No.31015/13/2019-Pricing
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 in Review application dated 24.01.2020 against National Pharmaceutical Pricing Authority's ("NPPA" herein) notification S.O. No. 2944(E) dated 14.08.2019. In exercise of its rights, under para 31 of the Drugs (Prices Control) Order, 2013 ("DPCO" herein) M/s. Cipla Limited ("Applicant" herein) filed petition for Review of decision challenging S.O. 2944(E), dated 14.08.2019 issued by the NPPA fixing the retail price of its formulation "*Formoteraol Fumarate Dihydrate* 6mcg + *Beclomethasone Dipropionate* IP 100 mcg Inhaler (MDI)".

Facts briefly stated,

2. On 7th February 2019, the applicant filing Form I under Para 15 of the DPCO, 2013 sought the Retail price of Rs. 730.00 for 120 Metered Doses of "*Formoteraol Fumarate Dihydrate 6mcg + Beclomethasone Dipropionate IP 100 mcg Inhaler (MDI)*".

3. On 10th May 2019, NPPA published the draft working sheets on its website, wherein after taking into consideration the Price to Retailer of a competitor company, it recommended a retail price of Rs. 1.46/dose for applicant's product. However, objections to the retail price in these draft working sheets were put forth by the applicant, through its letters dated 17.05.2019 and 26.07.2019 seeking opportunity to make a personal representation.

4. On 31st July 2019, Multidisciplinary Committee ("MDC" herein) of Experts, in its 12th meeting noted that the composition of the product of the applicant was same as that of M/s. Lupin Ltd, as included in the working sheet uploaded on NPPA's website. Reference was also made to the documents submitted by the applicant which, however, did not substantiate the study reports pertain to its product and had no separate license from DCGI, which is required in case of a new drug. Consequently, the MDC did not accept the representation of the applicant

and recommended the retail price of Rs. 1.46 per metered dose, as earlier uploaded by NPPA.

5. On 11th September 2019, a Review application was filed by the applicant against the NPPA's retail price notification S.O. 2944(E) dated 14.08.2019 claiming the same to be erroneous and contravening the provisions of DPCO, 2013 seeking directions to be issued to NPPA to re-calculate and re-fix the retail price of the subject formulation.

6. On 21st October 2019, the applicant appeared for a personal hearing. Notwithstanding the Review Application, applicant had simultaneously approached the Hon'ble High Court of Delhi through WP(C) No. 11222 of 2019. In its Order dated 21.10.2019, the Hon'ble Court had directed the department to consider the review application on merit, *vis-à-vis* binding the applicant that during the pendency of the same, it would implement the price notification.

7. On 20th November 2019, the applicant categorically informed that the company had launched the product without implementing the notified price, as it was not mandatory.

8. On 8th January 2020, the Review Application was rejected by the Department citing non-implementation of the retail price notification by NPPA. This Order was again challenged by the applicant before the Hon'ble Delhi High court vide WP (C) 1709/2020, wherein the Hon'ble High Court vide its order dated 18.02.2020 observed:

> *"The learned senior counsel for the petitioner submits that without prejudice to the rights and contentions of the petitioner, the petitioner is ready and willing to implement the ceiling/retail price, however, prays that its Review Petition be decided by the Department of Pharmaceuticals on merit.*
>
> *Having considered the submission made and binding the petitioner to its statement, the Department of Pharmaceuticals is directed to decide the application of the petitioner afresh and on merit."*

9. On 24th January 2020, the applicant moved a Representation, which, it seems was received first time in the department through the reminder sent by the Applicant vide letter dated 08.03.2021.

Personal Hearing

10. On 2nd July 2021, the applicant was given personal hearing through Video Conferencing. A brief presentation about the product's specialties was made by the technical experts on behalf of the applicant, besides the legal arguments by their counsel. Thereafter, the Applicant has made some fresh submissions on 12.07.2021. The stand of the applicant on the issues were:

i. The product has been developed by using extra-fine particles of *Beclomethasone Dipropionate* and F*ormoterol Fumarate Dehydrate* dissolved in Ethanol and a new propellant HFA 134a (CFC FREE) as a solution formulation. The development involves a highly complex manufacturing process, when compared to the conventional formulation of the competitor.

ii. The applicant's product also has an integrated dose counter. MDC, on the said ground, had allotted a separate price to M/s Glenmark in the same meeting of MDC held on 31.07.2019.

iii. No new drug license is required as there is no change in composition of the drug, the product is manufactured using technologically advanced inhaler making it different from other products and eligible for a different price.

iv. The applicant was given no opportunity to present the case before MDC.

v. Subject Matter Formulation is not a 'New Drug' as per the provisions of DPCO, 2013 and the Form I filed by the Company was out of abundant caution and erroneously done. It claimed that neither is Formoterol Fumarate Dihydrate a Scheduled Formulation nor is Beclomethasone Dipropionate a Scheduled Formulation and it has merely combined two non-scheduled formulations.

vi. The contention of the MDC that the documents given by the applicant were not relating to the product is unfounded.

vii. The Formulation was already approved by DCGI on 05.11.2011, and hence the expert Committee's opinion is erroneous. Further, mandatory prior approval from the Central Licensing Authority is not one of the pre-requisites for seeking retail price from the NPPA as per the provisions of the DPCO, 2013.

viii. Owing to the innovative and novel drug delivery system adopted by the applicant, the Subject Matter Formulation ought to be exempted by virtue of Explanation II to the DPCO 2013 cited as below:

"Explanation-II- Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc."

11. On the contrary, the contention of the NPPA on the facts stated in the hearing are as follows:

i. The retail price of the formulation was calculated based on market-based data, which was again confirmed in 69th Authority meeting held on 08.08.2019, based on the recommendation of 12th MDC meeting held on 31.07.2019.

ii. The applicant has represented its case before 12th MDC, though it was not put in the minutes of the meeting.

iii. Another representation dated 07.08.2019 of the applicant requesting for special price was considered by the Authority in the meeting, wherein it noted that no separate license of new drug was obtained from DCGI regarding incremental innovation, as claimed.

iv. With respect to applicant's stand that the formulation is not a new drug, the same is not tenable as the formulation *Budesonide + Formoterol* is a scheduled formulation as per the provisions of DPCO, 2013. Accordingly, any Fixed Dose Combinations (FDCs) containing *"Formoterol"* is a new drug as per the para 2(u) of DPCO, 2013 and existing manufacturer is required to apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order under para 15.

v. As regard contention of the applicant that the subject matter formulation is covered within Explanation II, DPCO, 2013, NPPA oppose this stand that since *"Formoterol"* is included in Schedule-I of DPCO 2013 without mentioning any specific salts, all salts of *Formoterol* are included in DPCO, 2013 as per Explanation 4 of DPCO, 2013. Accordingly, the subject formulation is a new drug and the applicant is required to take prior price approval as per provisions of DPCO, 2013.

Observations

12. At this juncture, it would be appropriate to take note of the order dated 18.02.2020 of Hon'ble Delhi High Court in WP (C) 1709/2020 directing the Department to decide the application of the petitioner afresh on merit.

13. Another significant aspect which needs to be noted at this juncture arises from representing the case before MDC, while NPPA's letter dated 17.10.2019 indicate that the applicant was allowed to make a detailed presentation/ demonstration before the Committee. However, the applicant vide letter dated 12.07.2021 has claimed that no opportunity of hearing before MDC was granted to them. On seeking clarification, NPPA vide their letter dated 21.03.2022 has maintained that the applicant was allowed to make presentation/ demonstration before MDC, but the same was not recorded in its minutes. Both NPPA and the applicant have opposite views and based on the available records, Reviewing Authority cannot establish the facts independently.

14. It may be noted that the claim of the applicant about allotting a separate price to M/s. Glenmark Limited for product innovation in the same meeting by MDC while rejecting their claim is to be corroborated with complete documentary evidence and technical justification(s), without the same it cannot be deliberated either side.

15. It was urged by the Applicant that the product was approved by the Drugs Controller General of India ("DCGI" herein) in the year 2011. On the other hand, countering the observations by the Authority about not having this approval by the company, the latter submits that the prior approval of DCGI is not required. Both submissions are not speaking in unison.

16. As was observed, the applicant has submitted technical details of the product as well as various study reports, which need to be considered by the MDC of Experts, which has the requisite qualification and expertise to examine the same.

Decision

17. On careful consideration of the entire facts and circumstances, Reviewing Authority is of the opinion that the S.O. No. 2944(E) dated 14.08.2019 issued by NPPA warrants interference pursuant to directions of the Hon'ble High Court of Delhi and subsequent developments. Matter requires remand for fresh Order on

merits by MDC and the NPPA, after analysis of the entire facts to avoid miscarriage of justice. Consequently, the impugned Order is referred back to NPPA to consider the issues raised by the applicant and to pass an appropriate order. The applicant will have liberty to file a Review before the department, if not satisfied by the fresh order passed by NPPA.

Issued on this, the 3rd day of October, 2022.

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

To:

1. Chairman, NPPA, YMCA Building, Jai Singh Road, New Delhi.
2. M/s Cipla Limited, CIPLA House, Peninsula Business Park, Lower Parel, Mumbai - 400013

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