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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 read with subsection (4) of section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015 in consultation with the Pricing Committee, Consumer Affairs Authority established under the provisions of the Consumer Affairs Authority Act, No. 9 of 2003 and all stakeholders and taking into consideration all other relevant factors including the provisions of the Consumer Affairs Authority Act, No. 9 of 2003.

Dr. RAMESH PATHIRANA,
Minister of Health.

Colombo,
26th of June, 2024.

Regulations

1. These regulations may be cited as the Medicines (Pricing Mechanism for determination of maximum retail price for a dosage form and a strength of a particular medicine) Regulations, No. 01 of 2024.
2. The object of these regulations shall be to establish a pricing mechanism for a dosage form and a strength of a particular medicine in order to ensure transparency and fairness.



3. (1) The maximum retail price of a dosage form and a strength of a particular medicine shall be determined by-

- (a) using an internationally recognized information portal for identifying the market share by value of different brands or Generic Names of drug formulations; and
- (b) verifying retail prices of the relevant dosage form and a strength of a particular medicine from retail pharmacies of different parts of the island and information provided by the State Pharmaceutical Corporation (SPC).

(2) The maximum retail price of a dosage form and a strength of a particular medicine shall be obtained by calculating the median of retail prices of all versions of brands and Generic Names of such dosage form and a strength of a particular medicine including originator of that particular drug dosage form and strength cumulatively having eighty percentage (80%) or more of the market share by value.

4. The maximum retail price of a dosage form and a strength of a particular medicine shall be calculated according to the following pricing mechanism-

- (a) Arranging of all the retail prices of all versions of brands and Generic Names of dosage form and a strength of a particular medicine including originator of such medicine having eighty percentage (80%) or more of the market share by value, in ascending order; and
- (b) Upon the arrangement of retail prices as referred to in paragraph (a), the median retail price shall be determined as below-
 - (i) If the product has an odd number of all available brands (originator plus generic) versions (n), the median retail price shall be considered as the value at position $(n+1)/2$; or
 - (ii) If the product has an even number of all available brands (originator plus generic) versions (n), the median retail price shall be considered by averaging the values at positions $n/2$ and $(n/2) + 1$.
- (c) For the purpose of determining the median retail price under sub paragraphs (i) and (ii) of paragraph (b) “n” shall be considered as the total number of all available branded (originator plus generic) versions of that particular drug formulation cumulatively having eighty percentage (80%) or more of the market share by value.

5. The maximum retail price of a dosage form and strength of a particular medicine calculated according to the above pricing mechanism, shall be published in the *Gazette*.

6. Any person who contravenes the provisions of these regulations shall commit an offence under these regulations and shall be triable under section 131 of the Act.

7. For the purpose of these regulations –

“Act” means the National Medicines Regulatory Authority Act, No. 5 of 2015;

“brand” means a name, term, design, symbol, trademark or any other feature that identifies one seller’s drug” as distinct from those of other sellers;

“Generic version of a medicine” means a formulation which having,

- (i) the same pharmaceutical form;
- (ii) bioequivalent;
- (iii) the same safety and efficacy properties

“market share by value” means the ratio of domestic sales in value on the basis of moving annual turnover of a brand or a generic version of a medicine in a calendar year and the sum of the total domestic value in Calendar year of all brands and generic versions of such medicine sold in the domestic market having the same strength and dosage form;

“retail price” means the ceiling price or the retail price plus taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;

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