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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,
Minister of Health, Nutrition and
Indigenous Medicine.

Colombo,
11th May, 2019.

Regulations

1. These regulations may be cited as the Medicines (Ceiling on Prices) Regulations, 2019 and shall come into operation on the date of publication of these regulations in the *Gazette* (hereinafter referred to as the “relevant date”).
2. There shall be a ceiling on prices of the medicines set out in the Schedule hereto (hereinafter referred to as “scheduled medicines”) from and after the relevant date.
3. The Maximum Retail Price limits in respect of the scheduled medicines shall be applicable to all brand names and generic names of the scheduled medicines.



4. On and after the relevant date, no manufacturer, importer, 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 any scheduled medicine set out in column II of the Schedule hereto, for the purpose of sale shall sell such medicine above the Maximum Retail Price stipulated in the corresponding entry in column V thereof.

5. Every person or institution referred to in regulation 4, who sells or offer for sale any medicine set out in the Schedule hereto, shall upon such sale issue a receipt clearly indicating the appropriate name and the price of such medicine.

6. Any manufacturer or importer who is in possession of a scheduled medicine for the purpose of sale who currently sells such medicine at a price less than the Maximum Retail Price stipulated in the Schedule may increase the existing price by only Fourteen Decimal Four per centum (14.4%) and any 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 such scheduled medicine for the purpose of sale shall maintain such medicine at such revised price.

7. Where any dosage form or strength of the scheduled medicine is not specified in such schedule, the maximum retail 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.

8. The Maximum Retail Price as set out in the Schedule hereto or the current retail price, whichever is less, of each unit of item in the stock of the scheduled medicines manufactured or available in the market, medical institution including a private medical institution, pharmacy or person who or which is in possession of such medicine 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.

9. Notwithstanding the provisions of regulation 8, the Maximum Retail Price of each unit shall be as set out in the Schedule on and after the relevant date. The Maximum Retail Price set out in the Schedule shall continue to be valid and effectual from the relevant date.

10. Any manufacturer, importer, 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 a scheduled medicine for the purpose of sale, who contravenes the provisions of these regulations commits an offence and shall be triable under section 131 of the National Medicines Regulatory Authority Act, No.5 of 2015.

11. It shall be the duty of every manufacturer, importer, 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 scheduled medicines for the purpose of sale, to display at every retail outlet the Maximum Retail Price of the scheduled medicines set out in the Schedule hereto.

12. 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 and by regulations published in *Gazette Extraordinary* No. 2086/37 of August 31, 2018 are hereby rescinded.

13. For the purpose of these regulations –

“dentist” shall have the same meaning as in the Medical Ordinance (Chapter 105);

“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;

“veterinary surgeon” means a person registered as a Veterinary Surgeon or a Veterinary Practitioner under the Veterinary Surgeons and Practitioners Act, No. 46 of 1956.

SCHEDULE

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
1	ALBENDAZOLE	Tablet/ capsule	400mg	36.04
2	AMOXICILLIN+CLAVULANIC ACID	Oral suspension	156mg/ 5ml	345.35
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	375mg	42.52
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	625mg	72.07
	AMOXICILLIN+CLAVULANIC ACID	Injection	1.2g	757.96
3	CLARITHROMYCIN	Tablet/ capsule	250mg	43.85
	CLARITHROMYCIN	Tablet/ capsule	500mg	88.89
	CLARITHROMYCIN	Oral suspension	125mg/5ml	523.72
4	AZITHROMYCIN	Tablet/ capsule	250 mg	45.17
	AZITHROMYCIN	Tablet/ capsule	500 mg	63.37
	AZITHROMYCIN	Oral suspension	200mg/ 5ml	210.21
5	CEFUROXIME	Tablet/ capsule	250 mg	54.66
	CEFUROXIME	Tablet/ capsule	500 mg	87.21
6	DOXYCYCLIN	Tablet/ capsule	100 mg	12.14
7	ACICLOVIR	Tablet/ capsule	200 mg	44.44
8	CIPROFLOXACIN	Tablet/ capsule	250 mg	6.91
	CIPROFLOXACIN	Tablet/ capsule	500 mg	10.22
9	LEVOFLOXACIN	Tablet/ capsule	250 mg	29.07
	LEVOFLOXACIN	Tablet/ capsule	500 mg	48.05
10	CEPHALEXIN	Tablet/ capsule	250 mg	9.85
	CEPHALEXIN	Tablet/ capsule	500 mg	18.02
	CEPHALEXIN	Oral suspension	125 mg/5 ml	318.32

SCHEDULE (Contd.)

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
11	CEFIXIME	Tablet/ capsule	100 mg	27.63
	CEFIXIME	Tablet/ capsule	200 mg	51.30
	CEFIXIME	Oral suspension	100 mg/5 ml	414.41
12	AMLODIPINE	Tablet/ capsule	5 mg	18.38
	AMLODIPINE	Tablet/ capsule	10 mg	25.59
13	DILTIAZEM	Tablet/ capsule	30 mg	3.25
	DILTIAZEM	Tablet/ capsule	60 mg	10.70
	DILTIAZEM	Tablet/ capsule	90 mg	25.71
14	LOSARTAN POTASSIUM	Tablet/ capsule	25 mg	8.83
	LOSARTAN POTASSIUM	Tablet/ capsule	50 mg	12.38
15	LOSARTAN + Hydrochlorothiazide	Tablet/ capsule	62.5 mg	23.36
16	ENALAPRIL	Tablet/ capsule	5 mg	7.21
	ENALAPRIL	Tablet/ capsule	10 mg	12.14
17	ATE NOLOL	Tablet/ capsule	25mg	3.60
	ATE NOLOL	Tablet/ capsule	50 mg	5.29
	ATE NOLOL	Tablet/ capsule	100 mg	15.62
18	NIFEDIPINE – sustained release	Tablet/ capsule	20 mg	4.45
19	CLOPIDOGREL	Tablet/ capsule	75 mg	21.03
20	ATORVASTATIN	Tablet/ capsule	5mg	7.72
	ATORVASTATIN	Tablet/ capsule	10 mg	13.40
	ATORVASTATIN	Tablet/ capsule	20 mg	21.14
	ATORVASTATIN	Tablet/ capsule	40 mg	29.74

SCHEDULE (Contd.)

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
21	ROSUVASTATIN	Tablet/ capsule	5 mg	25.83
	ROSUVASTATIN	Tablet/ capsule	10 mg	44.44
22	TELMISARTAN	Tablet/ capsule	20 mg	12.25
	TELMISARTAN	Tablet/ capsule	40 mg	19.46
	TELMISARTAN	Tablet/ capsule	80mg	36.52
23	ASPIRIN	Tablet/ capsule	75 mg	3.60
	ASPIRIN	Tablet/ capsule	100 mg	6.37
24	METFORMIN	Tablet/ capsule	500 mg	4.75
	METFORMIN-sustained release	Tablet/ capsule	500 mg	9.25
	METFORMIN	Tablet/ capsule	850 mg	8.89
25	GLIBENCLAMIDE	Tablet/ capsule	5 mg	2.64
26	GLICLAZIDE	Tablet/ capsule	80mg	13.58
27	THYROXINE	Tablet/ capsule	50 mcg	7.33
	THYROXINE	Tablet/ capsule	100 mcg	10.94
28	GLIPIZIDE	Tablet/ capsule	5 mg	9.50
29	IBUPROFEN	Tablet/ capsule	200 mg	1.33
	IBUPROFEN	Tablet/ capsule	400mg	4.45
30	DICLOFENAC SODIUM	Tablet/ capsule	50 mg	15.62
	DICLOFENAC SODIUM	Tablet/ capsule	100 mg	18.14
31	DICLOFENAC POTASSIUM	Tablet/ capsule	50 mg	13.16
32	PARACETAMOL	Tablet/ capsule	500 mg	1.57
33	SODIUM VALPROATE	Tablet/ capsule	200 mg	10.81

SCHEDULE (Contd.)

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
34	RISPERIDONE	Tablet/ capsule	1 mg	9.50
	RISPERIDONE	Tablet/ capsule	2 mg	11.11
35	OLANZAPINE	Tablet/ capsule	5 mg	12.01
	OLANZAPINE	Tablet/ capsule	10 mg	24.98
36	CARBAMAZEPINE	Tablet/ capsule	200 mg	14.41
37	ALPRAZOLAM	Tablet/ capsule	0.25 mg	7.81
	ALPRAZOLAM	Tablet/ capsule	0.5 mg	11.90
38	FLUOXETINE	Tablet/ capsule	20 mg	13.21
39	GABAPENTIN	Tablet/ capsule	100 mg	20.12
	GABAPENTIN	Tablet/ capsule	300 mg	39.82
40	BECLOMETHASONE	DP capsule (inhalation)	200 mcg	7.21
	BECLOMETHASONE	DP capsule (inhalation)	400 mcg	8.17
	BECLOMETHASONE	Metered dose inhaler (200 doses)	100 mcg	609.61
	BECLOMETHASONE	Metered dose inhaler (200 doses)	250 mcg	673.87
41	SALBUTAMOL	DP capsule (inhalation)	200 mcg	4.80
	SALBUTAMOL	DP capsule (inhalation)	400 mcg	6.61
	SALBUTAMOL	Metered dose inhaler (200doses)	100 mcg	372.37
42	METHYL PREDNISOLONE	Tablet/ capsule	4 mg	14.23
	METHYL PREDNISOLONE	Tablet/ capsule	16mg	49.25
43	OMEPRAZOLE	Tablet/ capsule	20 mg	5.41
44	PANTOPRAZOLE	Tablet/ capsule	20 mg	20.42
	PANTOPRAZOLE	Tablet/ capsule	40 mg	33.63

SCHEDULE (Contd.)

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
45	ESOMEPRAZOLE	Tablet/ capsule	20 mg	24.26
	ESOMEPRAZOLE	Tablet/ capsule	40 mg	46.13
46	DOMPERIDONE	Tablet/ capsule	10 mg	6.49
47	RABEPRAZOLE	Tablet/ capsule	10 mg	13.58
	RABEPRAZOLE	Tablet/ capsule	20 mg	25.89
48	ALENDRONIC ACID	Tablet/ capsule	70 mg	121.80
49	CEFTAZIDIME	Injection	500 mg	549.12
	CEFTAZIDIME	Injection	1 g	915.20
50	CEFTRIAZONE	Injection	250 mg	274.56
	CEFTRIAZONE	Injection	500 mg	514.80
	CEFTRIAZONE	Injection	1 g	800.80
51	CEFOTAXIME	Injection	500 mg	257.40
	CEFOTAXIME	Injection	1 g	429.00
52	FLUCONAZOLE	Tablet/ capsule	50 mg	28.60
	FLUCONAZOLE	Tablet/ capsule	150 mg	51.48
53	INSULIN SOLUBLE HUMAN	Injection	100 IU/1ml (10ml vial)	1,372.80
	INSULIN SOLUBLE HUMAN	Injection	100 IU/1ml (3ml cartridge)	686.40
	INSULIN ISOPHANE HUMAN	Injection	100 IU/1ml (10ml vial)	1,372.80
	INSULIN ISOPHANE HUMAN	Injection	100 IU/1ml (3ml cartridge)	686.40

SCHEDULE (Contd.)

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU/1ml)	Injection	100 IU/1ml (10 ml vial)	1,372.80
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU/1ml)	Injection	100 IU/1ml (3 ml cartridge)	686.40
54	GLIMEPIRIDE	Tablet	1 mg	8.18
	GLIMEPIRIDE	Tablet	2 mg	11.61
	GLIMEPIRIDE	Tablet	3 mg	19.45
	GLIMEPIRIDE	Tablet	4 mg	21.16
55	SITAGLIPTIN	Tablet	25 mg	17.16
	SITAGLIPTIN	Tablet	50 mg	32.60
	SITAGLIPTIN	TTablet	100 mg	55.48
56	TAMSULOSIN	Tablet/ capsule	0.40 mg	24.02
57	MONTELUKAST	Tablet	4 mg	13.73
	MONTELUKAST	Tablet	5 mg	17.16
	MONTELUKAST	Tablet	10 mg	24.02
58	PREGABALIN	Tablet/ capsule	50 mg	14.01
	PREGABALIN	Tablet/ capsule	75 mg	17.73
	PREGABALIN	Tablet/ capsule	100 mg	22.02
	PREGABALIN	Tablet/ capsule	150 mg	27.46
	PREGABALIN	Tablet/ capsule	300 mg	45.19

SCHEDULE (Contd.)

MAXIMUM RETAIL PRICES OF MEDICINES

<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 Retail Price (SLR)</i>
59	TOPIRAMATE	Tablet/ capsule	25 mg	22.88
	TOPIRAMATE	Tablet/ capsule	50 mg	36.61
	TOPIRAMATE	Tablet/ capsule	100 mg	59.49
60	LAMOTRIGINE	Tablet	25 mg	13.73
	LAMOTRIGINE	Tablet	50 mg	24.02
	LAMOTRIGINE	Tablet	100 mg	40.04

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