

**No.31015/41/2023-Pricing (E-23353)**  
**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 Abbott Healthcare Private Limited (hereinafter called the “Applicant”) filed a Review Application dated 10.02.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 195(E) dated 11.01.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the ceiling price of Metoprolol 100mg modified release Tablet.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 02.06.2023 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 ceiling price of the above drug and hence may be directed to revise the same on the following grounds:

3.1 Metoprolol 100mg tablet “Supermet XL 100mg 10s” were included in the revised Schedule-I of DPCO, 2013 notified on 11<sup>th</sup> November, 2022. Hence, the formulation “Supermet XL 100mg 10s” was also included in the draft calculation of ceiling price under the provisions of Para 4, 6, 10, 11, 14, 16, 17 and 18 of DPCO, 2013. Other manufacturers of Metoprolol 100mg tablet had implemented the WPI under Para 16 of DPCO, 2013 between April, 2022 to July, 2022 respectively. However, incorrect Price-to-Retailer (PTR) data of the brands ‘Prolomet XL 100mg Tablet XL 10 (of M/s Sun Pharma Laboratories Ltd.)’ and ‘Revelol XL 100mg Tablet 15 (of M/s IPCA Laboratories Pvt Ltd.)’ was considered for the purpose of fixing of ceiling price of Metoprolol 100mg tablet which resulted in a lower ceiling price being fixed. The same was proven to NPPA by the Applicant through the submission of representation (reference ASC/2022/12/44 dated 26.12.2022), within prescribed time period of 10 working days.

3.2 A delay in the implementation of revised MRP or PTR based on WPI impact should not be construed as non-implementation of WPI based revision. Non-reflection/delayed reflection of PTR in the market-based data provided by Pharmarack should not be construed as non-implementation of revised MRP, especially when pack

shots of the relevant month are provided as documentary evidence in support of price revision.

3.3 Pharmarack report for the month of September 2022 eventually reflected the revision in MRP for the formulations mentioned at Para 3.1 above, which are prior to the implementation of S.O. 5249(E) dated 11<sup>th</sup> November 2022 and subsequent revision of Schedule-I of DPCO, 2013. Therefore, ceiling price of Metoprolol 100mg tablet should have been fixed after considering the revised PTR as follows:

Sr. no.	Competitor Product Name	Company Name	PTR considered	PTR that should be considered
1	Prolomet XL 100mg Tablet XL 10	Sun Pharma Laboratories Ltd.	112.14	121.43
2	Revelol XL 100mg Tablet 15	IPCA Laboratories Limited	175.71	202.88

#### 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 As per para 9(5) of the DPCO 2013, the market-based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule. Accordingly, the Authority in its 104<sup>th</sup> meeting held on 23.11.2022 noted that the data to be considered for fixation of ceiling prices would be prices in the month of April, 2022 which is the month that is six months prior to date of issue of Notification SO No. 5249(E) dated 11.11.2022. However, taking cognizance of the time lag with which the price changes carried out due to revision in WPI is reflected/captured in the database; the Authority, under Para 9(7) of the DPCO 2013, decided that data for the month of July, 2022 may be considered for calculation of ceiling prices.

4.2 Metoprolol modified release 100mg tablet was non-scheduled formulation earlier and was added for the first time in Schedule-I of DPCO, 2013 vide Notification SO No. 5249(E) dated 11.11.2022. Hence, filing of Form-II is not applicable in this case. However, M/s Sun Pharma Laboratories Limited and M/s IPCA Laboratories Private Limited did not file Form-V with NPPA for the annual increase as per Para 20 of DPCO, 2013. Hence, the price revision has not been considered.

4.3 Therefore, it is clear that NPPA has taken correct PTR for brands “Prolomet XL 100mg Tablet XL 10” and “Revelol XL 100mg Tablet 15” for ceiling price calculation of the formulation ‘Metoprolol 100mg’ as available in market based data i.e. Pharmarack database.



## 5. Examination:

5.1 The Authority in its 104<sup>th</sup> meeting held on 23.11.2022 had decided, under Para 9(7) of the DPCO 2013, that data for the month of July, 2022 may be considered for calculation of ceiling prices to accommodate for the time lag with which the price changes carried out due to revision in WPI is reflected/captured in the database. Accordingly, prices as captured by the Pharmarack database for the month of July, 2022 were used for fixing the ceiling price of the subject formulation.

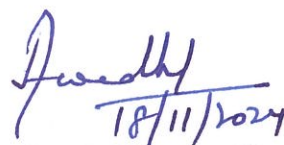
5.2 M/s Sun Pharma Laboratories Limited and M/s IPCA Laboratories Private Limited did not file Form-V with NPPA for the annual increase as per Para 20 of DPCO, 2013 till July, 2022. Hence, the price as captured by Pharmarack has been taken and price revision has not been considered.

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 prices of subject formulation is upheld and the Review Application under consideration is accordingly rejected.

Issued on this, the 18<sup>th</sup> day of November, 2024.



(Awadhesh Kumar Choudhary)

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

To,

M/s Abbott Healthcare Private Limited  
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15-16<sup>th</sup> Floor, Bandra Kurla Complex,  
Near MCA Club, Bandra (E),  
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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.