

No. 31015/29/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhavan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA.31 OF DPCO,
1995

Subject: Review application of M/s. Softesule Private Ltd. against NPPA notification No.1665 (E) dated 27.09.2007 for price fixation for 'Fersis Caps' under para 22 of DPCO 1995.

Ref. 1) Applicant Review application dated 18.03.2015
 2) NPPA notification under review S.O. No.1665(E) dated 27.09.07
 3) Record Note of discussions held in the personal hearing held in the matter on 20.07.2015

Whereas National Pharmaceutical Pricing Authority (NPPA), Government of India, vide price fixation Order S.O. No. 1665(E) dated 27.09.2007 fixed retail price of '**Fersis Caps**' under para 9 and 11 of DPCO 1995.

2. And whereas aggrieved by the above notification, **M/s. Softesule Private** Ltd. (hereinafter referred to as the Petitioner) submitted review application dated 18.03.2015 under para.22 of DPCO, 1995 for the review of NPPA Price fixation Order S.O.No. 1665(E) dated 27/09/2007 fixing retail price of of '**Fersis Caps**' under DPCO, 1995.

3. The issue relates to overcharging Notice issued by NPPA to M/s. Softsule Pvt. Limited on 18.08.2009 under DPCO, 1995. As per para 22 of DPCO, 1995 power to review is applicable in case any notification or order made under paragraph 3,5,8,9 or 10. Though over-charging is not covered under these paragraphs and these paras relates only to issue of Notification/Orders for fixation of price of the bulk drugs and formulations, review hearing was given based on the Order of Hon'ble High Court of Delhi dated 23.02.2015.

4. Petitioner has filed a Review application dated 18/03/2015 under para 22 of DPCO, 1995 against the NPPA Notification S.O 1665(E) dated 27/09/2007 wherein the Ceiling Price for scheduled formulation Fersis Caps have been notified in exercise of the powers conferred by sub-paragraph (1) and (2) of paragraph 9 and paragraph 11 of the DPCO, 1995. The Hon'ble

Delhi High Court has directed to the Reviewing authority to consider Review application if filed within four weeks and dispose of the review petition.

5. That the Petitioner Company is the manufacturer of the formulations of Ferisis Capsules which formulations are, inter alia, purchased by Alembic Ltd. and sold at the MRP fixed by M/s Alembic Limited as per the Agreement between the applicant and M/s Alembic Limited, which MRP is displayed on the label/carton of the said formulations and the price list issued in that behalf. It is pertinent to note that the main ingredients of the Ferisis Capsules are Carbonyl Iron 50mg, Beta Carotene 15%-5.17mg and Thiamine Hydrochloride IP 4.5/mg. Since first notification bearing SO No.1665(E) dated 27.09.2007 did not include Beta Carotene which is the main substance used in the manufacture of the formulations of the applicant the same is not covered under the notification.

6. Petitioner's written submissions were provided to NPPA and NPPA's comments thereon were given to the petitioner through record note of discussions on 20.07.2015. After considering the comments of NPPA petitioner raised the following points:-

7. This is an overcharging case in which NPPA had issued an overcharging notice, show cause notice and demand notice dt. 18.9.2009. The Petitioner had approached Hon'ble Delhi High Court against NPPA notice vide WP(C) No.1838/2014. In its Order dt. 23.2.2015 Hon'ble Delhi High Court had directed that the petitioner will file a review petition before the reviewing authority within 4 weeks and, if filed, review petition will be deliberated upon and a reasoned order shall be passed upon. The Hon'ble Delhi High Court also directed that the reviewing authority will also consider the contention of the petitioner that its response to the show cause notice was not considered by the respondent No. 2 i.e. NPPA in its entirety.

8. A review hearing was given to the petitioner on 20.7.2015 at 11.30 am. The petitioner representative referred to the notification dated 27.9.2007 and drawn attention to the notes under the said notification. The petitioner representative also referred to the notification dt. 27.11.2008 vide which the following provision was added to the notification No. 1665(E) dt. 27.9.2007:-

“Any other formulation/composition not covered in the above table that has any one of the scheduled drugs in Column No.(3), as one of its ingredients, it shall be subject to the price ceiling at Sl. No.1 or at Sl. NO.2 of the table, as the case may be, subject to Note 1 unless the manufacturer has got hereafter specific price fixed by the NPPA for that formulation.”

9. The petitioner representative also referred to the earlier notification No. 1066(E) dt. 11.7.2006 and referred to the note I and note III under the said notification. The company representative mentioned that as the note was not in

the 2007 notification of NPPA their formulation is not covered under the scheduled category and, therefore, they were not required to apply for price fixation under para 8(2) of DPCO 1995.

10. NPPA representative, however, mentioned that as per provisions a bulk drug covered under the scheduled category of DPCO 1995 if it is used by any company in its formulation then the petitioner is required to file a price approval application under para 8(2) of DPCO 1995. The petitioner did not file any price approval application. During the hearing the petitioner also confirmed of not having filed any such application under para 8(2) of DPCO 1995. NPPA representative mentioned that the bulk drug mentioned at Sl.No.31 of Schedule I that Vitamin B-1 (Thaimine) is a scheduled drug for which they have already issued the price notification. The petitioner representative desired a copy of the said notification fixing the price of bulk drug so that their reaction to the said notification is given. It was decided that NPPA will provide a copy of the bulk drug price fixation to the company on the company's official address within a week and the next date of hearing is fixed on Wednesday, the 12th August, 2015 at 11.30 AM.

11. Further to the hearing given to the Company on 20.07.2015 the petitioner's representative mentioned that they have received the DPCO Notification copy furnished by NPPA. They referred to the Notification of NPPA No.1665 dated 27.09.2007 and they further referred to the overcharging notice issued by NPPA on 18.08.2009 and amendment notification dated 27.11.2008. The Petitioner's representative mentioned that the ceiling prices were issued under para 9 of the DPCO 1995 and, therefore, reference to para 8.2 of the DPCO, 1995 is misconceived. Further, Company's representative mentioned that vide SO No.2809 dated 21.11.2008 NPPA has issued an amendment to their earlier notification dated 27.09.2007 stating that any further formulation/composition not covered to the table in the notification dated 27.9.2007 as one of the ingredients it shall be subject to the price ceiling at S.No.1 or S.No.2 as the case may be subject to the note 1 unless the manufacturer has brought hereafter, specific price fixed by the NPPA for that formulation.

12. Therefore, the petitioner representative argued that the over-charging should be effective from the date of the amendment by which they were covered under price control, i.e. 27.11.2008 and not 27.9.2007. The petitioner representative further mentioned that over-charging notice dated 18.08.09 pertain to NPPA Notification dated 27.09.07 under para 9. They further submitted that there cannot be retrospective effect to the amendment issued by NPPA on 27.11.08

13. NPPA representative mentioned that petitioner was required to take price approval under para 8.2 of DPCO 1995 as it is mandatory for the company to apply for price fixation which the petitioner failed. Therefore,

the entire sale of the company is covered under over-charging. The petitioner representative mentioned that para 8.2 proceedings, if any, are totally new proceedings and not covered and for which no notice has been given by NPPA to the petitioner. The petitioner was given no opportunity to represent their case against the proceedings under para 8, if ever they were initiated.

14. NPPA representative referred to para 9 and 11 of the DPCO 1995 stating that, if any manufacturer fails to submit the price application or furnish information, NPPA may by order fix the price in respect of the formulation. NPPA therefore fixed the price under para 9 of the DPCO 1995. Further, the petitioner representative mentioned that the formulation has been covered only by amendment dated 27.11.08 and earlier they were not covered under price fixation. The petitioner representative further mentioned that on default of para 8 price cannot be fixed under para 9 and any failure should have been covered under the same para. The petitioner representative provided two judgements – WPC 639/2009 and TC Healthcare WPC No.7400/09 vide which the petitioner representative stated that the interest has to be charged from the date of demand notice, i.e. 17.10.2013 and not from the date of accrual. NPPA representative further mentioned that they will provide relevant judgements where the interest is chargeable from the date of accrual.

15. NPPA issued ceiling prices under para 9 and para 11 of DPCO, 1995 vide their Order No. S.O. 1665(E) dated 27.09.2007. NPPA further issued an addendum to the said notification vide Order S.O. 2809(E) dated 27.11.2008 stating that any other formulation not covered in column No.(3) of the table contained in Notification dated 27.09.2007 which has any one of the scheduled drugs covered in column 3 of the original notification it shall be subject to the price ceiling.

16. NPPA representative mentioned that bulk drugs mentioned at S.No.31 of Schedule I, i.e. Vitamin B1 (Thaimine) is a scheduled drug for which they have already issued the price notification. Petitioner was required to file a Price application under Para 8 (2). During the review hearing given to the petitioner on 20.07.2015 the petitioner confirmed that they did not file any application for price fixation under para 8 (2) of the DPCO, 1995.

17. The petitioner representative desired a copy of the price fixation notification of vitamin B1. The price notification was given by NPPA to the petitioner before further hearing on 12.08.2015.

18. During the hearing the petitioner representative claimed that they have been covered under price control vide notification dated 27.11.08 and therefore the overcharging should be effective from 27.11.2008, i.e. the date of amendment of the notification and not from the date of original notification, i.e. 27.09.2007. The petitioner representative further mentioned that the overcharging notice dated 18.08.2009 pertains to NPPA notification dated 27.09.07 issued under para 9.

Department's comments -

- (i) Vitamin B1 is a scheduled drug under DPCO 1995 and as per definition in para 2 (v) a scheduled formulation means a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs. It is, therefore, clear that the formulation of the company which contained B1 was a scheduled drug as per the provisions of DPCO, 1995.
- (ii) As per provisions of para 8 (2) the manufacturer was required to submit an application in the prescribed format for price fixation. The petitioner failed to do that.
- (iii) Para 11 of DPCO, 1995 states "In case the manufacturer fails to submit an application for price fixation or revision or fails to provide information as required under the DPCO the Government may on the basis of such information as may be available with it by Order fix a price in respect of such formulations. It is evident from the facts mentioned above that NPPA exercised this power and issued ceiling price vide notification dated 27.09.2007 which was to be followed by all. But this notification did not cover all the ingredients of the formulation manufactured by the petitioner. To cover all other formulations NPPA issued an addendum to the notification on 27.11.2008. Therefore, the petitioner should have been covered under Notification dated 27.09.2007 had NPPA included the addendum dated 27.11.2008 in the initial stage while issuing notification on 27.09.2007. The petitioner, therefore, becomes liable for a price control of its formulation from the date the addendum is issued, i.e. 27.11.2008. If NPPA wishes to initiate action against the company for not filing its application under para 8 (2) it may do so as per the extant provisions of law.
- (iv) In regard to the submission of the petitioner that the interest is payable from the date of notice, it is stated that it has no merit as the petitioner started overcharging the consumer public right

since it was covered under price control and the overcharging has no relation with the notice but it is related to the date on which consumer public was overcharged.

Recommendation –

The company may be directed to pay their overcharging liability with effect from 27.11.2008, i.e. from the date S.O. No.2809 (E) was issued along with interest as per provisions of law. If NPPA wishes to initiate action against the company for not filing its application under para 8 (2) it may do so as per the extant provisions of law.

This issues with the approval of the Competent authority.

Issued on this date of 19th October, 2015.

(R.K. Maggo)
Director

1. M/s. Softesule Pvt. Ltd.,
86-A, LBS Mrg, Mulund (West),
Mumbai-4-00080.
2. The Member Secretary,
NPPA, YMCA Cultural Centre Building,
New Delhi-110001.

Copy to:-

1. PS to Hon'ble Minister (C&F)
Shastri Bhavan, New Delhi.
2. PSO to Secretary (Pharma), Shastri Bhavan, New Delhi.
3. PS to JS(Pharma)
4. Technical Director, NIC with the request to upload the review order on the Deptt Website.