

**No. 31015/55/2023-Pricing (E-23853)**  
**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 Unijules Lifesciences Ltd (hereinafter called the “Applicant”) filed a Review Application dated 20.04.2023 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 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 Unijules is engaged in manufacturing and marketing “NIOSCAN 300 (Iohexol Injection USP 300mg per ml) and NIOSCAN 350 (Iohexol Injection USP 350mg per ml)” containing “Iohexol Injection 300mg Iodine/ml” and 350mg Iodine/ml respectively.

3.2 NPPA fixed the ceiling price based on only one company’s product i.e. “Contrapaque 300mg Infusion 100 ml” and “Contrapaque 300mg Injection 20 ml” of M/s J.B. Chemicals and Pharmaceuticals Ltd. 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:

Sr. No	Company Name	Brand Name
1	Ocean Pharmaceuticals	Hexoimage 300-50 ml
2	Arco Lifesciences (I) Pvt Ltd	Parnmage 300 -50 ml
3	Genetek Lifesciences 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	CT Vision 300 -50 ml
	Genetek Lifesciences Pvt Ltd	CT Vision 300 -100 ml
4	GE Healthcare	Omnipaque 300 -50 ml
	GE Healthcare	Omnipaque 300 -100 ml
5	JodasExpoin Pvt Ltd	Iohexol Injection USP 300mg I/ ml 50 ml

	JodasExpoim Pvt Ltd	Iohexol Injection USP 300mg I/ ml 100 ml
6	Unjules Life Sciences Ltd	Nioscan 300- 20 ml
	Unjules Life Sciences Ltd	Nioscan 300- 50 ml
	Unjules Life Sciences Ltd	Nioscan 300- 100 ml
	Unjules Life Sciences Ltd	Nioscan 300- 500 ml

3.3 Since, other companies are 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.

#### 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 has been 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 111<sup>th</sup> Authority meeting held on 29.03.2023 and was notified at Rs. 15.07 for 300 mg iodine/ml and Rs.12.70 for 350mg 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.

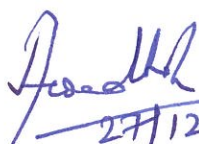
5.2 The Applicant has claimed that Iohexol is not used as a medication, but as a contrast medium in medical procedures such as angiograms at clinics and diagnostic centers. As a result, its supply chain differs from the typical retail distribution channels for pharmaceuticals. While Pharmatrak is designed 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 Pharmatrak 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 the 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 27<sup>th</sup> day of December, 2024.

  
27/12/2024  
(Awadhesh Kumar Choudhary)

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

### **To:**

M/s Unijules Lifesciences Ltd  
B # 35 & 36,  
MIDC Industrial Area,  
Kalmeshwar,  
Dist.: Nagpur-441501

### **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

