

**No. 31015/21/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 27.02.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Koye Pharmaceuticals Pvt. Ltd. (hereinafter called the applicant) against notification S.O. No. 544(E), dated 06.02.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Insulin Cartridges 3 ml 100 IU.

2. The applicant has contended as under:-

2.1 It seems that NPPA has worked out the price by clubbing the price of Cartridges and Vials. Cartridge is a unique product that is highly calibrated and manufactured using high precision as it is used in Insulin Pen to deliver exact amount of Insulin, whereas vial is a simple USP Type 1 glass which does not require any high precision and calibration and not require any type of device to deliver insulin. The following are the therapeutic advantages of cartridge :-

- a) Insulin Cartridges are always used with delivery device (Insulin PEN).
- b) Insulin Cartridges are less susceptible to contamination as it is always used with Insulin Pen and multiple puncturing of stopper is avoided as is the case in Vials.
- c) Insulin Cartridges delivers accurate dose as it is used with Insulin Pen whereas Vial dosing always varies.
- d) In Insulin Cartridges, there is no wastage of Insulin whereas in case of Vials drug is wasted in adjusting dosage/ extraction and pre administration.
- e) Insulin Cartridges provide immense ease and convenience leading to higher adherence & compliance to prescribed regimen as compared to Vials.

2.2 Company has submitted form one application for retail price approval of 3 ml cartridge 100 IU/ml and not for vials. Therefore, clubbing the PTR and MAT value of vial among cartridge is against the natural justice of law.

2.3 The product under consideration of the price application is non-scheduled but inadvertently the price application for the product was made.

2.4 The NPPA is well entitled to consider any price point prior to the application as also to provide for 16% retailers margin. However, the current prevailing prices of the product just prior to the price application are higher than the prices considered by the NPPA. Also the margins sought by the retailer on a non-scheduled product are 20% as against 16% on a scheduled product. Though the NPPA has provided 16% retailer margin, the trade channels will still seek the company to grant 20% as margins to retailers since it is non-scheduled further resulting in an adverse impact on the net realization to the company.

2.5 In view of above submission, Company requested this Department to issue necessary directive to NPPA to revise the retail price of subject formulation and grant us an opportunity of personal hearing considering para 11(3&4) of DPCO, 2013 (as in case of I.V fluids and injectable).

2.6 Company also mentioned that the current prevailing market prices are higher than the ones notified for their product.

2.7 Company requested to this Department to reconsider their application and consider only 3 ml cartridges while deriving the retail price.

3. Comments of NPPA:

1. Retail prices of the subject formulations fixed by NPPA vide S.O. No. 544 (E) dated 06.02.2018 are detailed below:-

S. No.	Name of the Formulation	Company's Product Composition	Notified Price (Rs.)
1	Human Insulin Injection	Insulin Biophasic Isophane Ph. Eur./USP (30% as soluble Insulin Injection and 70% as Isophane Insulin Injection) Each ml contains: r-human insulin (Regular) 100 IU /vial m-Cresol USP-0.16% w/v, Phenol IP 0.065% w/v	63.66
2	Human Insulin Injection	Insulin Biophasic Isophane Ph. Eur./USP (50% as soluble Insulin Injection and 50% as Isophane Insulin Injection) Each ml contains: r-human insulin (Regular) 100 IU /vial m-Cresol USP-0.16% w/v, Phenol IP 0.065% w/v	63.66
3	Human Insulin Injection	Soluble Insulin Ph. Eur./USP Each ml contains: r-human insulin (Regular) 100 IU /vial	63.66

3.2 NPPA fixed the retail prices of 3 variants of Insulin at Rs. 63.66 per ml based on the data provided by pharma-trac in accordance with the provisions of DPCO, 2013. DPCO, 2013 allows fixing ceiling/retail price based on formulation and does not differentiate between its packaging type i.e vial and cartridge. Further, there is no concept of cost based pricing in DPCO, 2013. In the form I application filed by the company for fixation of retail price, there is no mention of cartridge. Further the NLEM, 2015 does not differentiate based on packaging type of insulin like cartridge or vial while fixing the ceiling/retail price of subject formulation. In view of the above the contention of the company has no merit and may be rejected.

3.3 DPCO, 2013 allows retailer margins of 16% while calculating the ceiling/retail price. In view of the above the contention of the company has no merit and may be rejected.

3.4 Since, the subject formulation i.e. insulin 40 IU /ml is a schedule drug under NLEM, 2015 any variant of insulin would come under definition of 'new drug' under DPCO, 2013 if the company is an existing manufacturer of the scheduled formulation.

4. Examination:

Since the company has claimed many therapeutic advantages of the insulin cartridges vis-à-vis insulin vials and this is a matter to be examined by the experts, therefore, NPPA needs to refer the matter to the Committee of Experts to examine and recommend whether separate retail price can be fixed for Insuline Cartridges considering its therapeutic advantages. The recommendation of the Expert Committee may be examined by NPPA to take a decision about refixation of retail price of Insulin Cartridges 3ml 100 IU, on merit.

6. Decision:

"NPPA is hereby directed to refer the matter to the Committee of Experts to examine and recommend whether separate retail price can be fixed for Insuline Cartridges considering its therapeutic advantages. The recommendation of the Expert Committee may be examined by NPPA to take a decision about refixation of retail price of Insulin Cartridges 3ml 100 IU, on merit."

Issued on this date, the 26th day of June, 2018.

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

Copy to:-

1. M/s Koye Pharmaceuticals Pvt. Ltd., A-10, Art Guild House, Phoenix Market City Annexe, LBS Marg, Kamani, Kurla, Mumbai-400 070.
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.