

No.31015/5/2019-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi-110 001.

Order

1. This is an order on an application, dated 25.02.2019 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Cipla Limited (hereinafter called the applicant) against notification S.O.No. 1028(E) dated 26.02.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of their formulations Budesonide Inhalation (DPI) 200mcg/dose, Budesonide (A) + Formoterol (B) Inhalation (DPI) 100mcg (A)/200 mcg(A)/400 mcg(A) + 6 mcg (B) and Tiotropium Inhalation (DPI) 18 mcg/dose, and review application, dated 26.03.2019 for formulations Budesonide Inhalation (MDI) 200mcg/dose and Tiotropium Inhalation (MDI) 9 mcg/dose. The review applications are re-examined based on the direction / Order, dated 21.10.2019 passed by Hon'ble High Court of Delhi disposing of the WP (C) 11222/2019 filed by the company.

2. The main contentions of the review applications dated 25.03.2019 & 26.03.2019 are as under:-

- a) The NPPA did not publish the draft working sheets prior to issuance of the impugned ceiling price notification;
- b) The NPPA has erroneously considered the data as of August 2015 as the reference data, in violation of Para 9 of the DPCO 2013;
- c) The NPPA has not followed the formula prescribed under Para 4 of the DPCO 2013 while calculating the ceiling price of the subject matter formulations;
- d) The NPPA has failed to consider that no ceiling price has been calculated and fixed for the subject matter formulations till the issuance of the impugned ceiling price notification.

2.2 In its further submission, the company stated that while calculating the ceiling price of Budesonide 200mcg – MDI, the NPPA has considered the pack size 200 MDI instead of 120 MDI for Dr Reddy's Product SOLBIHALE-B INHALER DOSE 200. The company further submitted that Dr. Reddy's product viz. Solbihale-B is available only in the pack size of 120 and not 200, as has been erroneously noted by the NPPA. After taking into consideration the correct pack size of Dr. Reddy's product viz. 120 MDI pack size, the revised ceiling price as calculated by Cipla would be Rs 1.66, instead of Rs 1.48 as calculated by the NPPA.

3. NPPA's comments:-

3(i) The NPPA considered the data submitted by the pharmaceutical companies while revising the notified price of above mentioned formulations. With regard to draft working sheet it is stated that this exercise of publishing draft working sheet prior to notification is executed while fixing the ceiling/retail for the first instance. However, the instant case is related to the implementation of the directions issued by DoP against review orders. Therefore, contention of the company related to not publishing the draft working sheet prior to notification has no merit.

3(ii) The amended scheduled I of DPCO, 2013 (NLEM 2015) was notified in March 2016. Accordingly NPPA has been consistently taking the market data of August 2015, while fixing ceiling price of scheduled formulations and applicable WPI is given on it. Accordingly, the data of August 2015 was taken while fixing the ceiling price of DPI Inhalations, since it is scheduled formulation hence contention of the company has no merit.

3(iii) With respect to DPI-Inhalations, no specific data was available in pharma data. Accordingly, after verifications of data submitted by the concerned companies, NPPA fixed the ceiling price under para 4 of DPCO, 2013. Hence, there is no contravention of provisions of DPCO, 2013. Hence contention of the company has no merit.

4. Examination:

4.1 The main contentions of the company revolve on the following grounds:-

- (a) The NPPA did not publish the draft working sheets prior to issuance of the impugned ceiling price notification;
- (b) The NPPA has erroneously considered the data as of August 2015 as the reference data, in violation of Para 9 of the DPCO 2013;
- (c) while calculating the ceiling price of Budesonide 200mcg – MDI, the NPPA has considered the pack size 200 MDI instead of 120 MDI for Dr Reddy's Product SOLBIHALE-B Inhaler dose 200.

4.2 As regards (a) above, both Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) were included in revised schedule (in Section 28 of NLEM 2015) of DPCO. However, the NPPA had only fixed the ceiling price of MDI and not of DPI but included both MDI/DPI while notifying revised ceiling price giving WPI impact in the year 2017 vide SO 1039(E), dt.1.4.2017. Few Pharma companies, manufacturing the said product, filed review applications against the said notification. DoP vide its orders against the review applications of M/s Glenmark and Lupin directed the NPPA to fix the ceiling price of Dry Powder Inhalers. Accordingly, the NPPA fixed the separate ceiling price of DPI for the first time vide SO 1028(E), dated 26th February, 2019.

4.3 DoP vide its OM No.31015/44/2016-PI.I, dated 11.07.2016 had directed the NPPA to place a draft version of the price calculation sheets for the proposed revised price notifications, including wherever applicable, the PTR and MAT values

adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceutical firms.

4.4 The plea taken by the NPPA that the instant case is related to the implementation of the directions issued by DoP against review orders does not hold good here. It is a fact that the NPPA fixed the ceiling price of DPI to implement the review orders, but the fact remains that the same were fixed for the first time as the NPPA did not fix the ceiling price of DPI after its inclusion in the revised schedule-I (NLEM 2015) of the DPCO. Therefore, the exercise of publishing draft working sheet prior to notification should have been followed by the NPPA. In view of this, the NPPA needs to be directed to be more careful in future and the instructions conveyed vide its OM, dated 11.7.2016 should be strictly complied with.

4.5 As regards point (b) above, both Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) were included in revised schedule-I (in Section 28 NLEM, 2015) in DPCO vide DoP's OM dated 10th March, 2016. The NPPA fixed the ceiling price of DPI formulations vide SO 1028(E), dated 26.02.2019 for the first time based on the review orders issued by DoP. Since the ceiling prices of DPI formulations were fixed for the first time, the NPPA has rightly taken the PTR and MAT data of August, 2015, as was being taken in other scheduled formulations included in the revised Schedule-I of DPCO. Therefore, notifying the ceiling prices of DPI formulations by considering the data of August, 2015 and giving WPI impact for the subsequent years by the NPPA is in order and the contention of the company has got no merit and needs to be rejected.

4.6 Regarding point (c) above, the company has raised the issue of wrongly considering the PTR and MAT value of Budesonide 200mcg – MDI of Dr Reddy's Product Solbihale-B Inhaler. The company in its submission stated that Dr. Reddy's product viz. Solbihale-B is available only in the pack size of 120 and not 200. In support of its submission, the company submitted the IMS data.

4.7 The NPPA in its submission stated that as no specific data was available with pharmanac in respect to DPI-Inhalations, the ceiling prices were fixed after verifications of data submitted by the concerned companies. In view of the documentary proof submitted by the company, the NPPA needs to be directed to verify the data from the concerned company and after verifying, revise the ceiling price of the subject formulation, on merit.

5. Decision:

The NPPA is hereby directed to strictly comply with the instructions issued vide OM No.31015/44/2016-PI.I, dated 11.07.2016 and 31.01.2019 and ensure that draft version of the price calculation sheets for the proposed revised price notifications for the ceiling/retail price are displayed on the website of the NPPA for 10 clear working days.

The NPPA is further directed to verify the documentary proof submitted by the company about the Budesonide 200mcg – MDI of Dr Reddy's Product Solbihale-B Inhaler, and after verification, revise the ceiling price of the subject formulation, on merit, within fifteen days of the issue of the order.

Issued on this, the 1st day of May, 2020.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

Copy to :-

1. M/s Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001.
3. PS to Hon'ble Minister(C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary(Pharma), Shastri Bhawan, New Delhi for information.
6. Joint Secretary (Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website.