

No. 31015/31/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 01.05.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Imaging Products (India) Pvt. Limited (hereinafter called the applicant) against notification S.O. No.1461(E), dated 02.04.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) revising the ceiling prices of Gadobenate Injection.

2. The applicant has contended as under:-

2.1 The Applicant imports and markets an MRI contrast injection by the name Multihance from Bracco, Italy. The name of the salt contained in the said product is Gadobenate Dimeglumine, which falls under the Gadolinium class of compounds. The MRP of 10 ml of Multihance injection is INR 2060. However, in all instances, the Applicant has sold the said product at a price significantly lower than the MRP. Pertinently, the illustrative list of the major players and the details of their products in the MRI injectable space are as follows:

Salt name (Molecular name)	Brand name	Country of origin/ Marketed in India	MRP(inclusive of tax)	NPPA Directive price(inclusive of tax)
1) Gadopentate Dimeglumine	Magnevist 10 ml	Bayer Germany, Bayer Cadilla	1655.95	Impugned Order not Made applicable
2) Gadodiamide	Omniscan 10 ml	GE USA, Wipro - GE Healthcare	1925.00	Impugned Order not made applicable
3) Gadobutrol	Gadovist 10 ml	Bayer Germany, Bayer Cadilla	3363.00	Impugned Order not Made applicable
4) Gadoterate	Dotarem 10 ml	Guerbet, France Guerbet India	2480.00	Impugned Order not made applicable

2.2 Apart from the entities identified in the table, there are a multitude of players selling generic versions of the said products. What is relevant to the instant Petition is that the salts identified in the table too fall within the Gadolinium class of compounds. Yet, the NPPA, through the Impugned Notification, has capped the price of only one particular salt, namely Gadobenate, which affects only the Applicant and leaves untouched all other players who too are in the business of selling contrast media containing Gadolinium compounds. This is a significant departure from the practice of the NPPA wherein it has treated uniformly all compounds which fall within an identical or similar class. In this regard, it is important to note that while the Impugned Order also caps the price of Iohexol, which is a reference to a class of compounds, the reference to Gadobenate is a specific reference to a particular salt as opposed to the Gadolinium class of compounds it falls under. Therefore, on the face of it, the Impugned Order is arbitrary, inconsistent and discriminatory.

2.3 Further, from the Impugned Order it is unclear as to which of the Paragraphs of the DPCO has been applied in arriving at the capped price of INR 102.30 per ml for Gadobenate. In light of the availability of other contrast media containing Gadolinium class of salts, the Applicant is of the view that if at all the DPCO is to be applied to the Applicant's product, it must be applied to all such products containing Gadolinium compounds. Consequently, Paragraph 4 of the DPCO would apply to the computation of the price ceiling. Since the Impugned Order refers only to the Gadobenate salt in the Gadolinium class, it appears that Paragraph 4 has not been applied in arriving at the price ceiling. Assuming that in arriving at the ceiling price of Gadobenate the NPPA has indeed considered the availability of other Gadolinium class of compounds, then the discriminatory nature of the Impugned Order is starker since the Impugned Order does not apply to other Gadolinium salts.

2.4 Further, assuming that the approach of the NPPA in capping the price of Gadobenate is influenced by the 2016 amendment to the schedule of the DPCO, it renders the Impugned Order as well as the amended schedule liable to be revisited and revised for being inconsistent, arbitrary and discriminatory. It is evident that the Impugned Order is riddled with multiple flaws and inconsistencies, internal and external.

2.5 In light of the above enumerated facts and reasons, the Applicant requested to review the Impugned Order which specifically targets only Gadobenate in the entire Gadolinium class of compounds, which has the effect of affecting only the Applicant.

3. Comments of NPPA:

3.1 NPPA fixed ceiling price Rs. 98.90 per ml for Gadobenate Injection vide S.O. 3724(E) dated 23.11.2017 considering para 19 of DPCO, 2013.

3.2 NPPA vide O.M.No. 19(697)/2016-Div.II/NPPA dated 04.04.2016 had uploaded a list of scheduled formulation for which reference market base data required for price fixation was not available. The said list was subsequently amended and displayed again vide OMs dated 28.04.2016, 13.05.2016, 10.01.2017 and 08.07.2017. Copies of the aforesaid OMs were also sent to drugs manufacturers association requesting for submission of market base data. In the absence of market data NPPA fixed ceiling price Rs.98.90 per ml for Gadobenate Injection vide S.O. 3724(E) dated 23.11.2017.

Based on institutional data under para 19 of DPCO, 2013 company did not file review application against S.O. 3724(E) dated 23.11.2017.

3.3 As company has stated that their product multiHance injection contain 529 mg Gadobenate dimeglumine therefore ceiling price is applicable for their product and marketing of subject formulation by the company at MRP of Rs 2060 is a clear violation of para 13 and 14 of DPCO, 2013.

3.4 The issue of non compliance of ceiling price by some of the companies using Gadolinium class of compound in their product, will be examined separately in NPPA for appropriate action.

3.5 NPPA issued the notification No. SO 1461 (E) dated 02.04.2018 just to give effect of WPI on the earlier applicable ceiling price and therefore review against this notification is not sustainable.

4. Examination:

4.1 The company has filed the review application against SO 1461(E), dated 2.4.2018, vide which NPPA only revised the ceiling prices of all scheduled formulations just to give effect of Annual Wholesale Price Index. NPPA fixed ceiling price for Gadobenate Injection vide S.O. 3724(E) dated 23.11.2017 under para 19 of DPCO, 2013. Company did not file any review application against that notification.

4.2 Company was called for hearing on 29.5.2018, but no representative from the company turned up for hearing. Hence, ex-parte decision in the matter is being taken based on the submissions made by the company in its review application.

4.3 Since the company filed its application against SO 1461(E) dated 02.04.2018, which is issued just to give effect of WPI on the earlier applicable ceiling prices of all the scheduled formulations, review against this notification is not sustainable. Therefore, the review application deserves to be rejected.

5. Decision:

“NPPA notified SO 1461(E), dt.2.4.2018 only to give WPI increase effective from 1.4.2018 to all the scheduled formulations and not meant to re-fix the ceiling price of any formulation. Therefore, the grievances raised by the company have got no relevance and the application stands rejected.”

Issued on this date, the 4th day of September, 2018.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

Copy to:-

1. M/s Imaging Products (India) Pvt. Ltd., 15, IV Street Abhiramapuram, Chennai-600 018. (Tamil Nadu).
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website