**No.31015/27/2023-Pricing (E-23311)**
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 Ajanta Pharma Private Limited (hereinafter called the "Applicant") filed a Review Application dated 01.02.2023 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 Metoprolol Tablet 50mg.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 01.06.2023 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 The Applicant challenges the aforesaid impugned notification in respect of ceiling price fixation of Metoprolol Tablet 25mg and Metoprolol Tablet 50mg issued by NPPA as improper, misconceived as it has been carried out erroneously, arbitrarily, without jurisdiction by NPPA, in mechanical manner with wrongful inclusion of formulations manufactured by the Applicant, namely Met XL 25mg Tablet ER 20 (Metoprolol 25mg Tablet Extended Release) and Met XL 50mg Tablet ER 20 (Metoprolol 50mg Tablet Extended Release) having modified dosage, incremental innovation and novel drug delivery system.

3.2 The Applicant made representation to NPPA on 08/12/2022 within stipulated time against draft version displayed on its website on 01/12/2022, in respect of calculation of Metoprolol 25mg Tablet for wrongfully including formulation Met XL 25mg Tablet ER 20 (Metoprolol 25mg Tablet Extended Release) and Metoprolol 50mg tablet for wrongful inclusion of Met XL50 mg Tablet ER 20 (Metoprolol 50mg Tablet Extended Release), respectively, for ceiling price fixation under revised Schedule-I of DPCO, 2013 as aforesaid formulations manufactured by the Applicant are distinct, separate and different and cannot be equated with the plain conventional Tablets.

However, NPPA unjustly and illogically ignored the representation. The impugned notification ex-facie is bad, unreasonable and suffers from certain inaccuracies, arbitrariness, anomalies/ legal infirmities as hereunder:

3.2.1 The Applicant has been manufacturing its Metoprolol 25mg tablets having extended release modified dosage with brand name Met XL 25mg Tablet ER 20 and Metoprolol 50mg tablets having modified dosage of extended-release tablets with brand name Met XL 50mg Tablet ER 20. These are incremental innovation formulations and distinct and different from plain conventional tablets. The Applicant has been duly complying with provisions of the DPCO, 2013. Despite of fact that aforesaid modified dosage formulation of Metoprolol 25mg and Metoprolol 50mg manufactured by the Applicant are distinct, different to conventional plain tablets; without prejudice to its rights, the Applicant company in "interim" has duly implemented the ceiling price fixed in impugned notification by revising and reducing the maximum retail price (MRP) of its aforesaid formulations, by issuing revised Price List in Form-V in accordance with various provisions of the DPCO ,2013 and paragraph 31 of 'review'.

3.2.2 Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals has amended the DPCO, 2013 by revising its Schedule-I on the basis of NLEM, 2022 vide S O. No. 5249(E) dated 11th November 2022. Metoprolol is listed therein at item No. 10.1.4 under Section 10 of Cardiovascular Medicines, as below:

| 10.1 Medicine used in Angina | | | |
|---|---|---|---|
| | Medicine | Level of Health care | Dosage form(s)and strength(s) |
| 10.1.4 | Metoprolol | P, S,T | Tablet 25 mg<br>Tablet 50mg<br>Tablet 100mg<br>Modified Release Tablet 100 mg |
| | | S, T | Injection 1 mg/ml. |

In the aforesaid revised Schedule-I (NLEM, 2022) of the DPCO, 2013 Metoprolol 25mg and 50mg Tablet is listed with dosage form of plain/conventional tablet only and neither mentions nor includes or specifies modified release dosage tablet for Metoprolol 25mg and 50mg., therefore such formulations are outside the purview and not covered thereof.

3.2.3 It is pertinent to submit here that revised Schedule-I (NLEM, 2022) of the DPCO, 2013 at item No.10.1.4 for Metoprolol 100mg, itself mention and categorizes dosage forms for plain tablet as different and distant to modified release by mentioning both dosage forms i.e., plain /conventional 100mg tablets and modified release 100mg tablet, separately and distinctly. NPPA, itself has fixed and notified, separately, ceiling prices of Metoprolol 100mg plain and conventional tablet and Metoprolol 100mg modified dosage release Tablet vide S.O.195 (E) dated 11/01/2023, as under-

| Sl. no. | Name of Scheduled formulation | Dosage form and Strength | Unit | Ceiling Price in Rs. |
|---|---|---|---|---|
| 8 | Metoprolol | Modified Release Tablet 100 mg. | 1 Tablet | 13.37 |
| 9 | Metoprolol | Tablet 100 mg. | 1 Tablet | 9.93 |

Consequently, Metoprolol tablet in plain/ conventional dosage cannot be clubbed with modified release dosage as it would tantamount to be unreasonable, ultra vires, illegal, anomalous and not tenable.

3.2.4 Prior to aforesaid amendment of the DPCO, 2013 on 11th November 2022, earlier amendment in DPCO, 2013 was done vide S.O. 701(E) dated 10th March 2016 in Schedule-I on the basis NLEM, 2015 wherein Metoprolol tablet was listed at item no. 12.1.7. Importantly, it is necessary to point out that in existing aforesaid Schedule-I of the DPCO 2013, Metoprolol 25mg and Metoprolol 50mg plain tablets and sustained release tablets were specified separately and as under:

Schedule-I National List of Medicines (NLEM) 2015
Section 12- Cardiovascular Medicines

| 12.1 Medicine used in Angina | | | |
|---|---|---|---|
| | Medicine | Level of health care | Dosage form(s) and strength(s) |
| 12.1.7 | Metoprolol | P, S, T | Tablet 25mg<br>Tablet 50mg<br>SR Tablet 25mg<br>SR Tablet 50mg |

3.2.5 NPPA had notified separate ceiling prices of Metoprolol formulations plain/conventional tablets and modified dosage sustained release (SR) vide SO.1499 (E) dated 30.03.2022, as under-

| Sl. No. | Name of Formulation | Dosage and strength | Unit | Ceiling price in Rs. |
|---|---|---|---|---|
| 561 | Metoprolol | Capsule 25mg | 1 Capsule | 4.70 |
| 562 | Metoprolol | Capsule 50mg | 1 Capsule | 7.16 |
| 563 | Metoprolol | SR Tablet 25mg | 1 Tablet | 4.47 |
| 564 | Metoprolol | SR Tablet 50mg | 1 Tablet | 6.41 |
| 565 | Metoprolol | Tablet 25mg | 1 Tablet | 3.46 |
| 566 | Metoprolol | Tablet 50mg | 1 Tablet | 5.24 |

As evident from the above, Metoprolol plain conventional tablet and SR (sustained release) or ER extended-release (ER) tablets are distinct and different. NPPA itself has recognized and notified separate ceiling prices for the same in aforesaid notification under existing Schedule-I (NLEM, 2015). The Applicant had then duly

implemented and complied with the ceiling price fixed for Metoprolol tablet 25mg SR and Metoprolol tablet 50mg SR as fixed therein the said notification dated 30.03.2022.

3.2.6 By aforesaid Representations dated 08/12/2022, NPPA was informed that draft version of calculation of Metoprolol 25mg and Metoprolol 50mg Tablets for fixation of ceiling price under revised Schedule-I (NLEM, 2022) of the DPCO, 2013 is misconceived and suffers from inaccuracy, erroneous clubbing of PTR prices of Metoprolol 25mg and 50mg plain and conventional Tablets along with PTR prices of modified release dosage forms such as sustained release or extended-release tablets of Metoprolol 25mg and Metoprolol 50mg, which are distinct, different and not separately specified in revised Schedule-I and thus, Applicant's formulations Met XL 25mg Tablet ER 20 and Met XL 50mg Tablet ER 20, being materially different with incremental innovation and novel drug delivery system, require to be deleted from working calculation. However, NPPA totally ignored the representations and illogically carried out fixation of the ceiling prices with same baseless and wrong calculation and issued impugned notification.

3.2.7 Explanation no. 6 provided therewith in Revised Schedule-I (NLEM, 2022) of DPCO, 2013 further clarifies that incremental innovation or novel drug delivery System such as modified dosage release should be considered included only if specified in list, as hereunder-

> *'6. Innovation in medicine must be encouraged. The formulation developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulation, 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 /pricing etc'.*

Accordingly, formulations having novel drug delivery system such as modified release has to be specified in list and considered differently for price fixation.

3.2.8 On a similar matter of applicability of ceiling price notification of Plain/ Conventional Tablet on modified release dosage delivery system such as controlled release or extended- release tablet, the Hon'ble High Court of Delhi in judgment delivered on 31.10.2018 in Writ petition (c) 11802 of 2016 filed by Modi Mundi Pharma Pvt. LTD. versus Union of India & Ors, reported in *MANU/DE/4000/2018,* has inter-alia observed as hereunder;

> *"33. As noticed above, there are number of formulations listed in the First Schedule to the DPCO 2013, which specifically indicate the delivery system such as CR (Control Release) or ER (Extended Release) against such Medicines. Thus, in case where the intention was to include such formulations, the delivery system was specifically mentioned."*

The Hon'ble Court while allowing the aforesaid writ petition inter-alia held that the Explanation (2) to Schedule-I to the DPCO, 2013 expressly provides that formulation developed through incremental innovation or novel drug delivery system such as sustain

release/ control release would be considered included only if specified in the list against any medicine.

3.2.9 The Hon'ble Supreme Court, in its judgment delivered on 15th November 2019 in Civil Appeal No. 4687 of 201 filed by T.C. Healthcare & Anr. versus Union of India & Anr., reported in MANU/SC/1579/2019, observed that material on record shows that the DPCO is well aware of the existence of different systems of drug delivery. Hon'ble Court inter-alia observed as under –

> *"12. According to pharmacopeia's and US Food and Drug Administration's definitions, modification in drug release are often desirable to increase the stability, safety and efficacy of drug to improve the therapeutic outcome of drug treatment and/or to increase patient compliance and convenience of administration. In that context, the use of the term "sustained release" denotes the systems that maintain the rate of drug release over a sustained period..."*

3.2.10 In the matter having similar applicability issue of price notification of plain/conventional on drug delivery systems vis-a-vis modified release delivery systems Hon'ble High Court of Delhi in Modi Mundi Pharma Pvt. Ltd. case supra held that impugned price notification therein for plain/ conventional tablet cannot be extended to the formulation of CR tablet.

3.3 The Applicant is unduly subjected to irreparable losses due to ex-facie, bad, arbitrary, misconceived price fixation in impugned notification. In view of averments made hereinabove, the Applicant requested reviewing authority to withdraw the impugned notification SO 87(E) dated 06/01/2023 qua the formulations of Metoprolol 25mg Tablet Extended Release (i.e., Met XL 25mg Tablet ER 20) and Metoprolol 50mg Tablet Extended Release (i.e., Met XL 50mg Tablet ER 20) manufactured by the Applicant or in alternative impugned notification is suitably amended in respect of aforesaid applicant's formulations with immediate effect.

**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 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 may be seen that in case of Metoprolol 25mg, modified release tablet has almost 84.86% market share and in case of 50mg 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.

10/10/24

**(Awadhesh Kumar Choudhary)**
Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

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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