

No.31015/16/2019-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

Room no. 207, D Wing, Shastri Bhawan,
New Delhi-110 001.

Order

This is an order disposing of review application dated 01.12.2019 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Emcure Pharmaceuticals Limited (hereinafter called the applicant) against notification S.O. No. 4062(E) dated 08.11.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of Darunavir 800mg + Ritonavir IP 100mg.

2. The main contentions raised by the applicant are as under:

(i) The company submitted its Form I application for the Retail Price approval of Darunavir 800mg + Ritonavir IP 100mg Tablet to NPPA on 17th June 2019. The NPPA notified the retail price approval as Rs. 197.55/Tab vide S.O. 4062(E) dated 8th November, 2019.

(ii) NPPA had fixed the retail price of Darunavir 800 mg + Ritonavir 100mg for M/s Hetero Healthcare Limited earlier vide S.O. 5638(E) dated 02nd November, 2018 at Rs. 212.91/tablet based on the recommendation of Multidisciplinary Committee (MDC) of Experts in its 4th Meeting held on 27th September, 2018.

(iii) The Form-I application of the applicant was referred to the MDC in its 13th meeting held on 24th September, 2019, considering the fact that the Retail Price for the same formulation had previously been recommended by the Committee for M/s Hetero Healthcare Ltd on 27th September, 2018 (4th meeting) and the Retail price was declared by the Authority based on the MDC's recommendations.

(iv) The retail price declared previously for M/s Hetero Healthcare Limited at Rs 212.91/Tab should have been extended to them as per the existing practice of NPPA. The very fact that the same formulation was again referred to the MDC, not only resulted in a significant delay of almost 4 months for the price approval

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but also allowed NPPA to deviate from its current approach on Retail Price fixation.

(v) The company was given a retail price of Rs 197.55/tab for Darunavir 800 mg + Ritonavir 100 mg on 8th November, 2019 whereas M/s Hetero Healthcare Ltd was granted a different retail price of Rs. 212.91/tab on 2nd November, 2018. This led to a reduction in retail price to an extent of Rs 15.36/tab.

(vi) There are other similar cases where the subsequent applicants have been passed on the same retail price as was recommended to the first applicant based on the recommendation of MDC. The applicant highlighted one case considered in the same meeting of the Authority as under:

| Composition | Recent Company | Recent Notification | Recent Retail Price | Manufacturing & Marketing Company | Earlier Retail Price (Rs.) | Earlier Notification |
|----------------------------------------------------------------------------------|-------------------|-----------------------------|---------------------|-----------------------------------|----------------------------|-----------------------------|
| Dolutegravir- 50 mg, Lamivudine 300mg, Tenofovir Disoproxil Fumarate 300mg (TLD) | M/s Cipla Limited | S.O. 4062(E) dated 08.11.19 | 114.06 | M/s Mylan & M/s Emcure | 114.06 | S.O. 5638(E) dated 02.11.18 |

(vii) The case in table above indicate that the first time approval was granted a retail price on 2nd November, 2018 based on the recommendation of MDC held on 27th September, 2018 and the same retail price was passed on to the subsequent applicant namely M/s Cipla almost after a gap of one year.

(viii) The PTR of the same formulation was available in Jan, 2019 PharmaTrac data and the PTR is shown as Rs 2678.57 for 30 tab, i.e., Rs 89.28/tab. In spite of the fact that the data was available in PharmaTrac, the NPPA choose to extend the price already approved for Rs 114.06.

(ix) The applicant has claimed that two different principles have been applied in the same Authority meeting for similar cases held on 30.10.2019, where one applicant got the same retail price as recommended by MDC and approved earlier whereas the applicant's company got the PTR that too when the

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same formulation was not featuring in the Pharmatrac data. It has further claimed that the NPPA has gone one step ahead to take the PTR from Form-V submitted by M/s Hetero and extended the same PTR to the company.

(x) The applicant has claimed that picking up of the PTR value from Form-V uploaded on IPDMS is not consistent with the provisions of DPCO 2013. PTR value is considered from the PharmaTrac data, which is presently used data by NPPA. The company further stated that as the pricing regulator, the NPPA cannot pick & choose lower of the PTR from different sources. In case the PTR is not available on PharmaTrac, the Retail Price granted earlier should have been passed on to them, which it claims is the practice NPPA has been following all along, since the promulgation of DPCO, 2013 in May 2013.

(xi) The applicant has already implemented the retail price approved by the NPPA and filed the Form-V on IPDMS for Darunavir 800mg + Ritonavir 100mg on 05.12.2019.

Based on the above facts, the applicant has requested for issuance of directions to NPPA to extend the previously approved retail price of Rs. 212.91/tab. It has further requested that NPPA be advised/ directed to revise the retail price based on directions issued by the Department to ensure just & equitable retail prices to their formulation as stated above.

3. The comments of NPPA are as under:

(i) The authority fixed the Retail Price of Darunavir 800 mg + Ritonavir IP 100 mg based on the recommendation made in the 13th Meeting of Multi-Disciplinary Committee (MDC) of Experts on 24th September, 2019. The Committee had deliberated upon the matter in detail and recommended the retail price of each film coated tablet contained Darunavir 800 mg + Ritonavir IP 100 mg for M/s Emcure Ltd (marketer) and M/s Hetero Labs Ltd., (Manufacturer/Importer) at Rs 197.55 per tablet excluding GST based on the latest PTR as submitted by M/s Hetero Healthcare Ltd. in Form-V.

(ii) Earlier, the Retail Price of Rs 212.91 per tablet was notified for M/s Hetero Healthcare Limited. However, the PTR of M/s Hetero Healthcare Ltd was found to be Rs. 170.30 per tablet from Form-V. As per provisions of DPCO, 2013, 16% margin is added with PTR to arrive at the ceiling/retail price. Accordingly, by taking the PTR of M/s Hetero Healthcare Ltd as per Form-V, the Retail Price comes to Rs 197.55 per tablet excluding GST ($\text{Rs } 170.30 \times 1.16 = \text{Rs } 197.55$).

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(iii) The applicant has submitted Form-V dated 5th December, 2019 wherein the company followed the Retail Price fixed by NPPA vide SO 4062(E) dated 08.11.2019. However, the company has not mentioned "effective batch No. & date" in form V submitted.

4. Examination:

4.1 The review application is filed by the applicant with the contention that the retail price declared previously for M/s Hetero Healthcare Ltd at Rs 212.91/tab should have been extended to them as per the existing practice of NPPA.

4.2 In the instant case, while fixing the retail price of 'Darunavir 800mg + Ritonavir 100mg tablet' for Emcure Pharmaceuticals Ltd. (whose data was also not available in Pharmatrac), the retail price of the same composition which was earlier fixed for other company (M/s Hetero Healthcare Ltd.) notified for M/s Hetero Healthcare Limited for Rs 212.91 per tablet vide SO 5638(E), dated 2nd November, 2018 could have been used. However, the NPPA considered the PTR of Rs.170.30 per tablet, as the Form-V of M/s Hetero Healthcare Ltd. and fixed the retail price at Rs 197.55 per tablet by adding 16% retail margin to the PTR. The Authority fixed the retail price based on the recommendation of the Multidisciplinary Committee of Experts to extend the benefit of lower price to public and in public interest.

4.3 As per provisions in DPCO for calculation of retail price of new drug for existing manufacturers of scheduled formulations, para 5(1) and para 9(4) provide as under:

"5(1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4."

"9(4) The market based data for fixing the retail price of new drugs available in the market, shall be data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug."

4.4 The decision of the NPPA in its Authority Meeting to apply any other formula amounts to amending the provisions of DPCO, 2013 for which NPPA has no authority. Therefore, the NPPA need to fix the retail price of the aforesaid formulation strictly as per provisions of para 5(1) read with para 9(4) of DPCO, 2013 and consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the fixation of

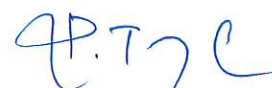
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drug price as per the simple average formula contained in para 4(1) of DPCO, 2013.

5. **Decision:**

The NPPA is hereby directed to fix the retail price of the formulation Darunavir 800 mg + Ritonavir IP 100mg for M/s Emcure Pharmaceuticals Limited strictly as per provisions of para 5(1) read with para 9(4) of DPCO, 2013 and consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the fixation of drug price as per the simple average formula contained in para 4(1) of DPCO, 2013.

Issued on this 25th day of June, 2021.



(Rajneesh Tingal)

Joint Secretary to the Government of India
(For and on behalf of the President of India)

To:

1. M/s Emcure Pharmaceuticals Limited, 904, Ansal Bhawan, 16, K.G. Marg, Connaught Place, New Delhi-110001.
2. Chairperson, National Pharmaceutical Pricing Authority

Copy to:

1. PS to Hon'ble Minister(C&F) for information.
2. PS to MoS(C&F) for information.
3. PSO to Secretary, Department of Pharmaceuticals for information.
4. Technical Director, NIC for uploading the order on Department's Website.
5. Joint Director (Pricing), Department of Pharmaceuticals