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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2446/34 - 2025 ජූලි මස 21 වැනි සඳුදා - 2025.07.21

No. 2446/34 - MONDAY, JULY 21, 2025

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L. D. B. 9/2016 (IV)

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 of 2015

REGULATIONS made by the Minister of Health and Mass Media 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 of National Medicines Regulatory Authority established under the aforementioned Act (in these regulations referred to as the "Authority"), 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. **Nalinda Jayatissa** (M.P.),
Minister of Health and Mass Media.

Colombo,
21st July, 2025.

Regulations

1. These regulations may be cited as the Medicines (Pricing Mechanism for Medicines) Regulations, No. 02 of 2025.
2. The pricing mechanism shall include the pricing mechanism for the Maximum Retail Price for an individual product (originator, brand or generic) (hereinafter referred to as MRP) and the pricing mechanism for the Maximum Ceiling Price for a dosage form and strength of a particular medicine or a particular group of medicines (hereinafter referred to as the MCP).
3. The Authority shall decide whether MRP or MCP is to be applied to regulate the price of a particular medicine.

PART I

Pricing Mechanism for the Maximum Retail Price (MRP)

4. The MRP shall be calculated according to the following formula –

   MRP = CIF+DT+SCTM

   MRP denotes the Maximum Retail Price (in local currency) of an individual product (originator, brand or generic);

   CIF denotes Cost, Insurance and Freight (in local currency);

   SCTM denotes Supply Chain Total Markup (in local currency);

   DT denotes Duties and Taxes paid to (in local currency)

5. It shall be lawful for the Authority to verify the Cost, Insurance and Freight (CIF) value declared by an importer, using external and internal reference pricing approaches.

6. The average United States Dollar exchange (Selling) rate of the past three months, published by the Authority based on the exchange rate of the Central Bank of Sri Lanka shall be considered for the purpose of determining the MRP.

7. The duties and taxes shall be considered if any and may be represented as a percentage of Cost, Insurance and Freight (CIF) in Sri Lankan rupees.

8. The Supply Chain Total Markup (SCTM) in Sri Lankan rupees shall be expressed as a percentage by CIF as follows: -

   SCTM= (β% CIF)

   β% may be expressed either as a single value (single slab) or as regressive values (multiple slabs).

9. The Authority may review the MRP biannually:

   Provided, however, the Authority may revise the MRP when there is a fluctuation of the exchange rate beyond an accepted tolerance level which the Authority will consider necessary in the public interest.

10. It shall be lawful for the Authority to recall MRPs issued based on market conditions as well as to improve access to the medicines and substitute them with a new MRP.

PART II

Pricing Mechanism for the Maximum Ceiling Price (MCP)

11. The MCP shall be determined by -

    (a) using an internationally recognized information portal for identifying the market share by value of different brands or generic versions of a particular medicine;

    (b) verifying retail prices of the relevant dosage form and strength of a particular medicine from retail pharmacies of different parts of the island and information provided by the State Pharmaceutical Corporation; and

    (c) using Internal Reference Prices, External Reference Prices and Supply Chain Total Markup.

12. The MCP shall be calculated according to the following statistical method -

(a) arranging all the retail prices of all versions of brands and generics of a medicine of a particular dosage form and strength in such particular group of medicines including the originator of such medicine in such particular group of medicines having substantial market share by value determined by the Authority;

(b) upon the arrangement of retail prices as referred to in paragraph (a), the median retail price of such medicines shall be determined as below-

(i) if the medicine has an odd number of all available versions of individual products (originator, brands, generic) (n), the median retail price of such medicines shall be considered as the value at position (n+1)/ 2;

(ii) if the medicine has an even number of all available versions of individual products (originator, brands, generic) (n), the median retail price of such medicines shall be considered by averaging the values at positions n/2 and (n/2) +1; or

(iii) for the purpose of determining the median retail price of such medicines under sub paragraphs (i) and (ii) "n" shall be considered as the total number of all versions of individual products (originator, brands, generic) of that particular medicine cumulatively having the market share by value as referred to in paragraph (a).

13. A person who sells a medicine shall not sell at a price higher than the MCP:

14. The MRPs of all branded or generic versions including the originator of an individual product determined by the Authority which are lower than the MCP shall not be increased.

15. Any new registration or reregistration of an individual product for which the MRP has not been determined previously, in the event of calculated MRP exceeding the MCP, the determined MRP for such product shall be the MCP.

16. Any new registration or reregistration of an individual product for which the MRP has not been determined previously, in the event of calculated MRP is less than the MCP, the determined MRP for such product shall be the MRP.

17. It shall be lawful for the Authority to revise the MCP issued based on market conditions as well as to improve access to medicines.

18. The Authority shall publish in the *Gazette* the MCP for a dosage form and strength of a particular group of medicines determined according to the pricing mechanism referred to in regulation 11.

19. The Authority shall, on the recommendation of the Pricing Committee of the Authority, consider explanatory notes and specific values (including beta and tolerance level for exchange rate fluctuation) applicable to the pricing mechanism and issue guidelines to that effect.

20. Any person who contravenes the provisions of these regulations commit an offence and shall be triable under section 131 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

21. For the purpose of these regulations –

"brand" means a name, term, design, symbol, trademark or any other feature that identifies one product licence holder's medicine as distinct from those of other product licence holders;

"market share by value" means the ratio of domestic sales in value on the basis of moving the 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 the Calendar year of all brands and generic versions of such medicine sold in the domestic market having the same strength and dosage form; and

"retail price" means the ceiling price or the retail price including 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.

22. 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 published in *Gazette Extraordinary* No. 2390/18 of June 28, 2024 and the Medicines (Pricing Mechanism for Medicines) Regulations No. 01 of 2025 Published in *Gazette Extraordinary* No. 2429/12 of March 25, 2025 are hereby rescinded without prejudice to anything previously duly done thereunder.

EOG 07 - 0280

PRINTED AT THE DEPARTMENT OF GOVERNMENT PRINTING, SRI LANKA.