**No.31015/05/2022-Pricing (E-21793)**
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
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Room No. 207, D Wing, Shastri Bhawan,
New Delhi-110 001.

**Order**

This is an order disposing of Review Application dated 13.07.2022 filed by M/s Sun Pharma Laboratories Limited (hereinafter called the Applicant) under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 2981 (E) dated 30.06.2022 by the National Pharmaceutical Pricing Authority (NPPA) for the Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin (IR) Tablets.

**2. Background**

Comments were sought from NPPA on the contentions of the Applicant in the Review Application. NPPA submitted their opinion vide letter in August 2022. Subsequently, the Review Hearing was held on 19.09.2022. After the hearing, Applicant made additional submissions on which NPPA gave its opinion vide letter dated 06.10.2022. Clarifications were also provided by the NPPA to some subsequent queries of DoP on the matter.

**3. Major contentions raised by the Applicant:**

3.1 The Applicant, through Review Application, has requested to revise the retail price of captioned formulation strictly as per provisions of para 5(1) read with para 9(4) of DPCO - 2013 and consider the Price to Retailer (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 on following grounds:

3.1.1. As per minutes of the Authority Meeting held on 28.06.2022, the captionedproduct was listed at Sr. No. 81 of Agenda 4.1 with the notified Retail price of Rs. 6.25. The captioned notified retail price is not calculated and fixed as stipulated in para 5(1) of DPCO - 2013 in spite of it being notified under para 5, 11 and 15 of DPCO - 2013. According to para 5(1) of DPCO - 2013, *"the retail price of the*

*new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4."*

3.1.2. Such decision is against one of the three key principles of NPPP - 2012 i.e. Market Based Pricing which clearly states that "Under Marked Based Pricing, the pricing would be based on widely available information in the public domain as against individual manufacturer level production costing data which would result in more transparent and fair pricing."

3.1.3. NPPA's working sheet used to transparently disclose the entire working of retail price calculation as required under para (4) including price of all brands available in the market for the given formulation having more than 1% market share. However, in the said matter, the draft working sheet uploaded for the captioned product on 14.6.2022 does not disclose retail price working based on market data reported by Pharma Trac.

3.1.4. Department of Pharmaceutical (DoP) vide its order No. 31015/16/2019-Pricing dated 25.06.2021 has already rejected the Retail Price fixed on the basis of PTR (Price to Retailer) as per Form V.

3.1.5. NPPA has not considered the market data of two companies, i.e., (i) M/s Medley Pharmaceuticals Ltd (marketer)/ M/s Exemed Pharmaceuticals (manufacturers) and (ii) M/s Dr. Reddy's Laboratories (marketer)/M/s Exemed Pharmaceuticals (manufacturers) for the subject formulation, which have market share of about 30%.

**4. Gist of clarifications made by NPPA:**

4.1. The retail price application of M/s Sun Pharma Laboratories Ltd for the formulation Dapagliflozin 5 mg + Metformin (IR) 500 mg tablet was fixed in the99th Authority meeting held on 28.06.2022 in line with the decision taken in the 82nd Authority meeting dated 23.12.2020 as detailed below:

(i) The Authority noted that the applications have been received for retail price fixation of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet. The Authority further noted that the Patent of Dapagliflozin was expired on 02.10.2020 making it an off-patent drug.

(ii) The Authority recalled the decision taken in its 72nd meeting dated 20.01.2020 regarding retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets in which it emphasized that the benefit of price reduction in case

of formulations becoming off-patent ought to be passed on to the consumers in public interest. The Authority in 72nd meeting decided to fix the retail price of FDCs of Metformin and Vildagliptin tablet by adding 16% retailer margin to the average Price to Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for FDCs of Metformin and Vildagliptin tablets to give the benefits of patent expiry of the drug Vildagliptin to consumers.

(iii) The Authority deliberated upon the matter in detail and decided to fix the retail price of FDC of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablets in line with the decision taken in the 72nd meeting 20.01.2020 regarding retail price fixation of FDC of Metformin and Vildagliptin tablets.

(iv) Accordingly, the Authority approved retail price fixation of FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet by adding 16% retailer margin to the average Price To Retailer (PTR) based on the Form-Vdata submitted by the companies for whom retail prices were earlier approved for FDCs of Dapagliflozin and Metformin Hydrochloride (Extended Release) tablet in public interest so as to extend the benefit of price reduction due to patent expiryto the consumers.

4.2. In line with the decision taken in the 82nd Authority meeting dated 23.12.2020, the retail price of retail price of Dapagliflozin 5 mg + Metformin (IR) 500 mg tablet for M/s Sun Pharma Laboratories Ltd has been fixed based on Form-V data of the companies to whom the retail price was fixed by NPPA.

4.3. The draft calculation sheets were also uploaded on NPPA website for 10 clear working days to invite comments, if any. However, the company did not make any representation and accordingly, the retail price was fixed.

4.4. The Department of Pharmaceuticals in its review order dated 19.07.2022 has upheld the decision and rejected the review application of M/s Torrent Pharmaceutical Ltd on similar grounds regarding retail price fixation of FDC Dapagliflozin + Metformin tablet.

4.5. Based on the similar principle, NPPA has fixed the price of various FDCs of Dapagliflozin + Metformin for around 80 applications till date.

4.6. M/s Sun Pharma has further quoted about the review order issued for Darunavir 800 mg + Ritonavir 100 mg tablet of M/s Emcure Pharma at point No. 5 in its letter dated 25.07.2022. In this context, it is mentioned that both the cases are completely different on following grounds:

(i) 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. Accordingly, 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).

(ii) As the data for the month of November, 2018 was not available, the matter was referred to Multi-Disciplinary Committee of Experts (MDC) as per the provisions of DPCO 2013.

(iii) The MDC in its 13th meeting recommended the retail price of each film coated tablet containing 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.

(iv) Accordingly, the Authority in its 70th meeting dated 20.10.2019 fixed the retail price for subject formulation based on the recommendation of MDC.

(v) M/s Emcure Pharma filed for review in which the following direction wasgiven:

*"The matter has been examined and it is noted that in the 70th Authority meeting of NPPA, no consistency was maintained. 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 Multi-Disciplinary Committee (MDC) of experts 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 2nd November, 2018 for M/s Hetero Healthcare Limited based on recommendations of the MDC held on 27th 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 24th September, 2019 and price fixed as per recommendations of MDC dated 24.09.2019. NPPA is requested 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. This 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."*

(vi) NPPA implemented the review direction and it was decided to extend theretail price as provided to M/s Hetero Healthcare to M/s Emcure Pharma.

(vii) Further, both the cases of M/s Emcure and M/s Sun Pharma Laboratories are different, as summarized below:

| M/s Emcure | M/s Sun Pharma |
|---|---|
| There was no patent related issue with respect to FDC of Emcure. | The price fixation is related to the FDC that had recently became off-patent at the time of price fixation for Sun Pharma. |
| The data was not available in Pharmatrac and hence price was fixed based on the recommendation of MDC. | Even though the data is available in Pharmatrac, the retail price was fixed based on Form-V to extend the benefit of price reduction due to expiry of patent. |
| The review was filed due to two different approaches applied, i.e., for M/s Cipla the extension of earlier price was allowed and for M/s Emcure, Form V data was adopted (instead of extension of earlier existing price) in the same Authority meeting. Hence, review was filed. The decision was taken in Review to maintain uniformity and consistency in the same meeting and to extend the price accordingly to M/s Emcure too. | Review is for deviation from provision of DPCO, 2013 provision (Para 5 and 15) towards fixation of retail price. In the similar case, retail price fixation of FDC Vildagliptin + Metformin, was also done on the same methodology, i.e. on Form V data base. Some of the companies filed review against the same. However, in the review, DoP accepted NPPA methodology of price fixation and rejected the review applications filed by various companies |

4.7 NPPA has not considered Form V of (i) M/s Medley Pharmaceuticals Ltd (marketer)/ M/s Exemed Pharmaceuticals (manufacturers) and (ii) M/s Dr. Reddy's Laboratories (marketer)/M/s Exemed Pharmaceuticals (manufacturers) for the subject formulation as retail prices of these companies were not fixed by them. This is as per the approach indicated in the minutes of the 72nd Authority meeting held on 20.01.2020 that read as *"The Authority deliberated upon the matter in detail and emphasized that benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest and decided to fix the retail price as per the Price To Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs."*

4.7.1 NPPA had not fixed the prices for these two companies for the formulations under consideration since no application was received for the same as per the available records. Though as per the Pharmatrac database, M/s Medley Pharma is not manufacturing Metformin and M/s Reddy's Laboratories started manufacturing in November 2013; the matter will be further got examined in detail by NPPA whether launch of the said formulations is without price approval.

## 5. Examination:

5.1. The contentions of the Applicant regarding the fixation of retail prices in contradiction of provisions of paras 4, 5, 9 and 15 of DPCO 2013, have already been addressed in the Seven different Review Orders all dated 19.07.2022, issued by the Department of Pharmaceuticals against the Review Applications submitted by the different applicants. The Review Orders dated 19.07.2022 relating to retail pricing of FDCs, held the following:

i. Order of NPPA upheld as being within the overall framework of DPCO, 2013.

ii. NPPA fixed the retail price so as to give benefit of price reduction after patent expiry to public. In most of the cases, price was considered / recommended by the MDC.

iii. Price fixation is as per market based Pricing (as prescribed by NPPP, 2012), though not strictly as per letter of DPCO, 2013, but is based on actual market prices of the formulations launched by other manufacturers.

iv. Authority acted in 'public interest' (even though Para 19 not specifically quoted) with transparency, consistency and without mala fides while keeping in view the Sustainable Development Goals (SDG), provisions of the Constitution and various court orders.

5.2 On the issue of citation of Review Order dated 25.06.2021, against the Review Application by M/s Emcure Pharmaceuticals Ltd. the facts of the case and substances of Review Orders have been given at para 4.6 of this Order. The core issue in this case related to inconsistency in orders passed by NPPA in two similar cases in a same meeting of the Authority. The case was remanded back to NPPA as a standalone case, not be quoted as precedence. NPPA reviewed and adopted same approach to fixing retail price for Emcure Pharmaceuticals Ltd. as was done for other drugs in the said meeting.

5.3 On the question of not considering the prices of two companies by NPPA for the purpose of retail price calculation of the FDC of the applicant, it is seen that the latter has followed the uniform policy of not taking into consideration of the prices of those companies, whose price was not given by them. Further NPPA has also undertaken

that it will initiate an inquiry to look into the case whether launch of the said formulations is without price approval.

## 6. Conclusion

Through the above detailed examination noted above, it is observed that although NPPA acted in a way, strictly not prescribed in DPCO, 2013, but it upheld the interest of public considering the ground realities. Also, there is nothing to show that NPPA acted with *mala fide* or with *ulterior motives*. It cannot be taken as *arbitrary and ad-hoc.*

## 7. Decision:

The action of NPPA fixing the Retail prices of the formulations of Dapagliflozin and Metformin (IR) Tablets of M/s Sun Pharma Laboratories Limited vide S.O. No. 2981 (E) dated 30.06.2022 is upheld and the review application under consideration is, accordingly, rejected.

Issued on this, the **10th day of May, 2023.**

**(Rajneesh Tingal)**
Joint Secretary to the Government of India
[For and on behalf of the President of India]

**To:**

M/s Sun Pharma Laboratories Limited,
Sun House, Plot No. 201 B/1
Western Express Highway Goregaon (E),
Mumbai-400063, Maharashtra, India

**Copy to:**

1. Chairperson, NPPA, New Delhi
2. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi
3. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
4. Technical Director, NIC for uploading the order on DoP's Website.
5. Guard File