

Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceuticals Pricing Authority

New Delhi, the 30 June, 2020

ORDER

S.O. **2151(E)** - Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-Pl.I dated 29th August, 1997, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 19 of the said Order to be exercised by the NPPA on behalf of the Central Government.

3. And whereas NPPA had received applications from several companies having major market share for upward revision of ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml under para 19 of DPCO 2013 citing reasons that the cost of APIs which constitute major portion of the input cost and mainly imported from China, has risen to a considerable extent making the companies entirely unviable to continue manufacture the formulations. The companies also contended that over the years the regulated price have decreased whereas there is consistent increase in the price of imported price of APIs thereby making commercially unviable for the drug manufacturers to manufacture the said product.

4. And whereas, Ministry of Health and Family Welfare (MoH&FW) has included Heparin injection 5000IU/ml as an essential medicine for treatment of COVID-19 patients. Further, reports of shortage have also been received for Heparin Injection.

5. And whereas, the Committee constituted to monitor export/import trends of APIs, formulations and medical devices needed for COVID-19 vide its report communicated through letter dated 19th June, 2020 has informed that there has been considerable increase in the price of API Heparin when compared to base year of September 2018. Accordingly, the Committee recommended short term upward price revision of Heparin Injection.

6. And whereas, the NPPA considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the pandemic situation of COVID-19 and opined that any situation of shortage due to price control needs to be seen from a public interest perspective. Accordingly, NPPA invoked extra ordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml by giving one time increase of 50% from the present ceiling price to be applicable upto 31st December 2020.

7. Therefore, in exercise of extra ordinary powers in public interest, conferred by paragraph 19 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) S.O. Number and date specified in column no. 6(a) & 6(b) mentioned in the table below, the National Pharmaceutical Pricing Authority, hereby fixes the prices as specified in column (5) of the Table below as ceiling prices exclusive of goods and services tax applicable, if any in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Existing S.O. No. & Date	
					6(a)	6(b)
(1)	(2)	(3)	(4)	(5)		
1.	Heparin	Injection 1000 IU/ml	1 ml	24.39	1213(E) Sl. No. 403	25.03.2020
2.	Heparin	Injection 5000 IU/ml	1 ml	60.54	1213(E) Sl. No. 404	25.03.2020

Note:

- (a) The ceiling price as specified in column (5) in respect of the formulations with dosage & strength mentioned in column (2) and (3) respectively would be applicable upto 31st December 2020.
- (b) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.
- (c) The provisions of para 13(2) of DPCO 2013 would not be applicable on the ceiling price specified in column (5) in respect of the formulations with dosage & strength mentioned in column (2) and (3) respectively.
- (d) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
- (e) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.
- (f) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- (g) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.
- (h) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- (i) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- (j) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.
- (k) The price of Heparin Sodium API would be monitored on a monthly basis upto 31st December 2020.

PN/208/76/2020/F

F. No. 8(76)/2020/ DP/Div-II/NPPA

Sd/-

(Prasenjit Das)
Asst. Director