GUIDELINE on Pricing Mechanism for Medicines in Sri Lanka

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NATIONAL MEDICINE REGULATORY AUTHORITY
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Content

1. INTRODUCTION

1.1. This guideline is issued by the **National Medicines Regulatory Authority (NMRA)** under the powers given in the **NMRA Act No. 5 of 2015** and should be read together with the Gazette Notification on **Pricing Mechanism for Medicines Regulations** published in **Gazette Extraordinary No. 2446/34 dated 21.07.2025.**

1.2. This guideline provides an explanation on methodology for calculation of the **Maximum Retail Price (MRP)** and **Maximum Ceiling Price (MCP)** for medicines in Sri Lanka

1.3. It explains the process of calculating, verifying, and reviewing the MRP and MCP.

1.4. The NMRA may review and update this guideline every six months or as necessary.

2. ABBREVIATIONS

BNF	British National Formulary
CIF	Cost, Insurance, and Freight
DGDA	Directorate General of Drug Administration (Bangladesh)
DT	Duties and Taxes
ERP	External Reference Price
IRP	Internal Reference Price
MCP	Maximum Ceiling Price
MRP	Maximum Retail Price
MSD	Medical Supplies Division
NMRA	National Medicines Regulatory Authority
NPPA	National Pharmaceutical Pricing Authority (India)
SCTM	Supply Chain Total Markup
SPC	State Pharmaceutical Corporation
USD	United States Dollar

3. MRP DETERMINATION FOR NEW APPLICATIONS (NEW REGISTRATIONS)

3.1 When a medicine is registered in Sri Lanka under a New Application, its MRP will be decided using the pricing mechanism explained in this guideline and Gazette No. 2446/34.

3.2 The applicant (manufacturer or local agent) must submit the price details including the following, using the standard format provided by the NMRA:

- The requested Maximum Retail Price (MRP) per unit dosage form in Sri Lankan Rupees
- The CIF (Cost, Insurance, and Freight) value per unit dosage form in United States Dollars (USD)
- MRP per unit dosage form in the Country of Origin
- MRP per unit dosage form in Regional Countries (if available)
- The expected annual quantity of the medicine to be imported.
- A declaration letter from the manufacturer confirming the CIF price, MRP of regional countries (if available) and the MRP in the country of origin
- A declaration letter from the Local Agent confirming the requested MRP
- A breakdown of local duties and taxes applicable to the product (if applicable) with documentary evidence such as CusDec documents

3.3. The MRP will be determined using the following formula:

MRP = CIF + DT + SCTM, where:

- MRP denotes the Maximum Retail Price (in LKR) of an individual product
- **CIF** = Cost, Insurance and Freight (Equivalent in LKR)
- **DT** = Duties and Taxes (in LKR)
- **SCTM** = Supply Chain Total Markup (in LKR)

3.4. NMRA will verify the declared CIF price using both **External Reference Prices (ERP)** and **Internal Reference Prices (IRP)** (see section 5 for details).

3.5. If the requested MRP is less than or equal to the NMRA calculated MRP, the requested MRP will be approved.

3.6. The final MRP will be printed on the **Registration Certificate** and/or **Import License** as applicable. It will also be published monthly on the NMRA website.

4 MRP DETERMINATION FOR EXISTING REGISTRATIONS (RE-REGISTRATIONS OR RENEWALS)

4.1. The MRP must be determined or revised for any product that is already registered at the time of applying for **re-registration, renewal, or an issuance of a new import license**.

4.2. The applicant (manufacturer or local agent) must submit the price details including the following, using the standard format provided by the NMRA:

- The requested Maximum Retail Price (MRP) per unit dosage form in Sri Lankan Rupees
- The CIF (Cost, Insurance, and Freight) value per unit dosage form in United States Dollars (USD)
- MRP per unit dosage form in the Country of Origin

- MRP per unit dosage form in the Regional Countries (if available)
- The expected annual quantity of the medicine to be imported.
- Quantities imported for the past three years (If available)
- Sales details for the past three years (If available)
- A declaration letter from the manufacturer confirming the CIF price, MRP in the regional countries (if available) and the MRP in the country of origin
- A declaration letter from the Local Agent confirming the requested MRP
- A breakdown of local duties and taxes applicable to the product (if applicable) with documentary evidence such as CusDec documents

4.3. NMRA will verify the declared CIF price using both **External Reference Prices (ERP)** and **Internal Reference Prices (IRP)** (see section 5 for details).

4.4. The MRP will be calculated using the **same formula** used for the New Applications as mentioned in 3.3

4.5. If the requested MRP is less than or equal to the NMRA calculated MRP, the requested MRP will be approved.

4.6. If the product had a previous MRP decided by NMRA the pricing committee will review and/or revise that MRP based on the **current exchange rate** and **market conditions and the pricing mechanism published in** Gazette **No. 2446/34** and this guideline.

4.7. The final MRP will be printed on the **Registration Certificate** and/or **Import License** as applicable. It will also be published monthly on the NMRA website.

5 CALCULATION OF MCP (MAXIMUM CEILING PRICE)

5.1 MCP shall be determined as prescribed in the **Gazette Extraordinary No. 2446/34**

5.2 Substantial market share by value for MCP calculation will be considered as 80% of the market value for section 12 (a) in the **Gazette Extraordinary No. 2446/34**

5.3 MCP is calculated using the **median retail price** in the market and verified with ERP and IRP.

5.4 NMRA shall review **market conditions and sales data** from:
- Pharmacies
- SPC
- International sources (e.g., IQVIA)

5.5 NMRA may issue a MCP for particular dosage form of a pharmaceutical product and/or revise the MCPs issued based on market conditions as well as to improve access to medicines

5.6 New or revised MCPs will be published in a Gazette Notification.

6 MRP FOR PRODUCTS UNDER GAZETTED MCP

6.1. For an individual product/brand (including the originator) or a generic of a particular dosage form and strength of a medicine already having a **Maximum Ceiling Price (MCP)** published in a Gazette, the MRP will be calculated following the same method described above.

6.2 If the calculated MRP is **higher** than the gazetted MCP for the product (if the MCP for this product is gazetted), the MRP for the product will be the **MCP**.

6.3 If the calculated MRP is **lower** than the MCP (if the MCP for this product is gazetted), then the calculated MRP will be the MRP of the product.

6.4 Sections 6.2 and 6.3 will be applicable to the MRP calculation of both New Registrations and Renewal or Re-registration of Existing Registrations.

6.5. If a product under the Gazetted MCP had a previous MRP decided by NMRA, the pricing committee will review and/or revise that MRP based on the **current exchange rate** and **market conditions and the price mechanism published in** Gazette No. **No. 2446/34** and this guideline.

6.6. Once determined, the MRP will be mentioned in the **Registration Certificate** and/or **Import License as** applicable. It will also be published monthly on the NMRA website.

7 CIF VERIFICATION

7.1. NMRA will verify the declared CIF (Cost, Insurance, and Freight) using External Reference Prices (ERP) and Internal Reference Prices (IRP) available for the product.

a) External Reference Pricing (ERP):

– Prices from the following countries and sources:

- India – National Pharmaceutical Pricing Authority (NPPA)
- Bangladesh – Directorate General of Drug Administration (DGDA)
- Pakistan – Drug Regulatory Authority
- British National Formulary (BNF)
- Price in the country of origin
- Any other recognized international platforms and data bases (e.g., IQVIA)

b) Internal Reference Pricing (IRP):

– Prices from:

- Previously approved MRPs for similar products
- Current retail prices in Sri Lanka
- Ministry of Health/Medical Supplies Division (MSD) tender prices
- State Pharmaceutical Corporation (SPC) prices
- Any other recognized international platforms and data bases (e.g., IQVIA)

8 CURRENCY CONVERSION AND EXCHANGE RATE

8.1. CIF values must always be submitted in United States Dollars (**USD)**.

8.2. NMRA will convert this to LKR using the average USD exchange (selling rate) of the past three months published by the NMRA based on the exchange rates of the Central Bank of Sri Lanka.

8.3. The average exchange rate published by the NMRA at the time of submission of the application for pricing, will be used as the exchange rate in the calculations for that particular application when determining the MRP.

8.4. NMRA may **review the fluctuation of the exchange rate every six months**.

8.5. However, if the exchange rate fluctuates by more than ±5% (higher or lower) at any point the Authority may review and revise the determined MRPs and MCPs if deemed necessary.

9 MRP CALCULATION AND SUPPLY CHAIN TOTAL MARKUP (SCTM)

9.1. MRP is calculated using:

MRP = CIF + Duties & Taxes (DT) + Supply Chain Total Markup (SCTM)

9.2. The Supply Chain Total Markup (SCTM) will be decided based on the **verified CIF** and will be expressed as a percentage by **verified CIF** in Sri Lankan rupees as follows:

SCTM= (β% CIF)

9.3. The **SCTM** may be based on a **multi-slab method** as below.

Verified CIF (Equivalent in Sri Lankan Rupees)	Applicable Markup (β %)
0 ≤ CIF < 40	**75%**
40≤ CIF < 2000	**65%**
2000≤ CIF < 6500	**55%**
CIF ≥ 6500	**45%**

9.4. Supply Chain Total Markups may be adjusted based on:
– Affordability to the public
– Availability of the medicine
– Market sustainability

10 MRP INCREASES AND REVISIONS

10.1. If a manufacturer or importer wants to **increase the MRP**, they must submit a **formal request** with evidence and documents.

10.2. The NMRA's Pricing Committee will evaluate the request and decide whether the MRP can be revised.

10.3. If the applicant does not agree with the Pricing Committee's decision, applicant can submit an appeal to the Appeal Committee of the NMRA.

11 COMPLIANCE

11.1. **All stakeholders** including manufacturers, importers, retailers, hospitals, private health care institutes must **not sell** any medicine above the **approved MRP or MCP**.

11.2. NMRA has the authority to **revise MRPs and MCPs** and take **legal action** against violators.

11.3. The MRP must be printed on the product labels, and retailers are required to prominently display the MRPs within their retail pharmacies.

12 FUTURE REVISIONS

12.1. MRPs and MCPs may be **reviewed/revised every 6 months** or earlier, depending on:
– Exchange rate fluctuations
– Market conditions
– Feedback from stakeholders

12.2. The **±5% threshold** for exchange fluctuation will be reviewed every 6 months and revised by the NMRA if necessary.

12.3. Any new/ revised MCPs will be **published in a Gazette**, and MRPs will be published in the NMRA website monthly.

13 RECORDS AND DOCUMENTATION

13.1. Manufacturers and importers must maintain records of:

– MRP submission forms
– Invoices/CIF declarations from the manufacturer
– NMRA correspondence about pricing

14 KEY DEFINITIONS

- **MRP**: Maximum Retail Price – the highest price a consumer can be charged by manufacturers, importers, retailers, hospitals, private health care institutes for an individual product (originator, brand or generic)
- **MCP**: Maximum Ceiling Price – the maximum limit of the selling price for a dosage form and strength of a particular medicine or a particular group of medicines, published by a Gazette Notification. All the MRPs should be equal or less than MCP
- **CIF**: Cost, Insurance, and Freight – cost of importing the product
- **ERP**: External Reference Price –International Reference Prices; price of a particular product in other countries, particularly in regional markets
- **IRP**: Internal Reference Price – prices based on local sources or previously approved prices in Sri Lanka
- **Market conditions:** Internal and external factors (such as policy changes, exchange rate fluctuations, shortages of Active Pharmaceutical Ingredients, global conflicts, economic crises or any other situation as decided by the NMRA etc.) that influence the pricing, availability, and competitiveness of pharmaceutical products in local and global markets.

15 RELATED LEGISLATIONS

- National Medicines Regulatory Act No. 5 of 2015
- Pricing Mechanism for Medicines Regulations Gazette Extraordinary No. 2446/34 dated 21.07.2025.
- Consumer Affairs Authority Act, No. 9 OF 2003
- Pricing Regulations, 2019. No. 2146/3 dated 21.10.2019
- Gazette No 2336/53 Dated 15-06-2023

16 FEEDBACK

Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk

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