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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 read with section 3, of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
19th August, 2021.

Regulations

The Medicines (Celling on Prices) Regulations of 2019 published in the *Gazette* Extraordinary No.2123/35 of May 15, 2019 is hereby amended by the repeal of the Schedule thereof and the substitution thereof of the following: -



SCHEDULE

(regulation 2)

No.	Column I Generic Name	Column II Root of administration or Dosage forms	Column III Strength	Column IV Maximum Retail Price (MRP) per unit (SLR)
1	ALBENDAZOLE	Tablet/ capsule	400mg	39.28
2	AMOXICILLIN+CLAVULANIC ACID	Oral suspension	156mg/ 5 ml	376.43
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	375mg	46.35
	AMOXICILLIN+CLAVULANIC ACID	Tablet/ capsule	625mg	78.55
	AMOXICILLIN+CLAVULANIC ACID	Injection	1.2g	826.17
	ACID			
3.	CLARITHROMYCIN	Tablet/ capsule	250mg	47.79
	CLARITHROMYCIN	Tablet/ capsule	500mg	96.89
	CLARITHROMYCIN	Oral suspension	125mg/5ml	570.85
4.	AZITHROMYCIN	Tablet/ capsule	250 mg	49.23
	AZITHROMYCIN	Tablet/ capsule	500 mg	69.07
	AZITHROMYCIN	Oral suspension	200mg / 5ml	229.12
5.	CEFUROXIME	Tablet/ capsule	250 mg	59.57
	CEFUROXIME	Tablet/ capsule	500 mg	95.05
6.	DOXYCYCLIN	Tablet/ capsule	100 mg	13.23
7.	ACICLOVIR	Tablet/ capsule	200 mg	48.43
8.	CIPROFLOXACIN	Tablet/ capsule	250 mg	7.53
	CIPROFLOXACIN	Tablet/ capsule	500 mg	11.13
9.	LEVOFLOXACIN	Tablet/ capsule	250 mg	31.68
	LEVOFLOXACIN	Tablet/ capsule	500 mg	52.37
10.	CEPHALEXIN	Tablet/ capsule	250 mg	10.73
	CEPHALEXIN	Tablet/ capsule	500 mg	19.65
	CEPHALEXIN	Oral suspension	125 mg/5 ml	346.96

No.	Column I Generic Name	Column II Root of administration or Dosage forms	Column III Strength	Column IV Maximum Retail Price (MRP) per unit (SLR)
11.	CEFIXIME	Tablet/ capsule	100 mg	30.11
	CEFIXIME	Tablet/ capsule	200 mg	55.91
	CEFIXIME	Oral suspension	100 mg/5 ml	451.70
12.	AMLODIPINE	Tablet/ capsule	5 mg	20.03
	AMLODIPINE	Tablet/ capsule	10 mg	27.89
13.	DILTIAZEM	Tablet/ capsule	30 mg	3.54
	DILTIAZEM	Tablet/ capsule	60 mg	11.66
	DILTIAZEM	Tablet/ capsule	90 mg	28.02
14.	LOSARTAN POTASSIUM	Tablet/ capsule	25 mg	9.62
	LOSARTAN POTASSIUM	Tablet/ capsule	50 mg	13.49
15.	LOSARTAN + Hydrochlorothiazide	Tablet/ capsule	62.5 mg	25.46
16.	ENALAPRIL	Tablet/ capsule	5 mg	7.85
	ENALAPRIL	Tablet/ capsule	10 mg	13.23
17.	ATENOLOL	Tablet/ capsule	25mg	3.92
	ATENOLOL	Tablet/ capsule	50 mg	5.76
	ATENOLOL	Tablet/ capsule	100 mg	17.02
18.	NIFEDIPINE - sustained release	Tablet/ capsule	20 mg	4.85
19.	CLOPIDOGREL	Tablet/ capsule	75 mg	22.92
20.	ATORVASTATIN	Tablet/ capsule	5mg	8.41
	ATORVASTATIN	Tablet/ capsule	10 mg	14.60
	ATORVASTATIN	Tablet/ capsule	20 mg	23.04
	ATORVASTATIN	Tablet/ capsule	40 mg	32.41

No.	Column I Generic Name	Column II Root of administration or Dosage forms	Column III Strength	Column IV Maximum Retail Price (MRP) per unit (SLR)
21.	ROSUVASTATIN	Tablet/ capsule	5 mg	28.15
	ROSUVASTATIN	Tablet/ capsule	10 mg	48.43
22.	TELMISARTAN	Tablet/ capsule	20 mg	13.35
	TELMISARTAN	Tablet/ capsule	40 mg	21.21
	TELMISARTAN	Tablet/ capsule	80mg	39.80
23.	ASPIRIN	Tablet/ capsule	75 mg	3.92
	ASPIRIN	Tablet/ capsule	100 mg	6.94
24.	METFORMIN	Tablet/ capsule	500 mg	5.17
	METFORMIN-sustained release	Tablet/ capsule	500 mg	10.08
	METFORMIN	Tablet/ capsule	850 mg	9.69
25.	GLIBENCLAMIDE	Tablet/ capsule	5 mg	2.87
26.	GLICLAZIDE	Tablet/ capsule	80mg	14.80
27.	THYROXINE	Tablet/ capsule	50 mcg	7.98
	THYROXINE	Tablet/ capsule	100 mcg	11.92
28.	GLIPIZIDE	Tablet/ capsule	5 mg	10.35
29.	IBUPROFEN	Tablet/ capsule	200 mg	1.44
	IBUPROFEN	Tablet/ capsule	400mg	4.85
30.	DICLOFENAC SODIUM	Tablet/ capsule	50 mg	17.02
	DICLOFENAC SODIUM	Tablet/ capsule	100 mg	19.77
31.	DICLOFENAC POTASSIUM	Tablet/ capsule	50 mg	14.34
32.	PARACETAMOL	Tablet/ capsule	500 mg	1.71

No.	Column I Generic Name	Column II Root of administration or Dosage forms	Column III Strength	Column IV Maximum Retail Price (MRP) per unit (SLR)
33.	SODIUM VALPROATE	Tablet/ capsule	200 mg	11.78
34.	RISPERIDONE	Tablet/ capsule	1 mg	10.35
	RISPERIDONE	Tablet/ capsule	2 mg	12.10
35.	OLANZAPINE	Tablet/ capsule	5 mg	13.09
	OLANZAPINE	Tablet/ capsule	10 mg	27.22
36.	CARBAMAZEPINE	Tablet/ capsule	200 mg	15.70
37.	ALPRAZOLAM	Tablet/ capsule	0.25 mg	8.51
	ALPRAZOLAM	Tablet/ capsule	0.5 mg	12.97
38.	FLUOXETINE	Tablet/ capsule	20 mg	14.40
39.	GABAPENTIN	Tablet/ capsule	100 mg	21.93
	GABAPENTIN	Tablet/ capsule	300 mg	43.40
40.	BECLOMETHASONE	DP capsule (inhalation)	200 mcg	7.85
	BECLOMETHASONE	DP capsule (inhalation)	400 mcg	8.90
	BECLOMETHASONE	Metered dose inhaler (200 doses)	100 mcg	664.47
	BECLOMETHASONE	Metered dose inhaler (200 doses)	250 mcg	734.51
41.	SALBUTAMOL	DP capsule (inhalation)	200 mcg	5.23
	SALBUTAMOL	DP capsule (inhalation)	400 mcg	7.20
	SALBUTAMOL	Metered dose inhaler (200 doses)	100mcg	405.88
42.	METHYL PREDNISOLONE	Tablet/ capsule	4 mg	15.51
	METHYL PREDNISOLONE	Tablet/ capsule	16mg	53.68
43.	OMEPRAZOLE	Tablet/ capsule	20 mg	5.89

No.	Column I Generic Name	Column II Root of administration or Dosage forms	Column III Strength	Column IV Maximum Retail Price (MRP) per unit (SLR)
44.	PANTOPRAZOLE	Tablet/ capsule	20 mg	22.25
	PANTOPRAZOLE	Tablet/ capsule	40 mg	36.65
45.	ESOMEPRAZOLE	Tablet/ capsule	20 mg	26.44
	ESOMEPRAZOLE	Tablet/ capsule	40 mg	50.28
46.	DOMPERIDONE	Tablet/ capsule	10 mg	7.07
47.	RABEPRAZOLE	Tablet/ capsule	10 mg	14.80
	RABEPRAZOLE	Tablet/ capsule	20 mg	28.22
48.	ALENDRONIC ACID	Tablet/ capsule	70 mg	132.76
49.	CEFTAZIDIME	injection	500 mg	598.54
	CEFTAZIDIME	injection	1g	997.57
50.	CEFTRIAZONE	injection	250 mg	299.27
	CEFTRIAZONE	injection	500 mg	561.13
	CEFTRIAZONE	injection	1g	872.87
51.	CEFOTAXIME	injection	500 mg	280.57
	CEFOTAXIME	injection	1g	467.61
52.	FLUCONAZOLE	Tablet/ capsule	50 mg	31.17
	FLUCONAZOLE	Tablet/ capsule	150 mg	56.11
53.	INSULIN SOLUBLE HUMAN	injection	100 IU/1ml (10 ml vial)	1,496.35
	INSULIN SOLUBLE HUMAN	injection	100 IU/1ml (3ml cartridge)	748.18
	INSULIN ISOPHANE HUMAN	injection	100 IU/1ml (10ml vial)	1,496.35
	INSULIN ISOPHANE HUMAN	injection	100 IU/1ml (3ml cartridge)	748.18

No.	Column I	Column II	Column III	Column IV
	Generic Name	Root of administration or Dosage forms	Strength	Maximum Retail Price (MRP) per unit (SLR)
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)		100 IU/1ml (10 ml vial)	1,496.35
	BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml)		100 IU/1ml (3 ml cartridge)	748.18
54.	GLIMEPIRIDE	Tablet	1 mg	8.92
	GLIMEPIRIDE	Tablet	2 mg	12.65
	GLIMEPIRIDE	Tablet	3 mg	21.20
	GLIMEPIRIDE	Tablet	4 mg	23.06
55.	SITAGLIPTIN	Tablet	25 mg	18.70
	SITAGLIPTIN	Tablet	50 mg	35.53
	SITAGLIPTIN	Tablet	100 mg	60.47
56.	TAMSULOSIN	Tablet/ capsule	0.40 mg	26.18
57.	MONTELUKAST	Tablet	4 mg	14.97
	MONTELUKAST	Tablet	5 mg	18.70
	MONTELUKAST	Tablet	10 mg	26.18
58.	PREGABALIN	Tablet/ capsule	50 mg	15.27
	PREGABALIN	Tablet/ capsule	75 mg	19.33
	PREGABALIN	Tablet/ capsule	100 mg	24.00
	PREGABALIN	Tablet/ capsule	150 mg	29.93
	PREGABALIN	Tablet/ capsule	300 mg	49.26
59.	TOPIRAMATE	Tablet/ capsule	25 mg	24.94
	TOPIRAMATE	Tablet/ capsule	50 mg	39.90
	TOPIRAMATE	Tablet/ capsule	100 mg	64.84
60.	LAMOTRIGINE	Tablet	25 mg	14.97
	LAMOTRIGINE	Tablet	50 mg	26.18
	LAMOTRIGINE	Tablet	100 mg	43.64

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 read with section 3, of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
19th August, 2021.

Regulations

The Medical Devices Pricing Regulations No.1 of 2017 published in the *Gazette* Extraordinary No.2006/45 of February 17, 2017 as amended by regulations published in the *Gazette Extraordinary* No.2114/54 of March 15, 2019 are hereby further amended by the repeal of the Schedule thereof and the substitution therefor of the following: -

SCHEDULE

INTRAOCULAR LENSES/LENSES WITH DELIVERY SYSTEM (PRELOADED/PROVIDED WITH CARTRIDGE)

<i>Column I</i>	<i>Column II</i>	<i>Column III</i>	<i>Column IV</i>
	Brand Name/Approved Name	Manufacturer	MRP (SLR)
1	AcrySert Preloaded delivery system	Alcon	21,200.00
2	AcrySof IQ SN60Wf with cartridge	Alcon	20,448.40
3	Tecnis 1 piece	Abbot Medical	20,197.70
4	enVista	Bausch & Lomb	19,325.70
5	Tecnis monofocal	Abbot Medical	19,325.70
6	Hoya iSert 251	Hoya	15,096.50
7	Nidek Nex-Load system SP SZ-1	Nidek	15,096.50
8	Aqua Sense Aaris	Aaren Scientific	12,218.90
9	Bi-flex HB (877FABY standard IOL)	Medicontur	11,118.00
10	Bunny HP	Hanita Marketing	10,845.50
11	I-Stream preloaded	MD Tech	9,226.85
12	Aurovue EV	Aurolab	6,174.85
13	AcrySof SP SA60AT with cartridge	Alcon	16,350.00
14	AcrySof EXPAND MA60MA with cartridge	Alcon	16,350.00
15	Sensar 1 piece	Abbot Medical	15,963.00
16	Sensar	Abbot Medical	14,660.50

<i>Column I</i>	<i>Column II</i>	<i>Column III</i>	<i>Column IV</i>
	Brand Name/Approved Name	Manufacturer	MRP (SLR)
17	AcrySof MP MA60AC	Alcon	13,341.60
18	Hoya PY60R	Hoya	9,853.60
19	Acriva UD (blue filter)	VSYS Biotech	8,611.00
20	Supra Phob Preloaded system	Appasamy	8,109.60
21	Acriva UD	VSYS Biotech	8,175.00
22	Akreos - MI60	Bausch & Lomb	18,459.15
23	Akeros AO	Bausch & Lomb	14,464.30
24	Akreos Adapt	Bausch & Lomb	13,516.00
25	Bunny AFM	Hanita Marketing	13,243.50
26	CT Asphina 404	Carl Zeiss Meditec	13,080.00
27	CT Spheris 204	Carl Zeiss Meditec	10,224.20
28	Bunny AF	Hanita Marketing	8,981.60
29	C-Flex Aspheric 970C/920H	Rayner	7,521.00
30	Aspira-aAY	Human Optics	7,106.80
31	Ocuva	VSYS Biotech	4,992.20
32	Auroflex	Aurolab	2,245.40
33	Seelens	Hanita Marketing	7,733.55
34	C-Flex IOL (Spherical 570C)	Rayner	6,376.50
35	Aspira AS	Human Optics	6,485.50
36	Tecsoft Tetra	Fred Hollows	5,995.00
37	Tecsoft Flex	Fred Hollows	5,613.50
38	Acryfold	Appasamy	3,815.00

09-50/2

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 read with section 3, of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
19th August, 2021.

Regulations

The Medical Devices (Pricing) Regulations of 2018 published in the *Gazette Extraordinary* No.2086/37 of August 31, 2018 as amended by regulations published in the *Gazette Extraordinary* No.2114/54 of March, 15,2020 are hereby further amended by the repeal of the Schedule thereof and the substitution therefor of the following: -

SEHEDULE

(regulation 2)

MAXIMUM RETAIL PRICES OF TWO SELECTED MEDICAL DEVICES

No.	Column I	Column II
	Brand Name/Approved Name	Maximum Retail Price (MRP) (SLR)
1	BLOOD GLUCOSE MONITERING SYSTEM	3,433.50 Per Unit
2	TEST STRIPS FOR BLOOD GLUCOSE MONITERING SYSTEM	62.13 Per Strip

09-50/3

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 read with Section 3, of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. KEHELIYA RAMBUKWELLA,
Minister of Health.

Colombo,
19th August, 2021.

Regulations

The Medical Devices Pricing Regulations No.5 of 2017 published in the *Gazette Extraordinary* No.2030/47 of August 4, 2017 as amended by regulations published in the *Gazette Extraordinary* No.2114/54 of March 15,2019 are hereby further amended by the repeal of the Schedule thereof and the substitution therefor of the following: -

SCHEDULE

(regulation 3)

No.	Column I	Column II
	Item	Maximum Retail Price (MRP)
1.	Bare Metal Stent	Rs. 29,920.50
2.	Drug Eluting Stent	Rs. 130, 800.00

09-50/4