No.31015/33/2023-Pricing (E-23322)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
.....

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

Order

M/s Lupin Limited (hereinafter called the "Applicant") filed a Review Application dated 02.02.2023 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 22.06.2023 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 NPPA has clubbed PTR of both plain formulation as well as innovative formulations like sustained release (SR), extended release (ER) etc. for arriving at the ceiling price of Metoprolol 25mg & 50mg tablet.

3.2 NLEM, 2015 specifically included both plain and sustained release of Metoprolol 25mg tablet and 50mg tablet in the First Schedule to DPCO, 2013. In fact, two separate notifications were issued by NPPA to fix the ceiling price of Metoprolol plain and sustained release i.e. vide notification being S.O. No. 1253 (E) dated 29.03.2016, price of Metoprolol 25mg and 50mg (SR tablets) was fixed and vide notification being S.O. No. 1351 (E) dated 02.06.2016, price of Metoprolol 25mg and 50mg (plain tablets) was fixed.

3.3 NLEM, 2022 includes plain Metoprolol 25mg tablet, 50mg tablet and 100mg tablet and modified release tablet 100mg in the First Schedule. DPCO, 2013 defines "non-scheduled formulation" to mean a formulation, the dosage and strengths of which are not specified in the First Schedule. Further, DPCO, 2013 defines "scheduled formulation" to mean any formulation, included in the First Schedule whether referred to by generic versions or brand name.

3.4 A conjoint reading of the definitions of "scheduled formulation" and "non-scheduled formulation" indicates that those drugs which are not mentioned in First Schedule of DPCO, 2013 clearly fall outside the scope of price ceiling.

3.5 Explanation 1 to NLEM, 2022 states that any dosage form of a medicine other than that included in First Schedule, but in same strength and route of administration, which does not demonstrate significant difference in terms of pharmacokinetics/ pharmacodynamics/ efficacy/ safety over the dosage form mentioned in the list, should be considered as included. However, such different dosage forms should be considered differently for purposes of procurement policy, pricing etc. Sustained release formulation is different from conventional forms in terms of pharmacokinetics/ efficacy.

3.6 Further, Explanation 6 to NLEM, 2022 states that innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc.

3.7 In view of the above, the Applicant stated that the formulations which use innovative forms or route of administration that render the formulations materially different from the one listed in First Schedule of DPCO, 2013 even though the medicine remains the same, would qualify to be non-scheduled formulations if not specifically included.

3.8 The Applicant drew reference to letter dated 20/09/2013 issued by the Department of Pharmaceuticals clarifying that the innovative dosage forms of the scheduled formulations have been opined not to be kept under price control as per the provisions of DPCO, 2013. And also to the Office Memorandum dated 06.12.2013 issued by the Ministry of Health & Family Welfare ('MOHFW') which clarified that innovative dosage forms are not to be considered as included in NLEM unless specifically indicated.

3.9 The Applicant mentioned that NPPA itself has at several occasions, issued separate notifications to fix the ceiling price of the formulation using different technology i.e. plain, CR & SR etc. [Attention drawn to S.O. No. 5938(E) dated 19/12/2022 wherein NPPA notified a separate ceiling price for Carbamazepine 400mg plain tablet and Carbamazepine 400mg modified release tablet as well as for Levetiracetam 750mg plain tablet and Levetiracetam 750mg modified release tablet and S.O. No. 195(E) dated 11/01/2023 wherein NPPA notified a separate ceiling for Metoprolol 100mg tablet plain and Metoprolol 100mg sustained release Thus, NPPA itself has taken and placed the interpretation that price notification with respect to normal release shall not cover sustained released technology or any other new innovative drug delivery system unless notified specifically.

3.10 The company stated that the Hon'ble Delhi High Court, in the case of Modi-Mundi Pharma Pvt. Ltd. v. Union of India and Ors., has held that even if a medicine is mentioned in First Schedule, but the specific dosages and strength has not been specified, the same would fall within the definition of non-scheduled formulation.

3.11 The company stated that, if NPPA continues to treat both plain and innovative dosage forms at par for pricing, it will ultimately force the manufacturers to restrict themselves to further research on new medicines and/ or to treat unmet medical needs of the population of the country. The manufacturers will be reluctant to conduct any fresh research or involve any special technology or improve their research and development skills as the same would involve additional cost. Different manufacturers adopt different technology for producing similar drugs or medicines having similar composition and the uniqueness and effectiveness of the drug varies on the basis of the technology used which is the driving factor to determine the price of any formulation, and under no circumstances can two formulations be compared if they are manufactured by using different technologies. Therefore, the Applicant requested to announce separate ceiling prices for normal release as well as innovative formulations.

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 in any formulation the data of only such variant 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 variant of the subject formulation is as follows:

MAT (Rs. in crore) 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 25mg, modified release tablet has almost 84.86% market share and in case of 50mg it has 86.46% share (July 2022 database). If the same are not considered to be scheduled as contended by the Applicant, 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 of 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:

M/s Lupin Limited
4th floor, World Trade Tower,
Barakhamba Road,
Connaught Place,
New Delhi- 110001.

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