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**PART I : SECTION (I) — GENERAL**

**Government Notifications**

L.D.B 9/2016 (II)

**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,  
15th March 2022.

**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 are hereby amended as follows: -

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

“1. These regulations may be cited as the Medicines (Ceiling on Prices) Regulations, 2019.”;



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

“2. The maximum retail price of the medicines in generic name specified in Column II of the Schedule hereto (hereinafter referred to as the “Scheduled Medicines”) in the dosage form or route of administration specified in the corresponding entry in Column III thereof of the strength specified in the corresponding entry in Column IV thereof shall be as specified in corresponding entry in Column V of the Schedule hereto.”;

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

“3. The maximum retail price of the Scheduled Medicines shall be applicable to all the brand names of the generic name of such Scheduled Medicines.”;

(4) by the repeal of regulation 4 thereof and the substitution therefor, of the following: -

“4. A 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 the Scheduled Medicines, for the purpose of sale shall not sell such Scheduled Medicines above the maximum retail price specified in Column V of the Schedule or revised retail price as may be determined in accordance with the provisions of regulation 6.”;

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

“6. (1) On the date of publication of these regulations, a manufacturer or importer who sells any Scheduled Medicine except paracetamol at a revised retail price under the Medicines (Ceiling on Prices) Regulations of 2019 published in *Gazette* Extraordinary No. 2123/35 of May 15, 2019 as amended by the regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 which is less than the 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 may increase proportionately such revised retail price by a total thirty-eight *per centum* (38%). The total increase of thirty-eight *per centum* (38%) includes the nine *per centum* (9%) increased by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 and the other twenty-nine *per centum* (29%) increased by these regulations.

(2) (a) On the date of publication of these regulations, a manufacturer or importer who sells a paracetamol at a revised retail price under the Medicines (Pricing of Paracetamol Tablets/Capsules 500mg) Regulations, 2022 published in *Gazette* Extraordinary No. 2269/11 of February 28, 2022 which is less than the maximum retail price specified in Column V of the Schedule hereto may increase proportionately such revised retail price by a total twenty-nine *per centum* (29%).

(b) For the avoidance of doubt, it is hereby declared that the total increase of thirty-five *per centum* (35%) by the Medicines (Pricing of Paracetamol Tablets/Capsules 500mg) Regulations, 2022 published in *Gazette* Extraordinary No. 2269/11 of February 28, 2022 included the increase of nine *per centum* (9%) of the paracetamol increased by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021.

(3) Notwithstanding the provisions of sub-regulations (1) and (2), such increase of revised retail price of the Scheduled Medicines shall not exceed the maximum retail price specified in Column V of the Schedule hereto.

(4) 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 the purpose of sale shall maintain the price of the Scheduled Medicines at the maximum retail price or revised retail price whichever is less.”;

6. by the repeal of regulation 7 thereof and the substitution therefor, of the following: -

“7. Where any dosage form or strength of the Scheduled Medicines and the maximum retail price of such dosage form or strength of Scheduled Medicines are not specified in Column V of the Schedule hereto, the National Medicines Regulatory Authority shall fix the price for the Scheduled Medicines in such dosage form or strength.”;

7. by the repeal of regulation 8 thereof and the substitution therefor, of the following: -

“8. Any manufacturer or importer shall print or mark on the commercial package or label of the Scheduled Medicines the maximum retail price specified in Column V of the Schedule hereto, or the revised retail price, whichever is less, in the stock manufactured or available in the market as expeditiously as possible:

Provided however, the maximum retail price or the revised retail price whichever is less shall be printed or marked in the commercial package or label of the Schedule Medicines before the expiry of a period of forty-five days from the date of publication of these regulations.”;

8. by the repeal of regulation 9 thereof :-

9. by the repeal of regulation 10 thereof and the substitution therefor, of the following: -

“10. Any person 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.

10. by the repeal of regulation 11 thereof and the substitution therefor, of the following: -

“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 the Scheduled Medicines for the purpose of sale, to display at every retail outlet the maximum retail price of the Scheduled Medicines or the revised retail price whichever is less.”;

11. by the insertion of definition for the term of expression “person”, immediately after definition of “medical practitioner”

“person” includes any body of persons corporate or unincorporate;”; and

12. by the repeal of the Schedule and the substitution therefor, of the following: -

## “ SCHEDULE

[Regulation 2]

### MAXIMUM RETAIL PRICES OF MEDICINE

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	50.67
2	AMOXICILLIN+CLAVULANIC ACID	Oral suspension	156mg/ 5ml	485.59
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	375mg	59.79

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	625mg	101.33
	AMOXICILLIN+CLAVULANIC ACID	Injection	1.2g	1065.76
3	CLARITHROMYCIN	Tablet/ capsule	250mg	61.65
	CLARITHROMYCIN	Tablet/ capsule	500mg	124.99
	CLARITHROMYCIN	Oral suspension	125mg/5ml	736.40
4	AZITHROMYCIN	Tablet/ capsule	250 mg	63.51
	AZITHROMYCIN	Tablet/ capsule	500 mg	89.10
	AZITHROMYCIN	Oral suspension	200mg/ 5ml	295.56
5	CEFUROXIME	Tablet/ capsule	250 mg	76.85
	CEFUROXIME	Tablet/ capsule	500 mg	122.61
6	DOXYCYCLIN	Tablet/ capsule	100 mg	17.07
7	ACICLOVIR	Tablet/ capsule	200 mg	62.47
8	CIPROFLOXACIN	Tablet/ capsule	250 mg	9.71
	CIPROFLOXACIN	Tablet/ capsule	500 mg	14.36
9	LEVOFLOXACIN	Tablet/ capsule	250 mg	40.87
	LEVOFLOXACIN	Tablet/ capsule	500 mg	67.56
10	CEPHALEXIN	Tablet/ capsule	250 mg	13.84
	CEPHALEXIN	Tablet/ capsule	500 mg	25.35
	CEPHALEXIN	Oral suspension	125 mg/5 ml	447.58

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
11	CEFIXIME	Tablet/ capsule	100 mg	38.84
	CEFIXIME	Tablet/ capsule	200 mg	72.12
	CEFIXIME	Oral suspension	100 mg/5 ml	582.69
12	AMLODIPINE	Tablet/ capsule	5 mg	25.84
	AMLODIPINE	Tablet/ capsule	10 mg	35.98
13	DILTIAZEM	Tablet/ capsule	30 mg	4.57
	DILTIAZEM	Tablet/ capsule	60 mg	15.04
	DILTIAZEM	Tablet/ capsule	90 mg	36.15
14	LOSARTAN POTASSIUM	Tablet/ capsule	25 mg	12.41
	LOSARTAN POTASSIUM	Tablet/ capsule	50 mg	17.40
15	LOSARTAN + Hydrochlorothiazide	Tablet/ capsule	62.5 mg	32.84
16	ENALAPRIL	Tablet/ capsule	5 mg	10.13
	ENALAPRIL	Tablet/ capsule	10 mg	17.07
17	ATENOLOL	Tablet/ capsule	25mg	5.06
	ATENOLOL	Tablet/ capsule	50 mg	7.43
	ATENOLOL	Tablet/ capsule	100 mg	21.96
18	NIFEDIPINE – sustained release	Tablet/ capsule	20 mg	6.26
19	CLOPIDOGREL	Tablet/ capsule	75 mg	29.57
20	ATORVASTATIN	Tablet/ capsule	5mg	10.85
	ATORVASTATIN	Tablet/ capsule	10 mg	18.83

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	29.72
	ATORVASTATIN	Tablet/ capsule	40 mg	41.81
21	ROSUVASTATIN	Tablet/ capsule	5 mg	36.31
	ROSUVASTATIN	Tablet/ capsule	10 mg	62.47
22	TELMISARTAN	Tablet/ capsule	20 mg	17.22
	TELMISARTAN	Tablet/ capsule	40 mg	27.36
	TELMISARTAN	Tablet/ capsule	80mg	51.34
23	ASPIRIN	Tablet/ capsule	75 mg	5.06
	ASPIRIN	Tablet/ capsule	100 mg	8.95
24	METFORMIN	Tablet/ capsule	500 mg	6.67
	METFORMIN-sustained release	Tablet/ capsule	500 mg	13.00
	METFORMIN	Tablet/ capsule	850 mg	12.50
25	GLIBENCLAMIDE	Tablet/ capsule	5 mg	3.70
26	GLICLAZIDE	Tablet/ capsule	80mg	19.09
27	THYROXINE	Tablet/ capsule	50 mcg	10.29
	THYROXINE	Tablet/ capsule	100 mcg	15.38
28	GLIPIZIDE	Tablet/ capsule	5 mg	13.35
29	IBUPROFEN	Tablet/ capsule	200 mg	1.86
	IBUPROFEN	Tablet/ capsule	400mg	6.26

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
30	DICLOFENAC SODIUM	Tablet/ capsule	50 mg	21.96
	DICLOFENAC SODIUM	Tablet/ capsule	100 mg	25.50
31	DICLOFENAC POTASSIUM	Tablet/ capsule	50 mg	18.50
32	PARACETAMOL	Tablet/ capsule	500 mg	2.97
33	SODIUM VALPROATE	Tablet/ capsule	200 mg	15.20
34	RISPERIDONE	Tablet/ capsule	1 mg	13.35
	RISPERIDONE	Tablet/ capsule	2 mg	15.61
35	OLANZAPINE	Tablet/ capsule	5 mg	16.89
	OLANZAPINE	Tablet/ capsule	10 mg	35.11
36	CARBAMAZEPINE	Tablet/ capsule	200 mg	20.25
37	ALPRAZOLAM	Tablet/ capsule	0.25 mg	10.98
	ALPRAZOLAM	Tablet/ capsule	0.5 mg	16.73
38	FLUOXETINE	Tablet/ capsule	20 mg	18.58
39	GABAPENTIN	Tablet/ capsule	100 mg	28.29
	GABAPENTIN	Tablet/ capsule	300 mg	55.99
40	BECLOMETHASONE	DP capsule (inhalation)	200 mcg	10.13

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	BECLOMETHASONE	DP capsule (inhalation)	400 mcg	11.48
	BECLOMETHASONE	Metered dose inhaler (200 doses)	100 mcg	857.17
	BECLOMETHASONE	Metered dose inhaler (200 doses)	250 mcg	947.52
41	SALBUTAMOL	DP capsule (inhalation)	200 mcg	6.75
	SALBUTAMOL	DP capsule (inhalation)	400 mcg	9.29
	SALBUTAMOL	Metered dose inhaler (200 doses)	100 mcg	523.59
42	METHYL PREDNISOLONE	Tablet/ capsule	4 mg	20.01
	METHYL PREDNISOLONE	Tablet/ capsule	16mg	69.25
43	OMEPRAZOLE	Tablet/ capsule	20 mg	7.60
44	PANTOPRAZOLE	Tablet/ capsule	20 mg	28.70
	PANTOPRAZOLE	Tablet/ capsule	40 mg	47.28
45	ESOMEPRAZOLE	Tablet/ capsule	20 mg	34.11
	ESOMEPRAZOLE	Tablet/ capsule	40 mg	64.86
46	DOMPERIDONE	Tablet/ capsule	10 mg	9.12
47	RABEPRAZOLE	Tablet/ capsule	10 mg	19.09
	RABEPRAZOLE	Tablet/ capsule	20 mg	36.40
48	ALENDRONIC ACID	Tablet/ capsule	70 mg	171.26
49	CEFTAZIDIME	INJECTION	500 mg	772.12



Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	CEFTAZIDIME	INJECTION	1 g	1286.87
50	CEFTRIAZONE	INJECTION	250 mg	386.06
	CEFTRIAZONE	INJECTION	500 mg	723.86
	CEFTRIAZONE	INJECTION	1 g	1126.00
51	CEFOTAXIME	INJECTION	500 mg	361.94
	CEFOTAXIME	INJECTION	1 g	603.22
52	FLUCONAZOLE	Tablet/ capsule	50 mg	40.21
	FLUCONAZOLE	Tablet/ capsule	150 mg	72.38
53	INSULIN SOLUBLE HUMAN	INJECTION	100 IU/1ml (10 ml vial)	1930.29
	INSULIN SOLUBLE HUMAN	INJECTION	100 IU/1ml (3ml cartridge)	965.15
	INSULIN ISOPHANE HUMAN	INJECTION	100 IU/1ml (10ml vial)	1930.29
	INSULIN ISOPHANE HUMAN	INJECTION	100 IU/1ml (3ml cartridge)	965.15
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)	INJECTION	100 IU/1ml (10 ml vial)	1930.29
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)	INJECTION	100 IU/1ml (3 ml cartridge)	965.15
54	GLIMEPIRIDE	TABLET	1 mg	11.51
	GLIMEPIRIDE	TABLET	2 mg	16.32
	GLIMEPIRIDE	TABLET	3 mg	27.35

Column I	Column II Generic Name	Column III Route of Administration/ Dosage forms	Column IV Strength	Column V Maximum Retail Price Per unit (SLR)
	GLIMEPIRIDE	TABLET	4 mg	29.75
55	SITAGLIPTIN	TABLET	25 mg	24.12
	SITAGLIPTIN	TABLET	50 mg	45.83
	SITAGLIPTIN	TABLET	100 mg	78.01
56	TAMSULOSIN	Tablet/ capsule	0.40 mg	33.77
57	MONTELUKAST	TABLET	4 mg	19.31
	MONTELUKAST	TABLET	5 mg	24.12
	MONTELUKAST	TABLET	10 mg	33.77
58	PREGABALIN	Tablet/ capsule	50 mg	19.70
	PREGABALIN	Tablet/ capsule	75 mg	24.94
	PREGABALIN	Tablet/ capsule	100 mg	30.96
	PREGABALIN	Tablet/ capsule	150 mg	38.61
	PREGABALIN	Tablet/ capsule	300 mg	63.55
59	TOPIRAMATE	Tablet/ capsule	25 mg	32.17
	TOPIRAMATE	Tablet/ capsule	50 mg	51.47
	TOPIRAMATE	Tablet/ capsule	100 mg	83.64
60	LAMOTRIGINE	TABLET	25 mg	19.31
	LAMOTRIGINE	TABLET	50 mg	33.77
	LAMOTRIGINE	TABLET	100 mg	56.30

13. The Medicines (Pricing of Paracetamol Tablets/Capsules 500mg) Regulations, 2022 published in *Gazette Extraordinary* No. 2269/11 of February 28, 2022 is hereby rescinded.

EOG 03-0897