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The Gazette of the Democratic Socialist Republic of Sri Lanka
EXTRAORDINARY

අංක 2336/53 - 2023 ජූනි මස 15 වැනි බ්‍රහස්පතින්දා - 2023.06.15
No. 2336/53 - THURSDAY, JUNE 15, 2023

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B 9/2016 (III)

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,
12.06.2023.

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 and regulations published in *Gazette Extraordinary* No. 2271/23 of March 15, 2022 and regulations published in the *Gazette Extraordinary* No. 2277/55 of April 29, 2022 are hereby further amended as follows:



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

- “6. (1) A manufacturer or importer who sells any Scheduled Medicine at a 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 as last amended by regulations published in *Gazette Extraordinary* No. 2277/55 of April 29, 2022 shall not sell such medicine at a price more than the Maximum Retail Price specified in Column V of the Schedule to these regulations.
- (2) A manufacturer or importer who sells any Scheduled Medicine at a revised retail price which is less than the Maximum Retail Price specified in Column V of the Schedule to the Medicines (Ceiling on Prices) Regulations of 2019 as last amended by regulations published in *Gazette Extraordinary* No. 2277/55 of April 29, 2022, shall reduce proportionately such revised retail price by a total sixteen *per centum* (16%).
- (3) 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 for the purpose of sale shall maintain the price of the Scheduled Medicines at the maximum retail price or revised retail price whichever is less.”.

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

“SCHEDULE

[regulation 2]

MAXIMUM RETAIL PRICES OF MEDICINES

| 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 | 59.59 |
| | | | | |
| 2 | AMOXICILLIN+CLAVULANIC ACID | Oral suspension | 156mg/ 5ml | 571.06 |
| | AMOXICILLIN+CLAVULANIC ACID | Tablet/ capsule | 375mg | 70.32 |
| | AMOXICILLIN+CLAVULANIC ACID | Tablet/ capsule | 625mg | 119.16 |
| | AMOXICILLIN+CLAVULANIC ACID | Injection | 1.2g | 1,253.33 |
| | | | | |
| 3 | CLARITHROMYCIN | Tablet/ capsule | 250mg | 72.50 |
| | CLARITHROMYCIN | Tablet/ capsule | 500mg | 146.99 |
| | CLARITHROMYCIN | Oral suspension | 125mg/5ml | 866.01 |
| | | | | |

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|---------------------------|---|-----------------------|--|
| 4 | AZITHROMYCIN | Tablet/ capsule | 250 mg | 74.68 |
| | AZITHROMYCIN | Tablet/ capsule | 500 mg | 104.78 |
| | AZITHROMYCIN | Oral suspension | 200mg/ 5ml | 347.58 |
| | | | | |
| 5 | CEFUROXIME | Tablet/ capsule | 250 mg | 90.38 |
| | CEFUROXIME | Tablet/ capsule | 500 mg | 144.19 |
| | | | | |
| 6 | DOXYCYCLIN | Tablet/ capsule | 100 mg | 20.08 |
| | | | | |
| 7 | ACICLOVIR | Tablet/ capsule | 200 mg | 73.47 |
| | | | | |
| 8 | CIPROFLOXACIN | Tablet/ capsule | 250 mg | 11.42 |
| | CIPROFLOXACIN | Tablet/ capsule | 500 mg | 16.88 |
| | | | | |
| 9 | LEVOFLOXACIN | Tablet/ capsule | 250 mg | 48.06 |
| | LEVOFLOXACIN | Tablet/ capsule | 500 mg | 79.45 |
| | | | | |
| 10 | CEPHALEXIN | Tablet/ capsule | 250 mg | 16.28 |
| | CEPHALEXIN | Tablet/ capsule | 500 mg | 29.81 |
| | CEPHALEXIN | Oral suspension | 125 mg/5 ml | 526.35 |
| | | | | |
| 11 | CEFIXIME | Tablet/ capsule | 100 mg | 45.68 |
| | CEFIXIME | Tablet/ capsule | 200 mg | 84.81 |
| | CEFIXIME | Oral suspension | 100 mg/5 ml | 685.25 |
| | | | | |

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|--------------------------------|---|-----------------------|--|
| 12 | AMLODIPINE | Tablet/ capsule | 5 mg | 30.39 |
| | AMLODIPINE | Tablet/ capsule | 10 mg | 42.31 |
| | | | | |
| 13 | DILTIAZEM | Tablet/ capsule | 30 mg | 5.38 |
| | DILTIAZEM | Tablet/ capsule | 60 mg | 17.69 |
| | DILTIAZEM | Tablet/ capsule | 90 mg | 42.51 |
| | | | | |
| 14 | LOSARTAN POTASSIUM | Tablet/ capsule | 25 mg | 14.59 |
| | LOSARTAN POTASSIUM | Tablet/ capsule | 50 mg | 20.46 |
| 15 | LOSARTAN + Hydrochlorothiazide | Tablet/ capsule | 62.5 mg | 38.62 |
| | | | | |
| 16 | ENALAPRIL | Tablet/ capsule | 5 mg | 11.91 |
| | ENALAPRIL | Tablet/ capsule | 10 mg | 20.08 |
| | | | | |
| 17 | ATENOLOL | Tablet/ capsule | 25mg | 5.95 |
| | ATENOLOL | Tablet/ capsule | 50 mg | 8.74 |
| | ATENOLOL | Tablet/ capsule | 100 mg | 25.82 |
| | | | | |
| 18 | NIFEDIPINE – sustained release | Tablet/ capsule | 20 mg | 7.36 |
| | | | | |
| 19 | CLOPIDOGREL | Tablet/ capsule | 75 mg | 34.78 |
| | | | | |
| 20 | ATORVASTATIN | Tablet/ capsule | 5mg | 12.76 |
| | ATORVASTATIN | Tablet/ capsule | 10 mg | 22.14 |

| 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 | 34.95 |
| | ATORVASTATIN | Tablet/ capsule | 40 mg | 49.17 |
| | | | | |
| 21 | ROSUVASTATIN | Tablet/ capsule | 5 mg | 42.70 |
| | ROSUVASTATIN | Tablet/ capsule | 10 mg | 73.47 |
| | | | | |
| 22 | TELMISARTAN | Tablet/ capsule | 20 mg | 20.25 |
| | TELMISARTAN | Tablet/ capsule | 40 mg | 32.17 |
| | TELMISARTAN | Tablet/ capsule | 80mg | 60.38 |
| | | | | |
| 23 | ASPIRIN | Tablet/ capsule | 75 mg | 5.95 |
| | ASPIRIN | Tablet/ capsule | 100 mg | 10.53 |
| | | | | |
| 24 | METFORMIN | Tablet/ capsule | 500 mg | 7.85 |
| | METFORMIN-sustained release | Tablet/ capsule | 500 mg | 15.29 |
| | METFORMIN | Tablet/ capsule | 850 mg | 14.70 |
| | | | | |
| 25 | GLIBENCLAMIDE | Tablet/ capsule | 5 mg | 4.35 |
| | | | | |
| 26 | GLICLAZIDE | Tablet/ capsule | 80mg | 22.45 |
| | | | | |
| 27 | THYROXINE | Tablet/ capsule | 50 mcg | 12.10 |
| | THYROXINE | Tablet/ capsule | 100 mcg | 18.09 |
| | | | | |
| 28 | GLIPIZIDE | Tablet/ capsule | 5 mg | 15.70 |

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|---------------------------|---|-----------------------|--|
| 29 | IBUPROFEN | Tablet/ capsule | 200 mg | 2.18 |
| | IBUPROFEN | Tablet/ capsule | 400mg | 7.36 |
| 30 | DICLOFENAC SODIUM | Tablet/ capsule | 50 mg | 25.82 |
| | DICLOFENAC SODIUM | Tablet/ capsule | 100 mg | 29.99 |
| 31 | DICLOFENAC POTASSIUM | Tablet/ capsule | 50 mg | 21.76 |
| 32 | PARACETAMOL | Tablet/ capsule | 500 mg | 3.49 |
| 33 | SODIUM VALPROATE | Tablet/ capsule | 200 mg | 17.88 |
| 34 | RISPERIDONE | Tablet/ capsule | 1 mg | 15.70 |
| | RISPERIDONE | Tablet/ capsule | 2 mg | 18.35 |
| 35 | OLANZAPINE | Tablet/ capsule | 5 mg | 19.87 |
| | OLANZAPINE | Tablet/ capsule | 10 mg | 41.29 |
| 36 | CARBAMAZEPINE | Tablet/ capsule | 200 mg | 23.81 |
| 37 | ALPRAZOLAM | Tablet/ capsule | 0.25 mg | 12.91 |
| | ALPRAZOLAM | Tablet/ capsule | 0.5 mg | 19.67 |
| 38 | FLUOXETINE | Tablet/ capsule | 20 mg | 21.85 |

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|---------------------------|---|-----------------------|--|
| | | | | |
| 39 | GABAPENTIN | Tablet/ capsule | 100 mg | 33.27 |
| | GABAPENTIN | Tablet/ capsule | 300 mg | 65.85 |
| | | | | |
| 40 | BECLOMETHASONE | DP capsule (inhalation) | 200 mcg | 11.91 |
| | BECLOMETHASONE | DP capsule (inhalation) | 400 mcg | 13.50 |
| | BECLOMETHASONE | Metered dose inhaler (200 doses) | 100 mcg | 1,008.03 |
| | BECLOMETHASONE | Metered dose inhaler (200 doses) | 250 mcg | 1,114.29 |
| | | | | |
| 41 | SALBUTAMOL | DP capsule (inhalation) | 200 mcg | 7.94 |
| | SALBUTAMOL | DP capsule (inhalation) | 400 mcg | 10.93 |
| | SALBUTAMOL | Metered dose inhaler (200 doses) | 100 mcg | 615.75 |
| | | | | |
| 42 | METHYL PREDNISOLONE | Tablet/ capsule | 4 mg | 23.53 |
| | METHYL PREDNISOLONE | Tablet/ capsule | 16mg | 81.44 |
| | | | | |
| 43 | OMEPRAZOLE | Tablet/ capsule | 20 mg | 8.94 |
| | | | | |
| 44 | PANTOPRAZOLE | Tablet/ capsule | 20 mg | 33.75 |
| | PANTOPRAZOLE | Tablet/ capsule | 40 mg | 55.60 |
| | | | | |
| 45 | ESOMEPRAZOLE | Tablet/ capsule | 20 mg | 40.11 |

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|---------------------------|---|----------------------------|--|
| | ESOMEPRAZOLE | Tablet/ capsule | 40 mg | 76.27 |
| 46 | DOMPERIDONE | Tablet/ capsule | 10 mg | 10.73 |
| 47 | RABEPRAZOLE | Tablet/ capsule | 10 mg | 22.45 |
| | RABEPRAZOLE | Tablet/ capsule | 20 mg | 42.81 |
| 48 | ALENDRONIC ACID | Tablet/ capsule | 70 mg | 201.40 |
| 49 | CEFTAZIDIME | INJECTION | 500 mg | 908.01 |
| | CEFTAZIDIME | INJECTION | 1 g | 1,513.36 |
| 50 | CEFTRIAZONE | INJECTION | 250 mg | 454.00 |
| | CEFTRIAZONE | INJECTION | 500 mg | 851.26 |
| | CEFTRIAZONE | INJECTION | 1 g | 1,324.18 |
| 51 | CEFOTAXIME | INJECTION | 500 mg | 425.64 |
| | CEFOTAXIME | INJECTION | 1 g | 709.39 |
| 52 | FLUCONAZOLE | Tablet/ capsule | 50 mg | 47.28 |
| | FLUCONAZOLE | Tablet/ capsule | 150 mg | 85.12 |
| 53 | INSULIN SOLUBLE HUMAN | INJECTION | 100 IU/1ml (10 ml vial) | 2,270.02 |

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|---|---|--------------------------------------|--|
| | INSULIN SOLUBLE HUMAN | INJECTION | 100 IU/1ml (3ml cartridge) | 1,135.02 |
| | INSULIN ISOPHANE HUMAN | INJECTION | 100 IU/1ml (10ml vial) | 2,270.02 |
| | INSULIN ISOPHANE HUMAN | INJECTION | 100 IU/1ml (3ml cartridge) | 1,135.02 |
| | BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml) | INJECTION | 100 IU/1ml (10 ml vial) | 2,270.02 |
| | BIPHASIC ISOPHANE INSULIN (AS INSULIN SOLUBLE HUMAN 30IU/1ml, INSULIN ISOPHANE HUMAN 70IU /1ml) | INJECTION | 100 IU/1ml (3 ml cartridge) | 1,135.02 |
| | | | | |
| 54 | GLIMEPIRIDE | TABLET | 1 mg | 13.53 |
| | GLIMEPIRIDE | TABLET | 2 mg | 19.19 |
| | GLIMEPIRIDE | TABLET | 3 mg | 32.16 |
| | GLIMEPIRIDE | TABLET | 4 mg | 34.99 |
| | | | | |
| 55 | SITAGLIPTIN | TABLET | 25 mg | 28.37 |
| | SITAGLIPTIN | TABLET | 50 mg | 53.89 |
| | SITAGLIPTIN | TABLET | 100 mg | 91.74 |
| | | | | |
| 56 | TAMSULOSIN | Tablet/ capsule | 0.40 mg | 39.72 |
| | | | | |
| 57 | MONTELUKAST | TABLET | 4 mg | 22.71 |

10A

I කොටස : (I) ඡේදය - ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ අති විශේෂ ගැසට් පත්‍රය - 2023.06.15
PART I : SEC. (I) - GAZETTE EXTRAORDINARY OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA - 15.06.2023

| Column I | Column II Generic Name | Column III Route of Administration/ Dosage forms | Column IV Strength | Column V Maximum Retail Price Per unit (SLR) |
|----------|---------------------------|---|-----------------------|--|
| | MONTELUKAST | TABLET | 5 mg | 28.37 |
| | MONTELUKAST | TABLET | 10 mg | 39.72 |
| | | | | |
| 58 | PREGABALIN | Tablet/ capsule | 50 mg | 23.17 |
| | PREGABALIN | Tablet/ capsule | 75 mg | 29.33 |
| | PREGABALIN | Tablet/ capsule | 100 mg | 36.41 |
| | PREGABALIN | Tablet/ capsule | 150 mg | 45.40 |
| | PREGABALIN | Tablet/ capsule | 300 mg | 74.73 |
| | | | | |
| 59 | TOPIRAMATE | Tablet/ capsule | 25 mg | 37.83 |
| | TOPIRAMATE | Tablet/ capsule | 50 mg | 60.53 |
| | TOPIRAMATE | Tablet/ capsule | 100 mg | 98.36 |
| | | | | |
| 60 | LAMOTRIGINE | TABLET | 25 mg | 22.71 |
| | LAMOTRIGINE | TABLET | 50 mg | 39.72 |
| | LAMOTRIGINE | TABLET | 100 mg | 66.21" |

(3) The provisions of these regulations shall come into effect on June 26, 2023.

EOG 06-0101