

No.31015/35/2023-Pricing (E-23325)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 340-B, A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s Astra Zeneca Pharma India Limited (hereinafter called the “Applicant”) filed a Review Application dated 03.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 87(E) dated 06.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Metoprolol Tablet 25mg and 50mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 15.09.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the Applicant, that NPPA has erred in determining the ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 Astra Zeneca submitted a representation to NPPA on 4.01.2023 regarding the draft computation for Metoprolol 25mg and 50mg, wherein both conventional uncoated tablets and modified release tablets were considered in the same calculation. NLEM 2022 list Metoprolol 25mg, Metoprolol 50mg, Metoprolol 100mg and Metoprolol Modified Release 100mg but does not contain Metoprolol Modified Release 25mg and Metoprolol Modified Release 50mg.

3.2 On 6.01.2023, NPPA has notified final ceiling prices for Metoprolol Tablet 25mg and 50mg. Considering that the modified release formulations for Metoprolol 25mg and 50mg were taken along with the conventional release formulation in NPPA’s draft calculation, Astra Zeneca reduced the ceiling price for “Seloken XL” Metoprolol modified release 25mg and 50mg tablets and had submitted Form-V for the same. However, on 12.01.2022, NPPA has notified the final ceiling prices for Metoprolol Tablet 100mg and Metoprolol modified release tablet 100mg with separate ceiling prices calculated for both the formulations.

3.3 NPPA applied differential pricing for Metoprolol 100mg conventional tablet versus Metoprolol 100mg Modified release tablets. NLEM 2022 does not contain

Metoprolol modified release 25mg and 50mg tablets. Therefore, NPPA appears to have erred in combining both plain formulation and modified release formulations of Metoprolol 25mg and 50mg tablets. Hence, the company has requested to review the price revision of Metoprolol modified release tablet 25mg & 50mg and remove the ceiling prices for these products.

4. Gist of clarifications made by NPPA:

NPPA on the other side argued that the instant review is not tenable on the following grounds:

4.1 The methodology approved and followed for the pricing of MR Variant/Conventional Variant by the Authority is as below:

“Wherever, MR variant is specifically mentioned in any formulation the data of only MR variants (CR, SR, XL, ER delayed release etc.) may be considered for fixation of ceiling price. However, where MR variant is not specifically mentioned, data of conventional as well as MR variants may be considered for ceiling price fixation. This is in line with methodology of NLEM 2015 also. Similarly, where DT/effervescent/soluble/MD, etc. is specifically mentioned in any formulation, the data of only such variants may be considered. However, in absence of any variant being specifically mentioned, the DT/effervescent /soluble/MD may be considered along with conventional form”

Further, the above methodology is same as was followed for fixation of ceiling prices under NLEM 2015. (Reference 105th Authority meeting).

4.2 The MR variants form an integral part of essential and lifesaving drugs and taking them out of price control is not the objective of SNCM. NLEM as well as Revised Schedule-I of DPCO, specifically mentions as below:

“All modified release formulations of same strength such as sustained release, controlled release, extended release, prolonged release etc. are included.”

4.3 Further, this methodology followed in relation to conventional / modified releases is same as followed for fixation of ceiling prices under NLEM 2015. Examples are:

Case 1: Formulation appearing in Schedule-I: Metformin 500mg

Since, the variant i.e. Conventional / modified is not stated in Schedule-I, all variants were considered included in Schedule-I and the ceiling price was fixed considering all the variants. Further, the ceiling price was applicable to all variants.

Case 2: Formulation appearing in Schedule-I: Metformin 1000mg and Metformin 1000mg MR

Since, both variants i.e. conventional and MR are specifically stated in the schedule, separate prices were fixed for both i.e. conventional and non-conventional variant. If the petitioner's suggestion is considered, the prices of Modified releases will not be covered under Schedule-I in case where only conventional variants are mentioned and will make the MR variants of the formulation de-regulated.

4.4 Further, the market shares of Plain/conventional and MR for the subject formulation is as follows:

MAT (Rs. In Crores) July, 2022

Formulation	Plain / Conventional	MR	Total
Metoprolol Tablet 25mg	35.24	197.53	232.77
Metoprolol Tablet 50mg	39.76	234.77	274.53

It is seen that in case of Metoprolol 25 mg, modified release tablet has almost 84.86% market share and in case of 50 mg it is 86.46% share (July 2022 database). If the same are not considered to be scheduled as contended by the company, majority of the market will become deregulated, which is not the intent of NLEM, 2022.

5. Examination:

5.1 The National List of Essential Medicines (NLEM) prepared by Standing National Committee on Medicines (SNCM) under Ministry of Health and Family Welfare (MoH&FW) forms the very basis of Schedule-I of the DPCO, 2013 which is amended, whenever the NLEM is revised. The latest NLEM (2022) was notified on 13.09.2022 and accordingly, Schedule-I to DPCO 2013 was revised on 11.11.2022 vide Gazette Notification SO No. 5249 (E).

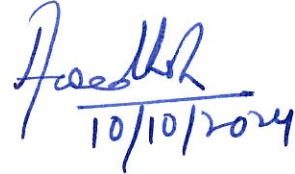
5.2 The NLEM is prepared with the objective of satisfying the priority health care needs of the population. The list is made based on disease prevalence, efficacy, safety and comparative cost-effectiveness of the medicines. The aim behind formulating NLEM is to ensure that these medicines are available in adequate quantity, in appropriate dosage forms and strengths with assured quality. NLEM does recognize such innovations in drugs where substantial improvements, effectiveness and efficacy have been introduced either in terms of quality or in the delivery system or both. Accordingly, NLEM mentions such innovative drugs separately under different categories commonly named as Modified Release (MR) versions in the same list where such criteria are fulfilled. When the same is not mentioned separately, then all such varieties of such drugs for the specified dosages are considered to be part of variants appearing in the list. The objective of NLEM, inter alia, is to ensure availability of the essential drugs as well. This objective may be adversely affected by the exclusion of different variants from the NLEM based on criteria such as MR etc., as such exclusion may encourage essential drugs simply moving out of NLEM. This may not be in line with the spirit and purpose of including these drugs in the list of essential medicines in the first instance.

5.3 Therefore, in view of the facts as at paras 5.1 and 5.2 above, arguments and logics given by NPPA are accepted.

6. Decision:

The action of NPPA fixing the ceiling price of Metoprolol Tablet 25mg and Metoprolol Tablet 50mg vide S.O. No. 87(E) dated 06.01.2023 is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 10th day of October, 2024.



10/10/2024

(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

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Copy to:

1. Chairperson, NPPA, New Delhi
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
3. Technical Director, NIC for uploading the order on DoP's Website.
4. Guard File