



**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

ORDER

1. This is an order disposing of a review application dated 16.01.2020, 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.4538(E), dated 18.12.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail prices of Synchronbreathe Inhaler Device.

2. The main contentions of the applicant are as given below :

2.1 The National Pharmaceutical Pricing Authority (NPPA) has erred by issuing notification no. S.O. 4538(E) dated 18th December, 2019, fixing ceiling price of Synchronbreathe Inhaler Device by ignoring the pharmacoeconomic principles as required under Para 15 of DPCO, 2013 and by restricting any price revisions for the device under Para 16 or 20 of the of DPCO, 2013.

2.2 The Multidisciplinary Committee of Experts in its 14th meeting dated 04.12.2019 recommended "that in case the incremental innovation is not supported by published journal, well designed study, adequate trial, conclusive clinical data then an incremental price increase of 15% be allowed. In Case, the incremental innovation is supported by published journal, well designed study, adequate trial, conclusive clinical data then an incremental price increase of 20% be allowed."

2.3 This recommendation of the Multidisciplinary Committee of Experts which the NPPA also notified vide its S.O. 4538(E) dated 18th December 2019 calculating the separate ceiling price on an arbitrary percentage based purely on clinical studies is ultravires the provisions of DPCO 2013 which vide Para 11 clearly dictates as under:

"(3) Notwithstanding anything contained in sub-paragraphs (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Price Control) Order , 2013, the government may fix and notify separate ceiling price or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specifies in the Drugs and Cosmetics Act , 1940 (23 out of 1940) and the rules made thereunder for the same formulation.

(4) The Government shall form a Committee of Experts , as it may deem fit, within a period of fifteen days from the date of issue of this order , to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameters."

Para 15(3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application."

2.4 Furthermore, the Multidisciplinary Committee of Experts also recommended that "the additional price of Rs. 67.20 (excluding GST) on the applicable ceiling price



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of the Inhalation Synchrobreathe Inhaler Device would remain fixed irrespective of the change in ceiling price of the Inhalation." This recommendation which the NPPA also notified vide its S.O. 4538(E) dated 18th December 2019 is in direct contravention of Para 16(2) which clearly states that "The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required."

2.5 The Multidisciplinary Committee of Experts was clearly provided a pharmacoeconomic working of the benefits of the Synchrobreathe Inhaler Device which was completely ignored.

Under the circumstances:

a. The formulation, "Budesonide 200mcg + Formoterol 6mcg MDI" and "Budesonide 400mcg + Formoterol 6mcg MDI" with Synchrobreathe Inhaler Device is a scheduled formulation which should be provided a separate ceiling price for the device under the provisions of Para 11(3) and 11(4) of DPCO, 2013 and not on an arbitrary, and unjust basis.

b. NPPA further has erred by not allowing the company an annual price increase by WPI for the Synchrobreathe Inhalation Device under the provisions of Para 16 of DPCO, 2013.

2.6 Under the circumstances, the applicant prayed as under:

(i) To consider and conclude that S.O. 4538 (E) dated 18th December, 2019 is ultra vires and contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of the captioned 'Synchrobreathe Inhalation Device';

(ii) To consider and conclude that the recommendation of the Multidisciplinary Committee of Experts for fixing of ceiling / retail price under Para 11(3) and 11(4) using an arbitrary percentage based on published reports is in contravention of DPCO, 2013;

(4) The Government shall form a Committee of Experts , as it may deem fit, within a period of fifteen days from the date of issue of this order , to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameters."

Para 15(3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application."

2.4 Furthermore, the Multidisciplinary Committee of Experts also recommended that "the additional price of Rs. 67.20 (excluding GST) on the applicable ceiling price of the Inhalation Synchrobreathe Inhaler Device would remain fixed irrespective of the change in ceiling price of the Inhalation." This recommendation which the NPPA also notified vide its S.O. 4538(E) dated 18th December 2019 is in direct contravention of Para 16(2) which clearly states that "The manufacturers may



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increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required."

2.5 The Multidisciplinary Committee of Experts was clearly provided a pharmacoeconomic working of the benefits of the Synchrobreathe Inhaler Device which was completely ignored.

Under the circumstances:

a. The formulation, "Budesonide 200mcg + Formoterol 6mcg MDI" and "Budesonide 400mcg + Formoterol 6mcg MDI" with Synchrobreathe Inhaler Device is a scheduled formulation which should be provided a separate ceiling price for the device under the provisions of Para 11(3) and 11(4) of DPCO, 2013 and not on an arbitrary, and unjust basis.

b. NPPA further has erred by not allowing the company an annual price increase by WPI for the Synchrobreathe Inhalation Device under the provisions of Para 16 of DPCO, 2013.

2.6 Under the circumstances, the applicant prayed as under:

(i) To consider and conclude that S.O. 4538 (E) dated 18th December, 2019 is ultra vires and contravention of provisions of Drugs (Prices Control) Order, 2013 in respect of the captioned 'Synchrobreathe Inhalation Device';

(ii) To consider and conclude that the recommendation of the Multidisciplinary Committee of Experts for fixing of ceiling / retail price under

Para 11(3) and 11(4) using an arbitrary percentage based on published reports is in contravention of DPCO, 2013;

(iii) To consider and conclude that the restriction on the company to not annual increase the price of the Synchrobreathe inhalation device based on WPI is in contravention of Para 16 (2) of DPCO 2013.

3. Comments of NPPA:

The authority in its 71st meeting held on 09.12.2019 fixed the additional price for Synchrobreathe inhaler at Rs. 67.20 (excluding GST) based on the recommendation of 14th meeting of multi-disciplinary committee of experts held on 04.12.2019.

3.2 On the request of the NPPA, DG, ICMR nominated two experts in pharmaeconomics in the multi-disciplinary Expert Committee. NPPA co-opted these two members in the multi-disciplinary committee of experts with expertise in pharmacoeconomics to assist in deliberations related to costing of new products. The committee deliberated upon the representation of M/s Cipla Ltd. for separate/special price of "Synchro breathe inhaler device" and noted the documents/journal/study report submitted by the company. The committee noted the demonstration made by M/s Cipla Ltd. in respect of its product "Synchro breathe inhaler device". Since, the claim of M/s Cipla Ltd. of incremental innovation was supported by published journal, well designed study, adequate trial, conclusive clinical data, the committee opined that 20% price increase may be allowed to the company for its product "Synchro breathe inhaler device". Accordingly, the committee recommended the additional price of Rs. 67.20 (excluding GST) on the ceiling price of inhalation having "Synchro breathe inhaler". The company's contention that NPPA ignores the pharmacoeconomics principles while fixing the additional price for



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Synchro breathe inhaler* device is not correct.

3.3 There is ceiling price for Budesonide 200mcg+ Formoterol 6 mcg-120 MDI inhalation and for Budesonide 400mcg-120 MDI inhalation and benefit of WPI under para 16 is applicable. The Committee recommended that the additional price of Rs. 67.20 (excluding GST) on the applicable ceiling price of the inhalation "Synchro breathe inhaler device" would remain fixed irrespective of the change in the ceiling price of the inhalation. The claim of the company for WPI benefit on additional price is not in accordance with the provisions of DPCO, 2013, since, the separate price for "Synchro breathe inhaler device" has been fixed under para 11(3) of DPCO, 2013.

3.4 The review application can only be filed when price is fixed under para 4, 5 and 6 of DPCO, 2013. In this connection, it may be stated that the separate price for "Synchrobreathe inhaler device" has been fixed under para 11(3) of DPCO, 2013. Therefore, review application of the applicant may not be considered under para 31 of DPCO, 2013 by DoP.

4. Examination:

The review application is filed by the company with the following two main contentions :-

- a. The ceiling price of Synchrobreathe Inhaler Device is fixed arbitrarily and on unjust basis by the NPPA;
- b. The NPPA has erred by not allowing the company an annual price increase by WPI for the Synchrobreathe Inhaler Device under the provisions of Para 16 of DPCO, 2013.

4.2 The company submitted an application to the NPPA seeking incremental separate price of 'Synchrobreathe Inhaler Device' for its formulation Budesonide 200mcg + Formeterol 6mcg 120MDI and Budesonide 400mcg + Formeterol 6mcg 120MDI. The company proposed incremental cost of Rs.240/- per device for Synchrobreathe Inhaler Device.

4.3 As per provisions in para 11(3)&(4), the application of the company was placed before the Multidisciplinary Committee of Experts for considering separate / special price of Synchrobreathe Inhaler Device. The Multi-disciplinary Committee of Experts also co-opted two members nominated by ICMR (Prof. Y.K. Gupta, Adviser(Projects), THSTI & Dr. Pooja Gupta, Asso. Prof., Deptt. of Pharmacology, AIIMS), with expertise in pharmacoeconomics to assist in deliberations related to costing of new products. The Committee deliberated the application in its 14th meeting held on 4.12.2019 and noted the documents/journal/study report submitted by the company and also noted the demonstration made by the company in respect of its product "Synchrobreathe Inhaler Device". After detailed deliberations, the Committee observed that since the claim of the company of incremental innovation is supported by published journal, well designed study, adequate trial, conclusive clinical data, it opined for allowing 20% price increase to the company for its 'Synchrobreathe Inhaler Device'. Accordingly, the Committee recommended the additional price of Rs.67.20 (excluding GST) on the ceiling of the inhalation having Synchrobreathe Inhaler device. The committee also recommended that the additional price of Rs.67.20 for the device would remain fixed.

4.4 While fixing the special price for Synchrobreathe Inhaler device, due consideration is given to all the relevant aspects, like documents/journal/study



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report and the demonstration made by the company and the recommendation of the Multidisciplinary Committee of Experts for the product is a well-thought decision. Therefore, the contention of the company that the ceiling price of Synchronbreathe Inhaler Device is fixed arbitrarily and on unjust basis by the NPPA, is not correct.

4.5 The company also contended that the NPPA has erred by not allowing the company an annual price increase by WPI for the Synchronbreathe Inhaler Device under the provisions of Para 16 of DPCO, 2013. As per provisions in para 16 of DPCO, the Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding year on or before 1st April of every year and notify the same on the 1st day of April every year. The impact of WPI is given on the ceiling price of schedule formulation and not on the device. In this case, the benefit of WPI will be applicable only on the scheduled formulation, i.e. Budesonide + Formeterol, and not on the Synchronbreathe Inhaler Device, which is a plastic container. Hence, the contention of the company has got no merit.

4.6 As per provisions in para 31 of DPCO, the review application can be filed when price is fixed under para 4, 5 and 6 of DPCO, whereas in the instant case the separate price for "Synchronbreathe inhaler device" has been fixed under para 11(3) of DPCO.

4.7 The separate price of the device is fixed after due deliberations in the Multidisciplinary Committee of Experts, which also noted the demonstration made by the company. Moreover, the impact of WPI is applicable only on the scheduled formulation, i.e. Budesonide + Formeterol in the instant case, and not on the Synchronbreathe Inhaler Device, which is a plastic container. Therefore, the review application is not sustainable and deserves to be rejected.

5. Decision:

The present review application is not sustainable and stands rejected.

Issued on this, the 7th day of July, 2020.

**(M.K. Bhardwaj)
Deputy Secretary**

For and on behalf of the President of India