No.31015/03/2021-Pricing (E-15879)
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 19.01.2021 filed by M/s Lupin Ltd (hereinafter called the Applicant) under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order S.O. No. 95(E) dated 08.01.2021 issued by the National Pharmaceutical Pricing Authority (NPPA) for the formulations of Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (SR) & Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (SR) tablet. NPPA has submitted their comments in the matter and hearing was accorded to both the parties.

2. Major contentions raised by the Applicant:

2.1 The Applicant has sought issuance of directions to NPPA to re-fix the Retail Price for the subject formulations based on the principles laid down under DPCO and relevant Pharmaco-economic principles on following grounds:

(i) The principles for fixation of Retail Price laid down under Para 5(1) & 15 read with para 9(4) of DPCO, 2013 were not followed by NPPA. Instead NPPA choose select PTRs of select manufacturers who had submitted Form V after launch of the said FDCs.

(ii) NPPA, as such, implemented a self-developed principle of fixing Retail Price of an off patented formulation in name of Public Interest, without invoking Para 19 of DPCO 2013 to fix Retail Price under supervision of SCAMHP.

(iii) DPCO, 2013 does not recognize difference between a patented product & off patented Product for the purpose of Retail Price Fixation nor National Pharmaceutical Pricing Policy (NPPP, 2012) recognizes the same. These measures which are outside the provisions of DPCO, 2013 discourage innovation.

(iv) NPPA has changed the Pre-Defined Market Based Source (Pharmatrac Data) to a different source (IPDMS).

(v) The decisions of NPPA are DPCO Plus decision, for which it is not competent as per provisions of DPCO, 2013.

3. Gist of clarifications made by NPPA:

3.1 The Authority in its 72nd Meeting dated 20.01.2020 had noted that the subject formulations under consideration were off-patent items and any fixation of retail prices on the basis of para 5 of DPCO 2013 by taking six-month prior data (when the patent was in force) would result in extending the price of patented products to off-patent products.

3.2 The Authority felt that benefit of price reduction in case of formulations becoming off-patent ought to be passed on to the consumers in public interest. As such, it fixed the price as per Price To Retailer (PTR) based on Form-V data submitted by the companies for whom retail prices were approved earlier for these subject FDCs.

3.3 The application in the present case was placed by NPPA before the Multi-Disciplinary Committee (MDC) of Experts in its 25th meeting held on 16.12.2020, which supported the recommendations of the Authority made in its 72nd meeting. The retail prices recommended by the MDC were approved in the 82nd meeting of the Authority held on 23.12.2020 and prices notified.

3.4 The incentive for incremental innovation, wherever applicable, was given by adding the maximum of the difference in presently applicable notified ceiling price to the amount.

4. <u>Examination:</u>

4.1 Perusal of the relevant records pertaining to these cases indicates that:

(i) The principle used by NPPA for fixation of retail prices in the case was first derived in its 72nd Authority meeting of NPPA held on 20.01.2020 while considering retail price fixation of Fixed Dose Combinations (FDCs) of Metformin and Vildagliptin tablets for two companies. The Authority had noted that the subject formulations were off-patent items and fixation

of retail prices on the basis of Para 5 of DPCO, 2013 by taking six-month prior data (when the patent was in force) would result in extending the price of patented products to off-patent products. It had further noted that in its earlier meetings held on 30.10.2019 and 09.12.2019, the Authority had approved the fixation of the retail prices of the subject FDCs for various companies under para 5 of DPCO, 2013 by taking six-month prior data, but those companies had launched their products at much lower prices than what was approved by the Authority earlier. The Authority, as such, had decided that the 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 based on Form-V data submitted by the companies for whom retail prices were earlier approved for these subject FDCs. It had also noted that the method was as per the principle followed in case of fixation of prices of anti-cancer drugs. It had further noted that the method would ensure that the benefit of price reduction due to expiry of patent would be made available to the public.

(ii) MDC subsequently in its 25th meeting held on 16.12.2020 had considered the case in question and decided for retail price fixation as per methodology decided in 72nd meeting of the Authority held on 20.01.2020. The recommendations of MDC were approved in 82nd meeting of Authority held on 23.12.2020.

4.2 It is noted that the Applicant in this review application has mainly contended that the NPPA has implemented a self-invoked principle for retail price fixation for which there is no provision in DPCO 2013. Further, it has been claimed that neither NPPP, 2012 nor DPCO, 2013 differentiate between a patented product & off patented Product for the purpose of Retail Price Fixation. The counter argument of NPPA is primarily that it has done so to give the benefits of patent expiry of the drug to consumers through discovery of price of off-patent drugs through market dynamics. Further, it has claimed that that the same method has been consistently adopted by it for price fixation of formulations, which have become off patent.

4.3 Further, referring to various provisions of NPPP, 2012 and DPCO, 2013 indicate that:

(i) NPPP, 2012 aims to strike a balance between the varying requirements – that of enabling the industry to grow and at the same time ensuring

affordable and reasonably priced medicines to the consumers, particularly the poorer masses. One of the key principles of the policy is 'market based pricing'.

(ii) DPCO, 2013, has been notified as per powers conferred by the Essential Commodities Act, 1955 and it prescribes the detailed procedure for fixation of ceiling prices of 'scheduled' drugs, retail prices of 'new' drugs by existing manufacturers as well as for monitoring the prices of scheduled as well as non-scheduled drugs by the government.

(iii) Para 19 of DPCO, 2013 authorizes the Government, in case of extra-ordinary circumstances, in public interest, to fix the ceiling price or retail price of any Drug for such period, as it may deem fit.

(iv) Para 32 of the DPCO, 2013 prescribes that provisions of the Order will not be applicable in certain cases, especially for patented drugs in specified circumstances.

(v) Government has authorized the NPPA to act on its behalf for implementing various provisions of DPCO. Further, the Government has amended DPCO, 2013 from time to time, as and when required.

(vi) Government has set up a Standing Committee on Affordable Medicine and Health Products (SCAMPH) on 21.01.2019 as a recommending body to NPPA regarding prices of drugs and health products.

4.4 On appreciation of all the facts, it is noted that the actions taken by NPPA are largely in line with the basic premise of NPPP, 2012 of ensuring affordable and reasonably priced medicines to the consumers while enabling the industry to grow, which is evident from the fact that on expiry of the patents, number of manufacturers have come forth to produce the same. Further, the actions of NPPA are broadly covered within one of the three key principles of the policy, i.e., market-based pricing'. The fixation of retail prices of formulations, though not strictly as per letter of DPCO, 2013, but is based on actual market prices of the formulations launched by other manufacturers (which was in fact less than the retail prices fixed by NPPA) after expiry of the patent of such drugs.

4.5 It is further to be noted that NPPA was set up by the Government vide Resolution dated 29.08.1997 as an independent body of experts (having expertise in the field of pharmaceuticals, economics and cost accountancy) to streamline and simplify the procedure of price fixation under DPCOs. Further, the retail price fixation in most of the cases under consideration has been recommended by the duly constituted Multi-Disciplinary Committee (MDC) of Experts, which were subsequently approved in the meetings of the Authority held from time to time. Although the, Government has set up SCAMHP, but it is a recommendatory body and consultation with it is not mandatory.

4.6 Further, the choice of law cannot be identified merely by interpretation of the Statutes, but the approach of the authorities also delves around the greatest good for the greatest number of people or simply said 'in public interest'. This is reflected, for example, in the decision of the Authority in determining the retail price of formulations in question, which at the given time were costlier and the price fixation strictly as per laid down provisions of DPCO would not have yielded the desired benefit to the public. Based on the test of presumed intention, at the stage of determination, the Authority had fixed the prices passing the benefit of price reduction resulting from patent-cliff to the public instead of the class constituting the manufacturers.

4.7 In order to achieve Sustainable Development Goals (SDG) 03 namely *"Ensure healthy lives and promote well-being for all at all ages"* and specifically the Target 3.8 to *"Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all"*, to which the government is committed, providing affordable drugs to the citizens is paramount, so by extending the benefit of price reduction arising from a subsequent event, the Authority has worked in achieving the said goal.

4.8 A second compelling reason for upholding the decision of Authority is to prefer 'public interest' in absence of choice is that such a decision harmonises with Articles 21, 39(e) & (f), 41 and 42 of the Constitution of India, meant to ensure a life with human dignity. The Right to life with human dignity enshrined in Article 21 derives its life-breath from the Directive Principles of State Policy and particularly clauses (e) and (f) of Article 39 and Articles 41 and 42.

4.9 Further, the Authority has acted with transparency, which is one of the most important preconditions for its functioning, by recording the rationale of

price fixation and placing the same in public domain. Further, the Authority has acted with consistency in similarly placed cases. Fraud or *mala fides* vitiates all solemn acts. However, the applicant has not alleged/ failed to place on record if the act of the Authority is influenced by *mala fide*.

4.10 NPPA, within the overall framework of DPCO 2013, has evolved a rational and transparent modality to meet the public interest and applied the same consistently. Every public authority has to function in a way where public interest is paramount. In this regard, the following decisions of the Hon'ble Supreme Court are also relevant to quote:

a. **Indian Pharmaceutical Alliance vs. Union of India, [2016 SCC OnLine Bom 5957], (Hon'ble SC):**

The Drugs Price Control Order is a beneficial piece of legislation and, therefore, must receive an interpretation consistent with its object and purpose.

b. **Indian Pharmaceutical Alliance vs. Union of India, [2016 SCC OnLine Bom 5957], (Hon'ble SC):**

The National Pharmaceutical Pricing Authority (NPPA) is a body of experts. It is guided by Para 19 and the DPCO as a whole so also the constitutional mandate indicated above. The power under Para 19 and which is discretionary is coupled with a duty. The extraordinary circumstances and the public interest by themselves are guiding factors and even if there are separate guidelines, which may have been issued but now withdrawn, does not mean that there is nothing to guide the exercise of power in terms of this para.

c. **Hon'ble Supreme Court in Union of India vs. Cynamide India Ltd (Hon'ble SC)**

Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life-sustaining foodstuffs and life-saving drugs is diabolic. It is a menace which has to be fettered and curbed. One of the principal objectives of the Essential Commodities Act, 1955 is precisely that. It must be remembered that Article 39(b) enjoins a duty on the State towards

securing 'that the ownership and control of the material resources of the community are so distributed as best to sub serve the common good'.

d. **Glaxosmithkline Pharmaceuticals Ltd. vs. Union of India, (Hon'ble SC)**

Reconsider the importance of the ground realities including the process of marketing while construing an exemption notification.

e. **Union of India vs. Unicorn Industries, (Hon'ble SC):**

"where public interest warrants, the principle of promissory estoppel cannot be invoked"

f. **Air India Ltd. vs. Cochin International Airport Ltd, (Hon'ble SC):**

The State, its corporations, instrumentalities and agencies have the public duty to be fair to all concerned. Even when some defect is found in the decision-making process, the court must exercise its discretionary powers under Article 226 with great caution and should exercise it only in furtherance of public interest and not merely on the making out of a legal point.

5. Conclusion

Through the above detailed examination and various Court decisions 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*.

6. Decision

The action of NPPA fixing the Retail prices of the formulations of Vildagliptin 50 mg + Metformin Hydrochloride 500 mg (SR) & Vildagliptin 50 mg + Metformin Hydrochloride 1000 mg (SR) tablet of M/s Lupin Limited is upheld and the review application under consideration is, accordingly, rejected.

Issued on this, the 19th day of July, 2022.

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

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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 Department's Website.
5. Guard File