ceiling on Prices) Regulations, No. 2 of 2016.
2. There shall be a ceiling on prices of the drug-formulations set out in the Schedule hereto (hereinafter referred to as “scheduled drugs”) which shall come into operation on the date of publication of these regulations in the *Gazette Extraordinary* (hereinafter referred to as the “relevant date”).
3. The ceiling on prices of the scheduled drugs shall apply to and in respect of all branded and generic versions of such drug-formulations.
4. On and after the relevant date, no manufacturer, importer, trader and pharmacist shall sell any scheduled drug set out in Column II of the Schedule hereto, above the Maximum Retail Price (MRP) stipulated in the corresponding entry in Column V thereof.
5. A manufacturer, importer, trader or pharmacist who currently sells a scheduled drug at a price less than the MRP stipulated in the Schedule is required to maintain the existing price without any price increase.



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 or pharmacy for sale on the relevant date shall be printed or marked in their respective commercial package or label as expeditiously as practicable, so however, before the expiry of a period of forty-five days from the relevant date.
7. Notwithstanding the provisions of regulation 6 above, 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 for a period of two years from the relevant date unless earlier revised.
8. The implementation of these regulations shall be the responsibility of the National Medicines Regulatory Authority, the Ministry of Health, Nutrition and Indigenous Medicine and the Consumer Affairs Authority.
9. Any manufacturer, importer, trader or pharmacist who contravenes the provisions of these regulations commits an offence and shall be triable under Section 132 of the National Medicines Regulatory Authority Act, No.5 of 2015.
10. It shall be the duty of every manufacturer, trader, importer and pharmacist to display at every retail outlet the MRP of the scheduled drugs set out in the Schedule hereto.

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 form</i>	<i>Column IV Strength</i>	<i>Column V Ceiling / maximum price (SLR)</i>
1	ALBENDAZOLE	Tablet	400mg	30.00
2	AMOXICILLIN + CLAVULANIC ACID	Oral suspension	156mg / 5ml	287.50
	AMOXICILLIN + CLAVULANIC ACID	Tablet	375mg	35.40
	AMOXICILLIN + CLAVULANIC ACID	Tablet	625mg	60.00
	AMOXICILLIN + CLAVULANIC ACID	Injection	1.2 g	631.00
3	CLARITHROMYCIN	Tablet	250mg	36.50
	CLARITHROMYCIN	Tablet	500 mg	74.00
	CLARITHROMYCIN	Oral suspension	125mg / 5ml	436.00
4	AZITHROMYCIN	Tablet	250 mg	37.60
	AZITHROMYCIN	Tablet	500 mg	52.75
	AZITHROMYCIN	Oral suspension	200mg / 5ml	175.00
5	CEFUROXIME	Tablet	250mg	45.50
	CEFUROXIME	Tablet	500mg	72.60
6	DOXYCYCLIN	Tablet	100mg	10.10
7	ACICLOVIR	Tablet	200mg	37.00
8	CIPROFLOXACIN	Tablet	250mg	5.75
	CIPROFLOXACIN	Tablet	500 mg	8.50

<i>Column I</i>	<i>Column II Generic name</i>	<i>Column III Route of administration / dosage form</i>	<i>Column IV Strength</i>	<i>Column V Ceiling / maximum price (SLR)</i>
9	LEVOFLOXACIN	Tablet	250mg	24.20
	LEVOFLOXACIN	Tablet	500mg	40.00
10	CEPHALEXIN	Capsule	250mg	8.20
	CEPHALEXIN	Capsule	500mg	15.00
	CEPHALEXIN	Oral suspension	125mg/5ml	265.00
11	CEFIXIME	Tablet	100mg	23.00
	CEFIXIME	Tablet	200mg	42.70
	CEFIXIME	Oral suspension	50mg/5ml	345.00
12	AMLODIPINE	Tablet	5mg	15.30
	AMLODIPINE	Tablet	10mg	21.30
13	DILTIAZEM	Tablet	30mg	2.70
	DILTIAZEM	Tablet	60mg	8.90
	DILTIAZEM	Tablet	90mg	21.40
14	LOSARTAN POTASSIUM	Tablet	25mg	7.35
	LOSARTAN POTASSIUM	Tablet	50mg	10.30
15	LOSARTAN + HCT	Tablet	62.5mg	19.45
16	ENALAPRIL	Tablet	5mg	6.00
	ENALAPRIL	Tablet	10mg	10.10
17	ATENOLOL	Tablet	25mg	3.00
	ATENOLOL	Tablet	50mg	4.40
	ATENOLOL	Tablet	100mg	13.00
18	NIFEDIPINE - sustained release	Tablet or capsule	20mg	3.70
19	CLOPIDOGREL	Tablet	75mg	17.50
20	ATORVASTATIN	Tablet	10mg	11.15
	ATORVASTATIN	Tablet	20mg	17.60
21	ROSUVASTATIN	Tablet	5mg	21.50
	ROSUVASTATIN	Tablet	10mg	37.00
22	TELMISARTAN	Tablet	20mg	10.20
	TELMISARTAN	Tablet	40mg	16.20
	TELMISARTAN	Tablet	80mg	30.40
23	ASPIRIN	Tablet	75mg	3.00
	ASPIRIN	Tablet	100mg	5.30

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PART I : SEC. (I) - GAZETTE EXTRAORDINARY OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA - 21.10.2016

<i>Column I</i>	<i>Column II Generic name</i>	<i>Column III Route of administration / dosage form</i>	<i>Column IV Strength</i>	<i>Column V Ceiling / maximum price (SLR)</i>
24	METFORMIN	Tablet	500mg	3.95
	METFORMIN - sustained release	Tablet or capsule	500mg	7.70
	METFORMIN	Tablet	850mg	7.40
25	GLIBENCLAMIDE	Tablet	5mg	2.20
26	GLICLAZIDE	Tablet	80mg	11.30
27	THYROXINE	Tablet	50mcg	6.10
	THYROXINE	Tablet	100mcg	9.10
28	GLIPIZIDE	Tablet	5mg	7.90
29	IBUPROFEN	Tablet or capsule	200mg	1.10
	IBUPROFEN	Tablet or capsule	400mg	3.70
30	DICLOFENAC SODIUM	Tablet	50mg	13.00
	DICLOFENAC SODIUM	Tablet	100mg	15.10
31	DICLOFENAC POTASSIUM	Tablet	50mg	10.95
32	PARACETAMOL	Tablet	500mg	1.30
33	SODIUM VALPROATE	Tablet	200mg	9.00
34	RISPERIDONE	Tablet	1mg	7.90
	RISPERIDONE	Tablet	2mg	9.25
35	OLANZAPINE	Tablet	5mg	10.00
	OLANZAPINE	Tablet	10mg	20.80
36	CARBAMAZEPINE	Tablet	200mg	12.00
37	ALPRAZOLAM	Tablet	0.25mg	6.50
	ALPRAZOLAM	Tablet	0.5mg	9.90
38	FLUOXETINE	Tablet	20mg	11.00
39	GABAPENTIN	Tablet	100mg	16.75
	GABAPENTIN	Tablet	300mg	33.15
40	BECLOMETHASONE	DP capsule (inhalation)	200mcg	6.00
	BECLOMETHASONE	DP capsule (inhalation)	400mcg	6.80
	BECLOMETHASONE	Metered dose inhaler (200 doses)	100mcg	507.50
	BECLOMETHASONE	Metered dose inhaler (200 doses)	250mcg	561.00

<i>Column I</i>	<i>Column II Generic name</i>	<i>Column III Route of administration / dosage form</i>	<i>Column IV Strength</i>	<i>Column V Ceiling / maximum price (SLR)</i>
41	SALBUTAMOL	DP capsule (inhalation)	200mcg	4.00
	SALBUTAMOL	DP capsule (inhalation)	400mcg	5.50
	SALBUTAMOL	Metered dose inhaler (200 doses)	100mcg	310.00
42	METHYL PREDNISOLONE	Tablet	4mg	11.85
	METHYL PREDNISOLONE	Tablet	16mg	41.00
43	OMEPRazole	Tablet	20mg	4.50
44	PANTOPRAZOLE	Tablet	20mg	17.00
	PANTAPRAZOLE	Tablet	40mg	28.00
45	ESOMEPRazole	Tablet	20mg	20.20
	ESOMEPRazole	Tablet	40mg	38.40
46	DOMPERIDONE	Tablet	10mg	5.40
47	RABEPRazole	Tablet	10mg	11.30
	RABEPRazole	Tablet	20mg	21.55
48	ALENDRONIC ACID	Tablet	70xmg	101.40

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