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EXTRAORDINARY

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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,
28th February, 2022.

REGULATIONS

1. These regulations may be cited as the Medicines (Pricing of Paracetamol Tablets/Capsules 500mg) Regulations, 2022.
2. The maximum retail price of Paracetamol Tablets/ Capsules 500mg as a generic name of the strength of five hundred milligrammes (500mg) whether dosage form is tablet or capsule shall be two rupees and thirty cents. (Rs. 2.30).



3. The maximum retail price of Paracetamol Tablets/ Capsules 500mg shall be applicable to all the brand names of the generic name of the Paracetamol Tablets/ Capsules 500mg.
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 Paracetamol Tablets/ Capsules 500mg, for the purpose of sale shall not sell such Paracetamol Tablets/ Capsules 500mg above the maximum retail price specified in regulation 2 or revised retail price as may be determined in accordance with the provisions of regulation 6.
5. Every person or institution referred to in regulation 4, who sells or offers for sale Paracetamol Tablets/ Capsules 500mg, shall upon such sale, issue a receipt clearly indicating the appropriate brand name and the price of the Paracetamol Tablets/Capsules 500mg.
6. (1) On the date of publication of these regulations, a manufacturer or importer who sells the Paracetamol Tablets/ Capsules 500mg 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 regulation 2 may increase proportionately such revised retail price by thirty-five *per centum* (35%).

Provided however, such increase of revised retail price of Paracetamol Tablets/ Capsules 500mg shall not exceed the maximum retail price specified in regulation 2.

- (2) 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 Paracetamol Tablets/ Capsules 500 mg for the purpose of sale shall maintain the price of Paracetamol Tablets/ Capsules 500mg at the maximum retail price or revised retail price whichever is less.
7. Where any dosage form or strength of the Paracetamol and the maximum retail price of such dosage form or strength of Paracetamol are not specified in regulation 2, the National Medicines Regulatory Authority shall fix the price for the Paracetamol in such dosage form or strength.
8. Any Manufacturer or importer shall print or mark on the commercial package or label of Paracetamol Tablets/ Capsules 500mg the maximum retail price specified in regulation 2 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 lable of Paracetamol Tablets/ Capsules 500mg before the expiry of a period of forty-five days from the date of publication of these regulations.

9. 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. 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 Paracetamol Tablets/ Capsules 500mg for the purpose of sale, to display at every retail outlet the maximum retail price of the Paracetamol Tablets/ Capsules 500mg or the revised retail price whichever is less.
11. 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 are hereby amended in the Schedule thereof by the repeal of item 32 thereof.

12. In 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);

“Person” includes any body of persons corporate or unincorporate;

“Private medical institution” shall have the same meaning assigned to it by the Private Medical Institutions (Registration) Act, No. 21 of 2006; and

“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.

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