

**No.31015/1/2016-PI.I**  
**Government of India**  
**Ministry of Chemicals & Fertilizers**  
**(deptt. of Pharmaceuticals)**  
\*\*\*\*\*

Janpath Bhavan, New Delhi

**O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO, 2013**

**Subject:** The review application of M/s Torrent Pharmaceuticals Ltd. under para 31 of DPCO against NPPA order No. S.O. 217(E) dated 22/01/2016 for withdrawing notification No.SO 1892(E), dated 13/7/2015 in respect of Deplatt CV 20 Forte capsule

**Ref:** 1) Applicant's Review application dated 18/2/2016  
2) NPPA Notification under review SO No.217(E), dated 22/1/2016  
3) Record Note of discussions dated 26/4/2016

Whereas National Pharmaceuticals Pricing Authority (NPPA), Government of India, vide S.O. No 217(E) dated 22/01/2016, withdrew notification No.SO 1892(E), dated 13.7.2015 in respect of Deplatt CV 20 Forte capsule.

2. And whereas aggrieved by the above notification, M/s Torrent Pharmaceuticals Ltd. (hereinafter referred to as "Petitioner") submitted review application dated 18/2/2016 under para 31 of DPCO, 2013 for review of NPPA Order SO No.217(E) dated 22/1/2016 in respect of Deplatt CV 20 Forte capsule under DPCO 2013.

3. The grievance of the petitioner raised in their review application dated 18.2.2016 were sent to NPPA and the comments of NPPA were given to the Petitioner through the Record Note of Discussions held in the Review Hearing on 26.4.2016. Record Note of discussions is made part of the review order. After considering the comments of NPPA, the Petitioner has raised following points on which comments given by NPPA representative, during the hearing and Government's comments on the issue is recorded subsequently against each point:

In the written submission, the Company representative stated that their review petition is with reference to the NPPA communication number 19(573)/2015/NPPA/Div II, dated 22.1.2016 wherein notification no. S.O. 1892 (E) dated 13<sup>th</sup> July 2015 has been withdrawn with immediate effect by NPPA. In this regard, the company has furnished following facts :-

- They applied for a retail price under Paragraph 15 of the DPCO 2013 since their company was an existing manufacturer of one of the scheduled formulation of the said combination i.e. Clopidogrel 75mg and the retail price was determined as per the provisions of Paragraph 5 of the DPCO 2013 in respect of the following new drug.

- Clopidogrel Bisulphate equivalent to Clopidogrel 75mg, Atorvastatin calcium equivalent to Atorvastatin 20mg (film coated) and Aspirin 150mg- pack size of 10 capsules.

Marketing by : Torrent Pharmaceuticals Ltd.

Manufactured by : Surien Pharmaceuticals Pvt. Ltd.

- Accordingly under provision of DPCO 2013 the retail price of the above product was notified at Rs. 7.00 per capsule vide S.O. No. 1892(E) dated 13<sup>th</sup> July. 2015. Also the company launched the above product in the market at price fixed by NPPA.

Surprisingly, they received letter dated 22<sup>nd</sup> January, 2016 for withdrawal of the price fixed vide S.O. No. 1892(E) dated 13<sup>rd</sup> July 2015 in respect of the said formulation as new drug under DPCO 2013. Following reasons for withdrawal has been specified therein:-

“It is noted that NPPA has already notified the ceiling price of Clopidogrel bisulphate equivalent to Clopidogrel 75mg, Atorvastatin calcium equivalent to Atorvastatin 20mg (as film coated) and Aspirin 150mg at Rs. 21.24 (excluding excise duty & local taxes if any) for 10 capsules vide S.O. No. 775(E) dated 10<sup>th</sup> April, 2012 under DPCO, 1995. Company has also been directed to follow the ceiling price notified under DPCO 1995 and submit the compliance report”.

- That the withdrawal of notification and direction to follow the ceiling price of DPCO, 1995 are not in consistence with the provisions of DPCO, 2013. Para 10 (3) of the DPCO. 2013 regulates the price of such scheduled formulations, which are specified in the Drugs (Prices Control) order, 1995 but not specified in the First Scheduled of DPCO 2013 the price of which are fixed and notified up to 31<sup>st</sup> May, 2012. As per the said para such prices shall remain effective for further one year i.e. up to the 30<sup>th</sup> May, 2013 and thereafter price of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this order. The above para regulates the price of the above formulations only till May 2013 and thereafter specifies that the prices of such formulations shall be regulated as in case of other non-scheduled formulations applicable only in cases of products which are available in the market on the date of promulgation of DPCO 2013.
- Whereas the formulation under reference was not in the market on the date of promulgation of DPCO, 2013 and the same was launched as per the drug license obtained on 27<sup>th</sup> February 2015. The product was launched only after due approval of price by NPPA vide notification dated 13<sup>th</sup> July 2015. As such there is no provision in the DPCO 2013 for withdrawal of price notification issued for new drug and make the ceiling price notified under DPCO, 1995 applicable in respect of new drugs and/or non-scheduled formulation launched subsequent to introduction of DPCO 2013. Company representative also mentioned that this has never been the intention of the NPPA 2012 and the DPCO-2013 to enhance the span of control by way of regulation the price of new drug/non-scheduled formulations based on ceiling price notified earlier on cost based formula except for existing formulations under Para 10(3) of the DPCO 2013.

In view of the above, they requested NPPA to withdraw the notification no. 19(573)/2015/DP/NPPA/Div.II dated 22<sup>nd</sup> January 2016, and allow them to continue with the new drug price fixed by NPPA vide S.O. No. 1892 (E) dated 13<sup>th</sup> July 2015.

#### 4. COMMENTS OF NPPA

(i) M/s Torrent Pharma, marketing company of the said formulation vide its Form- I application dated 19.6.2014 (received in NPPA on 24.6.2014), applied for price fixation of the above new drug formulation. The applicant company claimed the retail price of Rs.70.00 for a strip of 10's capsule.

(ii) NPPA had already fixed the ceiling price of Rs. 21.24 (excluding Excise duty & Local taxed, if any) for 10's capsule vide S.O. 775(E) dated 10.4.2012 under DPCO, 1995. Therefore, the instant product attracts the provision of para 10(3) of DPCO, 2013.

(iii) Company has been directed to follow the ceiling price notified under DPCO, 1995.

(iv) Deplatt CV forte also comes under the purview of ceiling price fixed under DPCO, 1995.

5. During the personal hearing, the company representative further informed that the price of product "Deplatt CV 20 Forte" was required to be fixed under para 15(2) of DPCO 2013 as a retail price of a new drug/pack and, therefore, para 10(3) of DPCO 2013 is not applicable in the instant case. In reply, NPPA representative stated that the product under reference is ceiling conforming pack and ceiling price of Rs.21.24 was already fixed by NPPA for this pack vide SO 775(E) dt. 10.4.2012 under DPCO 1995. Under para 10 of DPCO 2013, when a ceiling price is fixed for a pack **only upto 10% annual increase can be availed by a manufacturer/marketing company.** In case a manufacturer launches a new pack at this stage, manufacturers/marketers should follow the ceiling price already fixed by NPPA.

6. Thereafter, Company representative stated that the provision of fixation of aforesaid product used by NPPA is applicable in case of existing manufacturer under DPCO 1995 and as this is a new drug it has been applied by the company under para 15(2) and they have applied in form I for the same. The fixation by NPPA treating the formulation as scheduled one does not seem to be correct. Also, this product is not forming part of NLEM 2011 or NLEM 2015. Application of ceiling price of old DPCO 1995 to non-scheduled products would lead to the formulation under ceiling price indefinitely which is not the intention of NPPP 2012 and DPCO 2013.

In response to this, NPPA representative mentioned that NPPA only fixes the price for scheduled formulation and monitors the price of non-scheduled formulation. As this pack is a non-scheduled formulation, after implementation of DPCO 2013, NPPA is also monitoring the price of this pack because the price was already fixed by NPPA for this pack. NPPA has directed the company to follow the ceiling price fixed by NPPA under DPCO 1995 vide letter No.19(573)/2015/NPPA/Div.II dated 22.1.2016 and also issued SO No.217(E) dt. 22.1.2016 in this regard.

7. **Examination:**

On examination of the case, it is clear that the price of the same product had been fixed twice by NPPA – once as a scheduled drug under DPCO, 1995 on 10.04.2012 and in the second instance on 13.7.2015 as a new drug under DPCO 2013. In 2012, the ceiling price was fixed at Rs.21.24 for a pack-size of 10 capsules and in 2015, at Rs.70/- for 10 capsules. However, on realizing their mistake of fixing the price again as a new drug, of a drug which had earlier been a scheduled drug and after promulgation of the new DPCO become a non-scheduled drug, NPPA withdrew its earlier price Notification Order of 13.07.2015.

Para 10(3) of DPCO, 2013 clearly states that the prices of scheduled formulations specified in DPCO, 1995, which have not been specified in the first schedule of DPCO 2013, after a period of one year, these formulations are to be treated as non-scheduled drugs. By doing so, the Company has increased its retail price from Rs.21/- + 10% allowed escalation as non-scheduled drug, to Rs70/- directly which is a manifold increase.

It appears that the Company has applied as a new drug and claimed a price three times more than which was fixed in 2012. When NPPA realized this, they have withdrawn the price fixation as a new drug and rightly so in accordance with the provisions of the DPCO. The review petition is rejected as the action of the NPPA has been in accordance with the provisions of the DPCO.

8. **Government decision:**

**In view of the above, the review petition stands rejected.**

Issued on this date, the 30<sup>th</sup> day of August, 2016

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

**To**

1. **M/s Torrent Pharmaceuticals Limited, Torrent House, Off Ashram Road, Ahmedabad-380 009.**
2. **The Member Secretary, NPPA, YMCA Cultural Centre Building, New Delhi 110 001.**

**Copy to:**

- (i) **PS to Hon'ble Minister (C&F), Shastri Bhavan, New Delhi for information.**
- (ii) **PSO to Secretary (Pharma), Shastri Bhavan, New Delhi for information.**
  - a) **Technical Director (NIC) for uploading the order on Department's Website.**