

No. 31015/43/2018-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,  
New Delhi 110 001

Order

1. This is an order disposing of two separate review applications filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) (i) application dated 28.11.2018 filed by M/s Torrent Pharmaceuticals Limited (first applicant) and (ii) application dated 30.11.2018 filed by M/s Unichem Laboratories Limited (second applicant) against notification S.O. 5638(E), dated 02.11.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of formulations "Trilosar 6.25" and "Trilosar 12.5". The facts mentioned and the grounds taken in both the above mentioned review applications are identical, hence both the review applications are being disposed of with a single order.

2. The applicants have contended as under:-

2.1 NPPA notified retail price of formulation Trilosar 6.25, containing three salts, i.e. Losartan potassium 50mg+Chlorthalidone 6.25 mg+Amlodipine 5 mg vide 5638(E) dated 02.11.2018. However, regarding Losartan Potassium 50mg and Chlorthalidone 6.25 mg, NPPA considered retail price Rs 4.50 which was notified vide SO 583(E) dated 24.02.2016 for Cadila Pharmaceuticals Limited. Since this is a non scheduled combination, NPPA should have taken a price increase of 10% per year as per para 20 of DPCO to arrive at current price of subject formulations.

2.2 Similarly, for the formulation Trilosar 12.5, NPPA has considered retail price of Rs 4.55 for salts Losartan Potassium 50mg+Chlorthalidone 12.5 mg which was notified vide SO 3146(E) dated 10.12.2014 for Cadila Pharmaceuticals Limited, without considering price increase of 10% per year as per para 20 of DPCO to arrive at current price of subject formulations. While calculating retail price for 2015 for a formulation of another company, NPPA, in one of its meeting held on 25.5.2018 has taken a reference price of 2009 and taken increase @ 10% year on year for 6 years (2009 to 2015) to arrive at price of 2015.

2.3 Further, for arriving at the retail price of both the above formulations, NPPA has taken a base of Rs 2.33 per tablet for salt "Amlodipine 5 mg" (which is a scheduled formulation), notified vide SO 1686(E) dated 09.05.2016. However, NPPA has not taken Wholesale Price Index announced in April, 2017 for the year 2016 and announced in April 2018 for the year 2017 to arrive the price of subject formulation. The applicant is of the opinion that NPPA should have considered Rs 2.45 base price for Amlodipine which was notified vide SO 1461(E) dated 02.04.2018.

2.4 Moreover, for both the drugs, NPPA has taken a reduction of 20% on price of Rs 2.33 being a lower price in comparison with price of Losartan+Clorthalidone. Since actual notified prices are considered as a base for notifying retail price of their formulations, there was no need to reduce the price by 20%.

2.5 NPPA notified the retail prices for Trilosar 6.25 and Trilosar 12.5 on the basis of Form-I submitted by M/s Unichem Laboratories Limited (manufactured by M/s GKM New Pharma Ltd.) on 11.12.2017. M/s Torrent Pharmaceuticals Limited took over the India business of M/s Unichem Laboratories Limited on 14.12.2017. M/s Torrent Pharmaceuticals Ltd. stated that the data and related records were shifted in IPDMS (which includes Form 1/Form 2/Form 5/Form 3 etc. amongst other things to be shifted to Torrent) from Unichem portal to Torrent portal. Based on this understanding, the applicant was under the impression that Form I submitted by Unichem was considered as if applicable to Torrent as well. The applicant stated that NPPA was informed vide its letter dated 29.12.2017 about taking over the business of M/s Unichem Laboratories Limited. However, as per DPCO, NPPA is to look into the requirement of necessary documents which are to be submitted by the applicant and take necessary action, as per provisions of DPCO.

### 3. Comments of NPPA:

The retail prices of both the formulations have been correctly notified with the approval of Authority, as per para 5 and para 15 of DPCO considering the recommendations 4<sup>th</sup> Meeting of Multidisciplinary Committee of Expert held on 27.09.2018.

### 4. Examination:

4.1 NPPA fixed the retail price of formulation Trilosar 6.25, containing three salts, i.e. Losartan potassium 50mg + Chlorthalidone chlorthalidone 6.25 mg+Amlodipine 5 mg. Similarly the retail price was fixed for formulation Trilosar 12.5, containing Losartan Potassium 50mg+Chlorthalidone 12.5 mg+Amlodipine 5 mg. vide SO 5638(E), dated 02.11.2018. Out of the above three salts, Losartan and Chlorthalidone are non-scheduled medicines and Amlodipine is a scheduled medicine.

4.2 While fixing the retail price of Trilosar 6.25, for Losartan Potassium 50mg and Chlorthalidone 6.25 mg (combination of non-scheduled formulations), NPPA considered retail price of Rs 4.50 which was notified vide SO 583(E) dated 24.02.2016 for Cadila Pharmaceuticals Limited. Similarly for formulation Trilosar 12.5, NPPA considered retail price of Rs 4.55 for salts Losartan Potassium 50mg+Chlorthalidone 12.5 mg (combination of non-scheduled formulations) which was notified vide SO 3146(E) dated 10.12.2014 for Cadila Pharmaceuticals Limited. For salt "Amlodipine 5 mg" (scheduled formulation), NPPA has taken a base of Rs 2.33 per tablet notified vide SO 1686(E) dated 09.05.2016 for both the formulations.

4.3 The decision to extend the same retail price of Rs 4.50 per tablet notified for combination of non-scheduled medicines (Losartan Potassium 50mg and Chlorthalidone 6.25 mg) earlier in 2016 and Rs 4.55 for Losartan Potassium 50mg and Chlorthalidone 12.5 mg in 2014 is beyond the provisions of DPCO. NPPA should have taken the current base price of 2018 for both the strengths/combinations. NPPA also erred in considering the base price of Rs 2.33 notified in 2016 for Amlodipine 5 mg., instead of existing base price of Rs 2.45 base price notified vide SO 1461(E) dated 02.04.2018, which was available for consideration.

4.4 As per para 20(1) of DPCO, in case of non-scheduled formulations, the maximum limit fixed for increase in maximum retail price (MRP) is ten percent of MRP during preceding twelve months. The ten percent increase in MRP is the "maximum

limit". However, manufacturer is not bound to increase the MRP by ten percent. Manufacturers may or may not increase the maximum retail price. The increase can be between zero to ten per cent. Therefore, the contention of the applicants that NPPA should have taken a price increase of 10% per year as per para 20 of DPCO to arrive at current price of subject formulations, has got no merit.

4.5 In order to arrive at the reasonable current base price for both the strengths/ combinations, the impact of wholesale price index should be given for subsequent years to the retail price of Rs 4.50 per tablet notified in 2016 for combination of non-scheduled medicines (Losartan Potassium 50mg and Chlorthalidone 6.25 mg) and Rs 4.55 for Losartan Potassium 50mg and Chlorthalidone 12.5 mg notified in 2014. For scheduled formulation Amlodipine 5 mg, the prevalent ceiling price should be considered.

4.6 The example quoted by the applicants about NPPA taking increase @ 10% year on year for 6 years (2009 to 2015) to arrive at retail price for 2015 for a formulation of another company, is not identical to that of the present case. In that case, the retail price was fixed for a formulation that was included in DPCO, 1995 and for price fixation under DPCO 2013, the 10% year-on-year increase was in order.

4.7 As regards applicants' contention about reduction of 20% on price of Amlodipine 5mg tablet, i.e. Rs 2.33 being a lower price in comparison with price of Losartan + Clorthalidone, NPPA applied the reduction based on formula recommended in the Pronab Sen Committee report. As per Pronab Sen Committee Report, the cost of production of a tablet or injection decreases as the strength is increased. However, the other 'costs', such as promotional expenses and profit margins, which constitute a substantial fraction of the price of a formulation, do not exhibit the same behavior. To account for such 'cost', the Committee recommended appropriate value of 0.8 for tablets/capsules and 0.7 for injectibles for additional strength and dosage. Thus, Pronab Sen Committee recommended reduction of 0.2 for additional strength and dosage. On this analogy, reduction of 20% reduction on Amlodipine 5mg tablet price, (being lowest of Losartan Potassium 50mg+Chlorthalidone 6.25 mg and Amlodipine 5mg tablet) was applied to fix the retail price of new drug. Therefore, the 20% reduction carried out by NPPA is in order. Hence, the contention raised by the applicant has got no merit.

4.8 In view of the above examination, it is justified that the retail price of Trilosar 6.25 and Trilosar 12.5 are fixed by giving impact of wholesale price index for the subsequent years to the retail price being considered of earlier years and arrive at a reasonable current base price for the combinations Losartan Potassium 50mg+Chlorthalidone 6.25mg and Losartan Potassium 50mg+Chlorthalidone 12.5mg and also by taking the prevalent ceiling price of scheduled formulation Amlodipine 5 mg.

## 5. Decision:

NPPA is hereby directed to re-fix the retail prices of Trilosar 6.25 and Trilosar 12.5 by giving the impact of wholesale price index (WPI) for the subsequent years to the retail prices being considered of earlier years and arrive at a reasonable current base price for the combinations Losartan Potassium 50mg+Chlorthalidone 6.25mg and Losartan Potassium 50mg+Chlorthalidone 12.5mg and by considering the prevalent ceiling price of scheduled formulation Amlodipine 5 mg. The revised retail prices be notified within a period of thirty days of issue of the order.

Issued on this date, the 14<sup>th</sup> day of March, 2019.

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

Copy to:-

1. M/s Torrent Pharmaceuticals Limited, 115-116, Ground Floor, World Trade Centre, Babar Road, Connaught Place, New Delhi-110 001.
2. M/s Unichem Laboratories Limited, Unichem Bhawan, Prabhat Estate, Off. S.V. Road, Jogeshwari (West), Mumbai-400 102.
3. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
4. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
5. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
6. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
7. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
8. T.D., NIC for uploading the order on Department's Website