

F.No.31015/4/2019-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhawan,
New Delhi-110 001

Order

A review application was received in the Department on 27th March 2019 citing Hon'ble Punjab and Haryana High Court Order on WP no. 9246/2013 for review of all the issues involved, filed under paragraph 22 of the Drugs (Prices Control) Order, 1995 by M/s Ind-Swift Limited (Applicant hereinafter) against notification S.O. 1665(E), dated 27th September 2007 issued by the National Pharmaceutical Pricing Authority (NPPA hereinafter) fixing the retail prices of its formulation "Neurovit / Provita Caps "

2. Background

2.1 The applicant had initially not filed the review application. It had moved Hon'ble High Court of Punjab and Haryana at Chandigarh by way of a Writ Petition viz. WP No.9246/2013, which vide its order dated 14.02.2019 disposed of the said petition directing the petitioner (i.e. M/s Ind-Swift Private Limited, which is applicant in this review application) to file a review petition, and also granted a stay on the operation of the impugned order dated 27.09.2007 and the recovery notices issued to the applicant.

2.2 The hearing on the review application were initially fixed/ held on 17.07.2019, 14.08.2019, 17.10.2019, 27.12.2019, 28.01.2020 and 22.10.2020. Meanwhile, Hearing Authority changed and hearings convened on 07.01.2021, 01.07.2021 and 06.08.2021 were postponed. Finally, the representatives of the Applicant and the NPPA, attended the hearing through video conference on 17th September, 2021 where, the arguments of both the sides were heard.

3. Brief on Applicant's submission and Comments by NPPA thereon:

Applicant's submissions and point-wise comments of NPPA thereon are as under:

3.1 Company's Submissions:

- a. Being a SSI unit, they were not mandated to approach the Government for price approval as per the DPCO 1995.
- b. The said S.O. 1665 (E) dated 27.09.2007 was issued as per para 9 & 11 of the DPCO, 1995. The Company raised the issue regarding non-fixation of the prices under para 8 of the DPCO, 1995.
- c. The formulation manufactured/marketed by the applicant is not a multivitamin Scheduled formulation and the notified prices are not applicable to their product.
- d. Various salts cannot be expressed in a single rate for base element. Price derived from adjustment formula or price given in the adjustment formula for various base elements is not correct notwithstanding the fact that they cannot be included under price control.

3.2. Comments of NPPA:

- a. As per SO No. 134(E) dated 02.03.1995, in order to get benefit of exemption being SSI unit under para 8 of the DPCO, 1995, SSI units were required to apply to the Government within sixty days from the date of notification in case of existing units and sixty days from commencement of production in case of new units for benefit available to SSI units. The company neither could produce any specific order vide which exemption was granted to the company by DOP from price control nor even produce any evidence of submission of declaration to the Government of India as per SO 134 (E) dated 02.03.1995.
- b. NPPA fixed the ceiling price of Hard / Soft Gelatin Caps to the company's product Neurovit / Provita Caps under para 22 of the DPCO, 1995 vide SO No.1665(E), dated 27.09.2007. The company contention's regarding non-applicability of paragraph 11 of DPCO, 1995 on SSI units is wrong and misconceived. Paragraph 11 provides for fixation of price when the

manufacturer, importer of bulk drug or formulation fails to provide the requisite information for fixation of ceiling price.

- c. Paragraph 22 of the DPCO, 1995 provides power to review against any notification or order issued under paragraph 3,5,8,9 & 10 of the DPCO, 1995. Review of demand notice for overcharged amount issued under paragraph 22 of the DPCO,1995 is, however, not admissible.
- d. NPPA fixed the ceiling price in public interest. The company's contention is wrong, misconceived and not tenable. The company never submitted any documentary evidence regarding overcharging by other companies. Hence, mere allegation made by company cannot be accepted.
- e. For all vitamin formulations having composition within the prescribed range in Schedule V under the Drugs & Cosmetics Act, 1940, there was a need to develop a common adjustment formula for price fixation which can accommodate all the formulations. Accordingly, Authority developed and approved a formula for price fixation for aforesaid formulations.

4. Examination:

4.1 Paragraph 9 of the DPCO, 1995 empowers the government for fixing of ceiling price of the scheduled formulation and the price so notified is to be complied with by all the manufacturers of scheduled formulations including SSI units. The price fixed shall not be increased except without the prior price approval. Para 9 of DPCO, 1995 provides that

(1) "Notwithstanding anything contained in this Order, the Government may, from time to time, by notification in the Official Gazette, fix the ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations."

4.2 The price of the formulations mentioned in S.O. No. S.O. 1665 (E) dated 27.09.2007 was fixed by NPPA on *suo motu* basis in the public interest under para 9 and 11 of the DPCO, 1995 as no manufacturer had submitted any application in Form-III & IV to the NPPA for fixation of the price. Para 11 of the DPCO, 1995 clearly states that where any manufacturer, importer of a bulk drug or formulation fails to submit the application for price fixation or revision, as the case may be, or to furnish information as required under this Order,

within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be. Further, para 8 of the DPCO, 1995 provides for fixing of retail price of the scheduled formulations. On the other hand, para 9 of the DPCO, 1995 provides for fixing of ceiling price of scheduled formulations. Hence both the paragraphs 8 and 9 of the DPCO, 1995 are different in nature and have different application and applicability. Contention of the applicant regarding non-fixation of prices under para 8 of the DPCO, 1995 seems not tenable.

4.3 As Form-III was not submitted by the manufacturers, the price was notified based on available information as per the standard practice followed by the NPPA. The manufacturer was required to either file a review application to the Department of Pharmaceuticals if they were not satisfied with the notified price or they should have filed price application to the NPPA for their product giving details of various ingredients used if the composition was different. Under any circumstances, the applicant cannot be allowed to charge substantially higher price from the public.

4.4 NPPA had fixed the ceiling price of Hard /Soft Gelatin Caps to the applicant's product Neurovit / Provita Caps under para 22 of the DPCO, 1995 vide SO No.1665(E), dated 27.09.2007. At that time, the applicant did not file any review application within the stipulated period of 15 days of the date of publication of the notification. The applicant also did not follow the ceiling price notified vide SO No.1665(E), dated 27.09.2007.

The provisions of para 22 of the DPCO, 1995 is reproduced as under:

"Any person aggrieved by any notification issued or order made under paragraphs 3,5,8,9 or 10 may apply to the Government for a review of the notification or order within 15 days of the date of publication of the notification in the Official Gazette of the receipt of the order by him as the case may be and the Government may make such order, on the application as it may deem proper."

4.5 As per NPPA's SO No. 134(E) dated 02.03.1995, in order to get benefit of exemption being SSI unit under para 8 of the DPCO, 1995, SSI units were required to apply to the Government within sixty days from the date of notification in case of existing units and sixty days from commencement of production in case of new units for benefit available to SSI units. The applicant

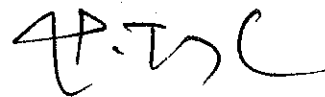
could neither produce any specific order vide which exemption was granted to them by the Department of Pharmaceuticals (DoP) from price control nor any evidence of submission of declaration to the Government of India as per provisions of SO 134 (E) dated 02.03.1995. Moreover, the price notified vide SO No. 1665(E) dated 27.09.2007 was a ceiling price under paragraph 9 of the DPCO, 1995 in respect of which no exemption was available to a SSI unit. Once ceiling price had been notified under paragraph 9 of the DPCO, 1995, all SSI units were covered under the said notification. Hence, the issue raised by the company is not tenable.

4.6 NPPA initiated the overcharging case against the applicant under para 13 of the DPCO, 1995 and issued various recovery notices to the company on 14.10.2008, 23.12.2008, 22.03.2010, 06.07.2010, 26.05.2011 and 06.02.2013. Before initiating the process of issue of recovery notice for overcharging, the applicant was given a personal hearing by NPPA, during which, the points raised by the applicant were found not tenable. Due to non-submission of quantitative data, which was required to be submitted by the applicant, demand notice was issued to them. After non-receipt of demanded amount from the applicant, the matter was forwarded by the NPPA to Collector for recovery.

5. Decision:

The issues raised in the review application dated 27.03.2019, other than the overcharging issue, are devoid of merit and hence the review application stands rejected. Issue of stay on overcharging amount does not come under the purview of DoP.

Issued on this, the 21st day of October, 2022.



(Rajneesh Tingal)

Joint Secretary

[For and on behalf of the President of India]

Copy to:

1. M/s Ind-Swift Private Limited, 781, Industrial Area, Phase-II, Chandigarh-160 002.
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), New Delhi
2. PSO to Secretary(Pharma), New Delhi
3. Technical Director, NIC for uploading the order on Department's Website.
4. Joint Director (Pricing), Department of Pharmaceuticals