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Title : DoP directs NPPA to re-fix ceiling price of 'Coagulation Factor VIII'

DoP directs NPPA to re-fix ceiling price of 'Coagulation Factor VIII'

Ramesh Shankar, Mumbai, Monday, September 12, 2016, 08:00 Hrs [IST]

The Department of Pharmaceuticals (DoP) has directed the national drug price regulator National Pharmaceutical Pricing Authority (NPPA) to re-fix the ceiling price of "Coagulation Factor VIII". The NPPA through its notification No. S.O. No.1405(E), dated 12.4.2016 had fixed the ceiling price of Coagulation Factor VIII.

Aggrieved by the notification, Baxter (India) Pvt. Ltd submitted a review application under paragraph 31 of the DPCO 2013 on 11.05.2016 against price fixation of Coagulation Factor VIII vide NPPA order No. S.O. 1405(E), dated 12.4.2016 issued under DPCO 2013.

In the review petition, the petitioner contended that their key product Hemofil M (Coagulation Factor VIII injections) Plasma derived have not been taken on record by the NPPA at the time of price fixation. Currently, the ceiling price as per the mentioned order has been set at Rs. 3,323 for 250IU dosage, taking into consideration Price to Retailer (PTR) of Intas Pharmaceuticals and Reliance Life Sciences as per working sheet dated 13th April, 2016 relating to prices as notified on 12th April, 2016. Baxter India holds >80 per cent of the market for Plasma derived Coagulation Factor VIII. The petitioner further argued that the prices for these products have not been considered during determining price ceiling for Coagulation Factor VIII, as notified on 12th April, 2016.

The petitioner requested the DoP to consider the price information for Hemofil M as supplied by and notify the updated ceiling price for Coagulation Factor VIII.

In reply, the NPPA stated that it has fixed the ceiling price Rs. 3323.60 per pack for Coagulation Factor VIII vide S.O 1405(E) dated 12/04/2016 under para 4, 10, 11, 14 & 16 of DPCO, 2013. Company is directed to approach NPPA in line with OM F. No. 19(714)/2016/Div.II/DP/NPPA dated 20/05/2016. Requisite information/documents by the company will be examined and suitable action may be taken by the Authority in this regard.

The contentions of petitioner and the NPPA were heard on 21st June, 2016.

After hearing both the parties, the reviewing authority DoP ordered, "NPPA is directed to re-fix the ceiling price of "Coagulation Factor VIII" after taking into consideration all data, furnished by the petitioner company and available from other sources, on merit within a period of one month from the date of issue of the Order of Reviewing Authority".