

F.No.31015/4/2022-Pricing (E-21148)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

Room No. 207, D Wing, Shastri Bhawan,
New Delhi-110 001

Order

This is an order disposing a review application dated 28th April 2022 of M/s INTAS Pharmaceuticals Limited (herein after called the applicant) against the notification S.O. No. 1833 (E) dated 18.04.2022 issued by the National Pharmaceutical Pricing Authority (herein after called NPPA) in respect of ceiling price of Globucel M containing Human Normal Immunoglobulin for Intravenous Use IP 5% Solution (Ig M Enriched) under para 31 of DPCO, 2013.

2. Background

NPPA vide notification S.O. 1833(E) dated 18.04.2022 has fixed Retail Price of Globucel M containing Human Normal Immunoglobulin for Intravenous Use IP 5% Solution (Ig M Enriched) for the Applicant at Rs. 177.85 per ml excluding GST. A Review Hearing was held on 4th August 2022. Further, the applicant again made some additional submissions on 10th August 2022, over which the opinion of NPPA was sought. Submissions by the applicant and NPPA have been discussed in brief in the following paras 3 and 4.

3. Submissions by the Applicant

The Applicant has requested to set aside the above notification issued by NPPA and fix the retail price of Globucel M in accordance with para 4(1), 5(1) and 15(2) and (3) of DPCO, 2013 at Rs. 5171.73, on the basis of price to retailer of Pentaglobin, which is already available in the market, on the following grounds:

3.1 The product Globucel M is an identical plasma therapeutic to the product Pentaglobin (manufactured by Biotest Pharma), having exactly the same formulation, specification product profile and quality attributes including all important

parameters like Double Immunodiffusion, Immunoelectrophoresis, PH, Osmolality, Total Protein and Protein composition, etc.

3.2 The fixation of price of Globucel M is against para 4(1), 5(1) and 15(2) and (3) of DPCO, 2013. As per the provision of DPCO, 2013 the retail price of a new drug available in the market has to be calculated in accordance to Para 5(1) of the Order.

3.3 The applicant's product is identical with Pentaglobin which is already available in the market at retail price of Rs. 6299/. This should have been the basis of averaging the price of retailer of all the brands and generic version of medicines having market share more than or equal to 1% of total turnover on the basis of moving annual turnover of that medicine. Accordingly, the price of Globucel M should have been Rs. 5171.73.

4. Comments by NPPA

4.1 Human Normal Immunoglobulin 5% infusion is a scheduled formulation under DPCO, 2013 and the present applicable ceiling price is Rs. 171.30 per ml excluding GST [SO. 1499(E) dated 30.03.2022].

4.2 The market data of the said formulation i.e. 'Human Normal Immunoglobulin for Intravenous Use IP 5% Solution (IgM enriched)' was not appearing in the Pharmatrac data. Therefore, the case was referred to Multi-Disciplinary Committee of Experts for consideration as to whether the formulation 'Human Normal Immunoglobulin for Intravenous Use EP 5% Solution (Ig M enriched)' could also be a scheduled formulation as Human Normal Immunoglobulin 5% infusion is a scheduled formulation under DPCO 2013.

4.3 As desired by MDC in its 38th meeting held on 24.01.2022, the applicant demonstrated its claim for significant therapeutic effect/ clinical efficacy of 'Human Normal Immunoglobulin for Intravenous Use IP 5% Solution (Ig M enriched)' over Normal Human Immunoglobulin 5% infusion in the 39th meeting of MDC held on 25.02.2022.

4.4 The applicant's claim of incremental innovation and advantage without increasing any side effect over Normal Human Immunoglobulin 5% has been duly examined by the MDC in its 37th, 38th, 39th and 40th meetings before granting additional 15% increase over the ceiling price of Normal Human Immunoglobulin 5% applicable at that time (SO No. 1330 dated 25.03.2021).

4.5 The applicant again made representation on 04.03.2022, which was placed in the 40th meeting of the MDC held on 14.03.2022. The Committee deliberated upon the representation and reiterated its decision taken earlier in the 39th meeting held on 25.02.2022.

4.6 Based on the recommendation of MDC, the Authority in its 96th meeting held on 24.03.2022 approved the retail price of 'Human Normal Immunoglobulin for Intravenous Use IP 5% Solution (Ig M enriched)' for M/s Intas Pharmaceuticals Ltd at Rs. 177.85 per ml excluding GST (i. e Rs.154.65 (Ceiling price vide notification No. 1330 dated 25.03.2021+ 15% on Rs. 154.65) and the same was notified vide SO. 1833(E) dated 18.04.2022.

4.7 The formulation 'Pentaglobin' was launched by M/s Paviour in 2012, i.e., before DPCO, 2013. Hence, it had not approached NPPA for price fixation under DPCO, 2013. Based on the concerns raised by MDC, NPPA has initiated necessary action under the provisions of DPCO, 2013 with respect to the formulation 'Pentaglobin 10ml' of M/s Paviour Pharmaceuticals Pvt. Ltd. and issued Preliminary Notice for suspected price violation during the period July 2016 to July 2017.

5. Examination

5.1 Human Normal Immunoglobulin 5% infusion is a scheduled formulation under DPCO 2013. Therefore, the whole examination depends on whether the formulation, as claimed by the applicant i.e. 'Human Normal Immunoglobulin for Intravenous Use EP 5% Solution (Ig M enriched)' could also be a scheduled formulation as Human Normal Immunoglobulin 5% infusion is a scheduled formulation under DPCO 2013.

5.2 The MDC in its 37th, 38th, 39th and 40th meetings have duly examined the applicant's claim of incremental innovation and advantage without increasing any side effect over Normal Human Immunoglobulin 5% and recommended for granting additional 15% increase over the ceiling price of Normal Human Immunoglobulin 5% applicable at that time.

5.3 NPPA has also initiated necessary action under the provisions of DPCO, 2013 with respect to the formulation 'Pentaglobin 10ml' of M/s Paviour Pharmaceuticals Pvt. Ltd. and issued Preliminary Notice for suspected price violation during the period July 2016 to July 2017.

6. Decision

The issues raised in the review application dated 28.04.2022, are devoid of merit and substance and hence the review application stands rejected. Issue of stay on overcharging amount does not come under the purview of DoP.

Issued on this, the 23rd day of November, 2022.



(Rajneesh Tingal)

Joint Secretary to the Government of India
[For and on behalf of the President of India]

To:

1. M/s Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S G Highways, Thaltej, Ahmedabad-380054.
2. Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.

Copy (for information) to:

1. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi.
2. PS to MoS(C&F), Shastri Bhawan, New Delhi.
3. Sr PPS to Secretary(Pharma), Shastri Bhawan, New Delhi.
4. Technical Director, NIC for uploading the order on Department's Website.