

No. 31015/54/2023-Pricing (E-23851)
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 J. B. Chemicals & Pharmaceuticals Ltd (hereinafter called the “Applicant”) filed a Review Application dated 18.04.2023 under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 1577(E) dated 31.03.2023 by the National Pharmaceutical Pricing Authority (NPPA). Vide its aforesaid Order, NPPA, inter alia, fixed the Ceiling price of Contrapaque 300mg infusion 100ml and Contrapaque 300mg injection 20ml containing Iohexol injection 300mg iodine/ml.

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 25.09.2023 and present 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 formulations “Contrapaque 300mg Infusion 100ml” and “Contrapaque 300mg Injection 20ml” were included in Schedule-I revised on 11.11.2022. Consequently, these formulations were also incorporated into the draft ceiling price calculation released in accordance with the provisions of Paras 4, 6, 10, 11, 14, 16, 17, and 18 of the Drug (Prices Control) Order, 2013.

3.2 Iohexol is not used as a medicine, but rather as a contrast media in clinics and diagnostic centers for procedures like angiograms. As such, its supply chain differs from the retail sale channels typically used for pharmaceuticals. While Pharmatrac is designed to capture secondary sales data for the retail sale of pharmaceuticals, it is not equipped to track secondary sales of medical devices or contrast media.

3.3 NPPA fixed the ceiling price based on only one company as appearing in the Pharmatrac database. Whereas, there are other companies in the market also selling brands containing “Iohexol Injection 300mg Iodine/ml”. Some companies are listed as below and not considered by NPPA for price fixation:

Brand Name	Company Name
Hexoimage 300-50 ml	Ocean Pharmaceuticals
Parnmage 300 -50 ml	Arco Lifesciences (I) Pvt Ltd

Optiscan 300 - 50 ml	Genetek Lifesciences Pvt Ltd
Optiscan 350-90 ml	Genetek Lifesciences Pvt Ltd
Optiscan 300-100 ml	Genetek Lifesciences Pvt Ltd
Omnipaque 300 -100 ml	GE Healthcare
Nioscan 300- 20 ml	Unijules Life Sciences Ltd
Nioscan 300- 50 ml	Unijules Life Sciences Ltd
Nioscan 300- 100 ml	Unijules Life Sciences Ltd
Nioscan 300- 500 ml	Unijules Life Sciences Ltd

3.4 Since, other companies also manufacturing / selling formulation “Iohexol Injection 300mg Iodine/ml”, the reduction as per Monopoly Conditions under para 6(1) is beyond the scope of the DPCO 2013. With the limitations of using the Pharmatrac data in the present case, NPPA may use para 9(1) and 9(7) of DPCO 2013 for having the appropriate data for price calculation.

4. Gist of clarifications made by NPPA:

4.1 Iohexol Injection was covered under NLEM, 2015 too as Iohexol Injection 140 to 350 mg iodine per ml and ceiling price was fixed at Rs. 15.08 per ml for the formulation Iohexol Injection 300mg iodine/ml on the basis of Pharmatrac database (based on one manufacturer – Contrapaque brand of JB Chemicals) and notified vide S.O. 3088(E) dated 20.09.2017. This price was further revised annually as per WPI and the latest ceiling prices under NLEM, 2015 effective from 01.04.2022 was Rs.18.46 per ml. The ceiling price for no other strength of the drug was fixed under NLEM, 2015.

4.2 Iohexol Injection continued under NLEM, 2022 as Iohexol Injection 140 to 350 mg Iodine per ml. From the Pharmatrac database, it was observed that Iohexol Injection is available in two strengths i.e. 300mg iodine/ml and 350mg iodine/ml. Therefore, based on available market data, the draft worksheet for two strengths of Iohexol was prepared as follows:

- a. **Iohexol Injection 300mg iodine /ml:** As only one company was appearing in the Pharmatrac database, its price was fixed as per Para 6(1) of DPCO, 2013. Accordingly, the reduction percentage was as observed in the case of Iohexol Injection 350mg iodine/ml. The ceiling prices for this formulation is fixed at Rs. 15.07/ml as against Rs. 18.46/ml effective on 01.04.2022.
- b. **Iohexol Injection 350mg iodine /ml:** The price of Iohexol Injection 350mg iodine /ml was fixed for the first time. Therefore, inter brand price capping at lowest price of the brand plus 10% for the same company was applied and ceiling prices of Rs. 12.70 per ml was fixed under Para 19 of DPCO, 2013.

4.3 The draft worksheets were uploaded on NPPA’s website on 09.02.2023 for 10 workings days to invite comments, if any. However, no company filed representation against the draft uploaded worksheets within 10 working days. Therefore, the ceiling price uploaded on website was approved in 111th Authority meeting held on 29.03.2023 and was notified at Rs. 15.07 for 300mg iodine/ml and Rs.12.70 for 350 mg Iodine/ml vide S.O. No. 1577 (E) and S.O. No.1579(E) respectively dated 31.03.2023. These prices were further increased as per WPI and effective price from 01.04.2023 are Rs. 16.89 for 300mg iodine/ml and Rs. 14.23 for 350mg Iodine/ml respectively.

5. Examination

5.1 NPPA followed the set procedure for ceiling price fixation as used for all other formulations and used the market based data as available in the Pharmatrac. The draft worksheet was also uploaded on website to invite comments. However, no company filed any representation against the draft worksheet uploaded.

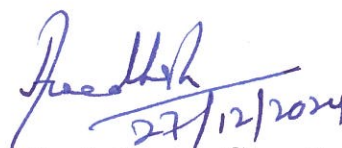
5.2 The Applicant has claimed that Iohexol is not used as a medication, but as a contrast medium in medical procedures such as angiograms at clinics and diagnostic centers. As a result, its supply chain differs from the typical retail distribution channels for pharmaceuticals. While Pharmatrac is designed to capture secondary sales data for retail pharmaceuticals, it is not equipped to track secondary sales of medical devices or contrast media. In this context, the Applicant also gave evidence to the effect that the sales value captured by Pharmatrac was significantly lower than their total sales volume and that multiple companies in the market are selling brands containing "Iohexol Injection 300mg Iodine/ml".

5.3 The claim of the applicant cannot be denied. Therefore, as a special case of drug being mainly sold to diagnostic centres and hospitals, NPPA may utilize the powers given to it under paras 9(1) and 9(7) of DPCO, 2013 to explore other database to capture the representative market for ceiling price fixation in the present case.

6. Decision

In the backdrop of above, the case of Ceiling Price of "Iohexol injection 300mg iodine/ml" is being referred back to NPPA for examination as per the extant provisions of DPCO, 2013.

Issued on this, the 27th day of December, 2024.



(Awadhesh Kumar Choudhary)

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

To:

J.B. Chemicals & Petrochemicals Limited,
Neelam Center, B Wing, 4th Floor,
Hind Cycle Road,
Worli, Mumbai-400030

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

