

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

\*\*\*

Room No. 207, D Wing Shastri Bhawan,  
New Delhi-110001

Order

A Review Order dated 25<sup>th</sup> June 2021 was issued disposing the review application dated 01.12.2019 filed by M/s Emcure Pharmaceuticals Limited (herein after called the applicant) against notification S.O. No. 4062(E) dated 08.11.2019 issued by the National Pharmaceutical Pricing Authority (herein after called NPPA) under Para 31 of the Drugs Prices control Order, 2013 (herein after called DPCO, 2013) fixing the retail price of "Darunavir 800mg + Ritonavir IP 100mg as Rs. 197.55 per tablet, with following directions:

*"The NPPA is hereby directed to fix the retail price of the formulation Darunavir 800 mg + Ritonavir IP 100 mg 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."*

2. Pursuant thereto, NPPA vide their letter dated 9<sup>th</sup> August 2021 informed that the matter was deliberated in the 91<sup>st</sup> meeting of the Authority held on 29.07.2021 and it was noted that:

*".... M/s Emcure Pharmaceuticals Limited had applied for retail price fixation of Darunavir 800 mg + Ritonavir 100 mg tablet in the month of June, 2019. As per the provisions of DPCO, 2013, the data of six months earlier than the month of receipt of the application was to be considered for calculation of retail price (i.e. November 2018) under Para 9(4) of DPCO, 2013. From analysis of latest Pharmatrac data available at that time, it was noted that the data for the month of November, 2018 was not available. Further, the market based data of Darunavir 800 mg + Ritonavir 100 mg tablet was not even available for twelve months before November 2018 in AIOCD-AWACS Pharmatrac database. Hence, the matter was*

referred to Multi-Disciplinary Committee of experts. The Multidisciplinary Committee of Experts in its 13<sup>th</sup> meeting recommended the retail price of each film coated tablet contained Darunavir 800 mg + Ritonavir 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. The Authority noted that the retail price had been recommended based on Form-V data which is in line with the data as per Para 9(2) of DPCO, 2013. Hence, the Authority in its 70<sup>th</sup> meeting dated 20.10.2019 fixed the retail price based on the recommendation of Multidisciplinary Committee of Experts.

The Authority deliberated upon the matter in detail and observed that since the data is not available, the retail price could not be calculated as per Para 5(1) read with para 9(4) of DPCO 2013 towards implementation of the review order. Accordingly, the Authority decided to refer the matter to DoP.

In view of the above, since the data is not available, the retail price could not be calculated as per Para 5(1) read with para 9(4) of DPCO 2013 towards implementation of the review order. Accordingly, NPPA referred the matter to the Department of Pharmaceuticals (DoP) for further direction."

3. In light of the foregoing, the matter was re-considered in the Department and it was noted that:

".....in the 70<sup>th</sup> Authority meeting of NPPA, no consistency was made. While in the case of formulation 'Dolutegravir-50 mg, Lamivudine 300mg, Tenofovir Disoproxil Fumarate 300mg' the retail price notified on 02.11.2018 for M/s Mylan and M/s Emcure, based on the recommendation of MDC held on 27.09.2018, was passed on to the subsequent applicant, viz., M/s Cipla almost after a gap of one year, without referring again to MDC. Whereas, the retail price of Darunavir 800 mg + Ritonavir 100 mg, which was already fixed on 2<sup>nd</sup> November, 2018 for M/s Hetero Healthcare Limited based on recommendations of the MDC held on 27<sup>th</sup> September, 2018, but the application of M/s Emcure for the same product was again referred to the MDC for consideration in its meeting held on 24<sup>th</sup> September, 2019 and price fixed as per recommendations of MDC dated 24.09.2019.

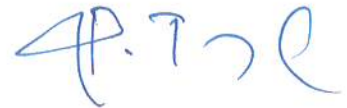
4. Based on the observations made in para 3 above, NPPA was asked vide letter dated 5<sup>th</sup> April, 2022 to re-consider the matter so as to maintain uniformity and consistency in considering cases of similar nature and specifically those which were considered in the same meeting of the authority. Limiting the scope of the

instant Order, it was clarified that the said decision will, however, be standalone and not act as a precedent in other cases, where the NPPA might have taken action(s) on merit of such cases, as appropriate.

5. Pursuant thereto, NPPA has since revised the price of the formulation under consideration of M/s Emcure Limited vide their price Notification dated 9<sup>th</sup> May 2022 fixing Price of Darunavir 800mg + Ritonavir IP 100mg as Rs. 212.91 per tablet.

6. Review order dated 25<sup>th</sup> June, 2021 accordingly stands modified to the extent as indicated above.

Issued on this 4<sup>th</sup> day of October, 2022



(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, KG Marg, Connaught Place, New Delhi-110001.
2. Chairman, National Pharmaceutical Pricing Authority, YMCA Building, Jai Singh Road, New Delhi.

**Copy to:**

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