

**No. 31015/39/2014-PI.I**  
**GOVERNMENT OF INDIA**  
**MINISTRY OF CHEMICALS & FERTILIZERS**  
**DEPARTMENT OF PHARMACEUTICALS**

B Wing, Janpath Bhavan, New Delhi

**ORDER BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013**

**Subject:** Review application of M/s. Ranbaxy Laboratories Ltd. against fixation/revision of ceiling prices of Gentamicin Injection 40 mg/ml, Renitidine Injection 25 mg/ml and Dexamethasone injection 4 mg/ml. vide NPPA notification S.O. No. 1157(E) dated 28/4/2014 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013).

**Ref.** 1) Applicant's three Review applications dated 26.5.2014  
2) NPPA notification under review S.O. No.1157(E) dated 28/4/2014  
3) Record Note of discussions held in the personal hearing held in the matter on 20.6.2014, 8.10.2014 and 25.11.2014

-----

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No.1157(E) dated 28/4/2014 fixed/revised ceiling price of Gentamicin Injection 40 mg/ml, Renitidine Injection 25 mg/ml and Dexamethasone injection 4 mg/ml. under DPCO, 2013 included.

2. And whereas aggrieved by the above notification, M/S Rabaxy Laboratories Ltd. (hereinafter referred to as the Petitioner) submitted three review applications dated 26.5.2014 under para.31 of DPCO, 2013 for the review of NPPA Price fixation Order S.O.No.1157 (E) Dated 28.4.2014 fixing Ceiling price of Gentamicin Injection 40 mg/ml, Renitidine Injection 25 mg/ml and Dexamethasone injection 4 mg/ml. under DPCO, 2013

3. The grievance of the Petitioner raised in their review applications dated 26.5.2014 were sent to NPPA and the comments of NPPA thereon were given to the Petitioner through the record note of discussions held in the hearing. Record note of discussion is made integral part of the review order. After considering the comments of NPPA the Petitioner has raised the following points, on which comments given by NPPA representative during the hearing and Department's comments on the issue is recorded subsequently against each point:-

NPPA comments: NPPA representative mentioned that they are considering total sales audit(TSA) as provided by IMS for price fixation under DPCO 2013.

Petitioner: The Petitioner representative sought clarification as to what TSA data includes. He requested for further details as to the basis on which TSA data was taken into consideration by NPPA, whether any direction to the said effect had been issued by any authority and/or the same was being done in a discretionary manner. As per Petitioner representative on the basis of his knowledge derived from IMS, SSA data pertains only to the sales to the chemists/retailers. Petitioner representative mentioned that their product is sold to retailers and institutions through their authorised distributors.

NPPA comments: NPPA representative mentioned that as per information provided by IMS, TSA report includes SSA, hospital secondary data and sales made to doctors through stockists. In TSA report, price of any product is captured at PTR(Price to Retailer) level for all

the three channels. The data provided to NPPA by IMS is price to retailer only and did not include institutional sales made by the petitioner directly to the institutions. The practice of PTR data of TSA report of IMS is in line with DPCO 2013 and NPPA has consistently following this practice for price fixation. Consideration of SSA data would also not reflect market shares of all players.

**Petitioner:** The Petitioner representative stated that NPPA basis of adopting TSA data is incorrect. Furthermore NPPA's contention that TSA data reflects PTR is also incorrect. Hospital/institutional and sales to doctors cannot be considered as sale to retailer under DPCO. Retailer is defined under section 2(z) of DPCO 2013 and means a dealer carrying on the retail business or sales of drugs to customers. Neither can hospitals, institutions or doctors be stated to be dealers carrying on retail business of sales of drugs to customers. Thus taking into account sales made to such persons is contrary to the provisions of DPCO 2013 which provides for the price to retailer only to be taken into account. NPPA's contention that the data IMS provided to them is priced to retailer only and did not include institutional sales by the petitioner, is contrary to their own submissions as TSA data takes into account institutional sales. TSA data does not correctly reflect Price to Retailer. DPCO 2013 does not in any paragraph provide for TSA data to be taken into account and NPPA's contention that TSA data is being taken into account on the basis of DPCO 2013 provisions is incorrect.

**Department's comments:**

During the hearings two different sets of data both provided by IMS was presented by the petitioner and by NPPA. The data provided by the Petitioner pertained to SSA data which as per the petitioner relates to the sales to the chemists/retailers. The petitioner representative also mentioned that their product is sold to retailers and institutions through their authorised distributors. NPPA representative informed that they have been using TSA data which as per NPPA includes SSA data, hospital secondary data and sales made to doctors, stockists. The petitioner representative mentioned that using TSA data is incorrect as hospital/institutional sales and sales to doctors cannot be considered as sales to retailer under DPCO 2013. The petitioner representative, in support of his arguments referred to para 2(z) where the definition of retailer mentioned dealers carrying on retail business of sales of drugs to retailers.

The precise point for consideration is whether the sales to hospital, institution and doctors should be considered as PTR (price to retailer). As per the definition contained in para 2(o) of DPCO 2013 "the market share means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form".

Moving annual turnover as per para 2(s) also means cumulative sales value for 12 months in domestic market. Further para 2 (zd) defines wholesaler means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency. It is, therefore, clear that intention of framers of DPCO 2013 is to include all the domestic sales and exclude only the overseas sales by the petitioner. Doctors do not purchase the medicines for their personal consumption but they are given to the patients for which the patient pays to the doctor by compounding the cost of medicine in medical charges or otherwise. Further there is no justification why the benefit of cheaper price at which companies make supplies to the hospitals, institutions, doctors, etc. should not be passed on to the consumers.

The action of NPPA in considering TSA data is as per the provisions of DPCO 2013, is in the larger consumer interest and has been uniformly applied by NPPA across the board. The review application of the petitioner therefore deserves to be turned down.

**Recommendation:**

4. The review application of the petitioner is turned down having no merits.
5. Based on the above and other documents on record, the Government has decided as under:

“The review application of the petitioner is turned down having no merits.”

Issued on this date 18<sup>th</sup> February, 2015.

(A.K. Sah )

Under Secretary to the Government of India  
For and on behalf of the President of India

To

1. M/s Ranbaxy Laboratories Ltd.,  
Plot No 90, Sector 32,  
Gurgaon-122001 (Haryana)
2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D, NIC for uploading the order on Department's Website.