No.31015/07/2022-Pricing (E-22638)

GOVERNMENT OF INDIA

MINISTRY OF CHEMICALS & FERTILIZERS

DEPARTMENT OF PHARMACEUTICALS

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Room No. 340 (B), A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

M/s *Zydus Health Care Limited* (hereinafter called the "Applicant") filed a Review Application dated 11.07.2022 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). Vide its aforesaid Order, NPPA, inter alia, fixed the retail price of Sitagliptin 50/100mg & Metformin Hydrochloride 500/1000 mg (ER/SR) Tablets

2. On the aforesaid plaint, reference was invited by the Department of Pharmaceuticals from NPPA. Both the parties entered appearance on 26.06.2023 and presented their respective logics.

3. Major contentions raised by the Applicant:

It was contended, on behalf of the applicant, that NPPA has erred in determining retail price of the above drug and hence may be directed to revise the retail price of their formulation on the following grounds:

3.1 NPPA has fixed the Retail Prices by its own self designed Pricing mechanism and did not follow the Market Based Data (MBD) for price fixation (Para 5(1) read with Para 9(4) or under Para 15 of DPCO 2013 by applying the Principles of Pharmacoeconomics). Further, there is no other pricing mechanism available under the provisions of DPCO 2013 except under Para 19 of DPCO 2013.

This self-designed and self-invoked Pricing Principle of NPPA is used to reduce the price by 50% w.r.t. drugs which has become/on the verge of becoming off Patent, so as to pass on the benefit of price reduction to the consumers. As per the provisions of DPCO 2013, the lower of claimed price and calculated price based on market data, would be allowed.

This clearly highlight that the self- designed and self-invoked pricing mechanism adopted by NPPA is with a single objective of pushing down lowering of the proposed Retail Prices even at the cost of going outside the mandate offered as per the provisions of DPCO 2013.

This methodology has the following flaws:

a. Outside the scope of DPCO 2013 as it does not permit to apply Para 15 if the formulation in question is available in domestic market and relevant database is available.
b. This also underestimates the initiative of indigenous generic manufacturer(s) of off patented / going to be off patented formulations being offered to consumers at drastically lower MRPs.
c. Reduction of 50% as followed by NPPA is purely hypothetical and without any authentic database.
d. Reduction in the MRPs of off patented formulations is guided by various other factors namely the Therapeutic Category the formulation in question belongs to and number of Brands being introduced in post Patent period.
e. If the Public or consumer Interest is of such a paramount importance in the matter of off Patented formulations or those formulations which are going to be off patented soon and where Market Dynamics is not believed to do justice to the public interest / Patient interest, invoking Para 19 may be considered by the Authority.

3.2 Review Order No. 31015/16/2019-Pricing dated 25.5.2021 whereby DoP have communicated the decision that "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"

3.3 MDC in its meeting held on 14.3.2022, 8.4.2022 & 2.6.2022 noted that "Sitagliptin" has become / or going to become off Patent shortly. It further noted that if the Retail Price is calculated under Para 5(1) Read with Para 9(4) the benefit of lower prices due to expiry of the Patent may not be passed on the Patients. DoP has constituted the MDC by name and not by designation vide its latest order dated 9.2.2018, which is as follows:

- Advisor (Cost), NPPA – Convener
- Dr. K. Bangarurajan , Jt. Drug Controller, CDSCO-Member
- Dr. Saranjit Singh, Ph.D., ex- Dean as an expert from NIPER-Member
- Representative ICMR / DHR- Member. (Dr. Vijay Kumar, Sc. G)

3.4 Following were Present on 14.3.2022:

- Advisor (Cost), NPPA– Convener
- Dr JJ Cherian, Scientist D, ICMR- Member, Representative ICMR

Following were Present on 08.04.2022:

- Advisor (Cost), NPPA – Convener
- Dr JJ Cherian, Scientist D, ICMR- Member, Representative ICMR

Following were Present on 02.06.2022:

- Advisor (Cost), NPPA – Convener
- Dr JJ Cherian, Scientist D, ICMR- Member, Representative ICMR

In all cases, others present in above MDC meeting were either invited or co-opted experts. They were not member(s) authorized by DoP. Therefore, Recommendations by the above MDC on requisite dates is legally not tenable on account of incomplete Quorum / Coram.

4. Gist of clarifications made by NPPA:

The contentions made in the review petitions regarding fixation of retail prices of FDC of 'Sitagliptin 50/100 mg +Metformin 500/1000 mg (ER/SR) tablets' are not tenable on the following grounds:

4.1. The issues raised by the applicant are similar to earlier review order of the same petitioner for the formulation "Dapagliflozin + Metformin tablet", wherein DoP upheld the methodology adopted by the NPPA and rejected the review petition.

4.2 The prices of the formulation Sitagliptin + Metformin ER/SR Tablets for M/s Zydus Healthcare Limited was fixed based on the recommendation of the 42nd meeting of MDC held on 02.06.2022, wherein the Committee noted that the formulation 'Sitagliptin' has become off-patent on 5th /6th July 2022. The Committee also recalled the decision taken in its 40th meeting dated 14.03.2022 and approved by the Authority in its 96th meeting dated 24.03.2022 regarding retail price fixation of FDCs of 'Sitagliptin and Metformin tablet' in which the Authority decided as follows:

4.3 The Authority noted that the formulation "Sitagliptin" has become / is on the verge of becoming off-patent and observed that, in line with the decision taken in its 89th meeting dated 28.06.2021, if the calculation is based on six month prior market data, the price of the patented period would be taken into consideration and hence the price rationalization due to expiry of the patent may not pass on to the patients.

4.4 The Authority further noted that matter was placed before the 40th meeting of the Multidisciplinary Committee of Experts held on 14.03.2022 which in line with decision taken in the 89th Authority meeting dated

28.06.2021, recommended to fix the retail price as per the following methodology.

"The Committee observed that the market data of the FDCs of Sitagliptin and Metformin tablet is also available and noted that if the retail price is calculated based on six-month prior based on six-month prior market data, the price of patented period would be taken into consideration and benefit of price reduction due to medicines which has become / is on the verge of becoming off-patent would not pass not on to the consumers.

(i) The Committee deliberated upon the matter in detail and is of the opinion that the price of drugs be reduced in respect of the drugs which has become / on the verge of becoming off-patent so as to pass the benefit of price reduction to the consumers and that a reduction of 50% be allowed on the patented component of FDCs i.e. 'Sitagliptin' to arrive at the retail price.

(ii) Accordingly, the Committee recommended to allow retail price for the FDCs of Sitagliptin and Metformin tablet in line with the decision taken in its 33rd meeting held on 21.06.2021. However, where the calculated retail price of the FDC of formulation based on six-month prior market data as per the provisions of DPCO 2013 is lower than claimed price and the calculated price, the Committee recommended that the same would be allowed."

(iii) The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and approved the fixation of the price of new drugs as per the methodology stated by the Multidisciplinary Committee of Experts

4.5 The review order issued for Darunavir 800 mg + Ritonavir 100 mg tablet of M/s Emcure Pharma had different issues than the issues raised in the current review petition, namely:

i. There was no patent related issue with respect to FDC of Emcure.
ii. The data was not available in Pharmatrac and hence fixed based on the recommendations of MDC.
iii. The review was filed in the case of M/s Emcure 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; however, in the current review matter, same methodology was followed for all the companies

4.5 The members/co-opted members, who have attended the meetings were as follows: Meeting dated 14.03.2022.

i. Representative of CDSCO.
ii. Representative of ICMR.
iii. Representative of NIPER.
iv. Representative of AIIMS (Co- opted)
v. Representative of IPC (Co- opted)
vi. Representative of NPPA

Meeting dated 08.04.2022.

i. Representative of CDSCO
ii. Representative of ICMR
iii. Representative of NIPER
iv. Representative of AIIMS (Co- opted)
v. Representative of AIIMS (Co- opted)
vi. Representative of NPPA

Meeting dated 02.06.2022

i. Representative of CDSCO
ii. Representative of ICMR
iii. Representative of NIPER
iv. Representative of AIIMS (Co- opted)
v. Representative of IPC (Co- opted)
vi. Representative of NPPA

5. Examination:

5.1. In seven different Review Orders, all dated 19.07.2022, the Department of Pharmaceuticals has already addressed the applicant's concerns regarding the fixing of retail prices with reference to paragraphs 4, 5, 9, and 15 of the DPCO 2013, against the various Reviews Applications submitted by the various applicants. The Review Orders dated 19.07.2022 pertaining to the retail price of FDCs stated the following:

i. The order of NPPA was sustained because it fits within the general framework of DPCO 2013.
ii. The NPPA fixed the retail price so that the public may benefit from price reductions after the patent expired. In most cases, the MDC considered/recommended the pricing.
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. While keeping in mind the Sustainable Development Goals (SDG), provisions of the Constitution, and other court rulings, authority acted in the 'public interest' (even though Para 19 was not directly referenced) in a transparent and consistent manner, and without malice.
v. The same viewpoint was restated and confirmed by the DoP in its Review Order dated May 10, 2023. The same order also resolved the contention of the conflicting decisions in the matter of the Review Order dated 25.06.2021, which was issued in response to Emcure Pharmaceuticals Ltd's Review Application.

5.2 On the question of the DoP's order dated 9.2.2018 constituting the MDC by name and not by designation, it is noted that the said committee was established with the approval of HMCF and consists of members with specific designations, to be nominated from various organisations, pursuant

to Order No. 31015/14/2017-Pricing dated 30.11.2017. The committee is also empowered to bring in other experts as needed. Subsequent orders in this respect have been issued within the broad framework set up by the original order.

6. Conclusion

Through the foregoing extensive investigation and different Court decisions, it is apparent that, while NPPA behaved in a manner strictly not prescribed in DPCO, 2013, it protected the public's interest in light of the ground facts. 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 Sitagliptin 50/100mg and Metformin Hydrochloride 500/1000 mg (ER/SR) Tablets of M/s Zydus Health Care 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 26th day of July, 2023.

26/07/2023

(Awadhesh Kumar Choudhary)
Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

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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