

F.No.31015/2/2022-Pricing (E-21147)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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

Order

This is an order disposing two review applications dated 26th April 2022 filed by M/s La Medica Life Sciences Private Limited (herein after called the applicant) under para 31 of DPCO, 2013 against the notification S.O. No. 1782 (E) dated 12.04.2022, issued by the National Pharmaceutical Pricing Authority (herein after called NPPA) in respect of retail price fixation of a new Drug 'Metformin Hydrochloride Prolonged release 500 mg + Glemipride 2 mg' [FDC-1] and 'Metformin Hydrochloride Prolonged release 500 mg + Glemipride 1 mg' [FDC-2].

2. Background

M/s La-Medica Life Sciences had submitted application for pricing of both of the formulations in Form-I on 25.01.2022. NPPA vide its notification S.O. 1782(E) dated 12.04.2022 has fixed retail price of these FDCs manufactured by the applicant at Rs. 8.24 per tablet for FDC-1 and at Rs. 5.63 for FDC-2 excluding GST. A Review Hearing was held on 25th July 2022 and subsequent thereto, the applicant furnished fresh submissions vide their letter dated 26th July 2022 reiterating their earlier stand. As both the review applications submitted on the same date contain completely the same issue that is coming out of same notification by NPPA for two different formulations, a single order is being passed.

3. Gist of submissions of the Applicant

3.1 The Applicant has requested NPPA to consider the price of Rs. 138.39 (per pack of 15 tablets -, i.e., Rs. 9.23 per tablet) for FDC-1 and Rs. 94.64 (per pack of 15 tablets -, i.e., Rs. 6.31 per tablet) for FDC-2, as claimed in Form I application and sought approval for retail price at Rs. 9.23 and Rs. 6.31 per tablet respectively.

3.2 As NPPA fixes the Retail price without GST, the company had not specifically mentioned the prices to be exclusive of GST in their Form I application and construed that the NPPA would also treat the above Retail price as exclusive of GST and would fix the Retail price accordingly. NPPA, however, in their draft price proposal indicated that the company had applied for retail price as including GST and reduced the GST @12% from the retail price claimed by the company and approved the retail price of Rs. 8.24 and Rs. 5.63 per tablet respectively, excluding GST.

3.3 During the review hearing, the applicant submitted that being a new entrant and undertaking the exercise of submitting Form-I for the first time, they had mistakenly overlooked the draft retail prices on NPPA's Website, which are displayed by the latter as per their standard practice. Therefore, this slip on applicant's part may be condoned and they be allotted the prices previously claimed by them, which are already below the worked out retail price by NPPA, as per provisions of DPCO, 2013.

4. Gist of comments of NPPA

4.1 The applicant did not specify whether the claimed price by them is inclusive of GST or exclusive of GST.

4.2 As per practice, NPPA considers the retail price claimed as inclusive of GST, if applicant does not specifically mention about the same in Form I application. Hence, the retail price of Rs. 9.23 per tablet claimed by M/s La-Medica Life Sciences was considered inclusive of GST or Rs. 8.24 per tablet for FDC-1. Similarly, the retail price of Rs. 6.31 per tablet claimed by M/s La-Medica Life Sciences was considered inclusive of GST or Rs. 5.63 per tablet for FDC-2.

4.3 The worked out retail price as per provisions of DPCO, 2013 was Rs. 9.73 per tablet excluding GST for FDC-1. Similarly, it was Rs. 6.89 per tablet excluding GST for FDC-2. Since the price claimed by the company, i.e., Rs.8.24 (exclusive of GST) for FDC-1 and Rs. 5.63 (exclusive of GST) for FDC-2 was lower than the worked out / uploaded price of Rs. 9.73 per tablet and Rs. 6.89 per tablet (exclusive of GST in both cases), the same were proposed as price for the formulation applied by the company.

4.4 The draft version of the Price calculation sheet was uploaded on NPPA's website on 14.02.2022 for comments within ten working days in line with the DoP's OM No. F. No. 31015/44/2016-PI. I dated 11.07.2016. However, no representation was received from the applicant within the prescribed period.

4.5 The price uploaded on NPPA's website was deliberated in the 96th Authority Meeting held on 24.03.2022 and notified vide gazette notification S.O. No. 1782(E) dated 12.04.2022.

4.6 The contention of the applicant that it should be provided an opportunity for revision of prices on the grounds that it was filing the Form- I application for the first time and the prices claimed by them are exclusive of GST is not tenable as it was granted a period of 10 working days to make any representation, but failed to do so. As such, the Review application filed by the applicant may be treated as closed.

5. Examination

5.1 The Review Application highlighted the issue that the Applicant had not indicated whether the price claimed was with or without GST and in absence thereof as per its past precedent NPPA considered the same to be inclusive of GST. Further, the applicant did not represent within 10 days' window when the draft working sheet was posted on NPPA's website. During the Review Hearing, the Applicant has accepted its ignorance and submitted that being a new company, they lacked the experience and were filling the Form-I for the first time.

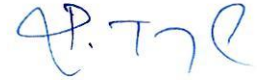
5.2 Department vide OM No. F. No. 31015/44/2016-PI. I dated 11.07.2016 had earlier directed that the draft working sheet should be put in public domain so as to bring transparency in the whole process of Pricing. Further, NPPA also issued the OM F. No. 19 (78) / 2014 / Div. II / NPPA dated 09.01.2018, about partially revised format of Form-I for applications of new drug under Para 2 (u) of DPCO 2013, which clearly contains the point 1 (j) as "*The retail price for approval (with / without GST, if any)*".

5.3 It is established that the NPPA has followed its standard practice continuously without any discretion and deviation. Further the ignorance of law, rules and regulations cannot be the valid grounds for getting any relief in case of not abiding by the same.

6. Decision

The review applications dated 26.04.2022 are, thus, devoid of merit and hence the same stand rejected.

Issued on this, the 30th day of January, 2023.



(Rajneesh Tingal)

Joint Secretary to the Government of India
[For and on behalf of the President of India]

To

1. M/s La Medica Life Sciences Private Limited, B-10, 3rd Main Road, Industrial Estate, Rajaji Nagar, Bengaluru-560010
2. Chairman, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001

Copy (for information) to:

1. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi.
2. Sr PPS to Secretary(Pharma), Shastri Bhawan, New Delhi.
3. Technical Director, NIC for uploading the order on Department's Website.