

No. 31015/6/2017-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A- Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s J.B. Chemicals & Pharmaceuticals Ltd. against price fixation of "Nifedipine Soft Gelatin Capsules 10 mg." vide NPPA order No. S.O. 4128(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 10.01.2017
2) NPPA notification under review S.O. 4128(E), dated 22.12.2016
3) Record Note of discussions held in the personal hearing held in the matter on 07.03.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s J.B. Chemicals & Pharmaceuticals Ltd. (hereinafter called the petitioner) against notification S.O. No.4128(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Nifedipine Soft Gelatin Capsules 10 mg.

2. The petitioner has contended as under:-

- I. The worksheet for calculation of ceiling price of formulation Nifedipine 10 Mg- Conventional Capsule notified vide S.O. 4128 (E) dated 22ND December, 2016 NPPA has erred by considering their formulation "NICARDIA 10 MG CAPSULE 10" which is a **Soft Gelatin Capsule** and not covered in the First Schedule of DPCO, 2013.
- II. AND WHEREAS, Explanation 1 to First Schedule of DPCO, 2013 reads as under: **"if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included"**. The Report of the Core Committee for Revision of National List of Medicines published in November 2015 explained dosages form covered in NLEM, 2015 as under: "Oral solid dosage forms include tablet, capsule, sachet, etc. Tablets include film coated, uncoated, sugar coated etc. Capsules include hard gelatin capsule, soft gelatin capsules etc. **(Unless specified, capsules mentioned in the NLEM are considered as hard gelatin capsules).**"
- III. AND WHEREAS, the company submits control sample and drug license clearly stating the specialized dosage type as Soft gelatin capsule. Thus, their formulation is a Non Scheduled formulation and ceiling price cannot be made applicable to the formulation.
- IV. AND WHEREAS, the Price to Retailer (PTR) of two formulations, namely: 'Calcigard 10mg Capsule 20' and 'Depin 10mg Capsule 100' have been incorrectly considered to be much lower than actual. Further, the aforesaid two packs are having market share at less than 1% of MAT for August, 2015

and must not be considered in the calculation of ceiling pricing under the provisions of Para 4 of DPCO, 2013. They have enclosed herewith a certificate vide **Annexure V** for the formulation Nifedipine 10 Mg Soft Gelatin Capsules with MAT of all packs for August, 2015.

Under the circumstances:

- a. Soft Gelatin Capsules continues to be excluded from the First Schedule of DPCO, 2013 as they are not '**conventional capsules**' as clearly specified in the Report of the Core Committee for Revision of National List of Medicines published in November 2015, Soft Gelatin Capsules are non scheduled unless specifically mentioned in the National List of Essential Medicines, 2015 (hereinafter referred to as NLEM, 2015).
 - b. Their formulations namely; "NICARDIA 10 MG CAPSULE 10" must not be considered in the calculation of ceiling price for aforesaid formulation for conventional Hard gelatin capsules.
 - c. NPPA should notify the ceiling price under the provisions of Para 4 of DPCO, 2013 for NIFEDIPINE CAPSULE 10 MG after removal of their Non Scheduled formulation for conventional hard gelatin capsules only.
- V. Having been aggrieved by the errors in calculation of ceiling price, they prayed as under:-
- a. To consider and conclude that NPPA had erred in pricing of their formulation Nifedipine Capsule 10 MG under Notification no. S.O 4128 (E) dated 22ND December, 2016 by:
 - (i) Considering incorrect PTR of certain formulations.
 - (ii) Considering PTR of packs with less than 1% market share.
 - (iii) Considering Soft Gelatin Capsules in the calculation of ceiling price for conventional hard gelatin Capsules.
 - b. To consider and conclude that Nifedipine soft gelatin capsules are not conventional capsules as covered under the First schedule of DPCO, 2013.
 - c. Pass a speaking order in respect hereof.
 - d. Any other order in interest of this manufacturer.

Comments of NPPA:

- I. Ceiling price of Rs. 0.79 per capsule for **Nifedipine 10mg Capsule** was notified vide S.O. 4128(E) dated 22.12.2016 as per para 4, 10, 11, 14, 16, 17 & 18 under DPCO 2013.
- II. The company stated that correct methodology was not followed in arriving at the ceiling price for **Nifedipine 10mg Capsule**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the

provisions of DPCO, 2013 and as per the decisions of 27th Authority meeting held on 29.3.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	NPPA has considered the PTR and MAT value of their formulation Nicardia 10mg Soft Gelatin Capsule while arriving the ceiling price for Nifedipine 10mg Capsule which is not as per the provisions of DPCO, 2013.	Nifedipine 10mg Capsule is included under section 12.3 of NLEM 2015. NPPA has considered the PTR and MAT value of their formulation Nicardia 10mg Soft Gelatin Capsule for working out the ceiling price of this formulation, which is in conformity with the provisions of explanation to note (1) of DPCO S.O. 701 (E) dated 10.3.2016 and as per 27 th Authority meeting decision held on 29.3.2016.
2.	Company has pointed out that their product Nicardia 10mg Soft Gelatin Capsule is a non-schedule formulation as it is not specified capsule mentioned in NLEM 2015.	NPPA fixed the ceiling price for Nifedipine 10mg Capsule as per the decision of 27 th Authority Meeting held on 29.3.2016. there is no merit in company representation. NPPA has fixed the ceiling price for this pack strictly within the provisions of DPCO, 2013.
3.	Company has also raised objection against inclusion of Calcigard 10mg & Depin 10mg capsules in calculation sheet on the ground of MAT % even those having MAT of less than 1%.	NPPA has included PTR & MAT value of Calcigard 10mg & Depin 10mg capsule considering the decision of 27 th Authority Meeting held on 29.3.2016, regarding ceiling price fixation based on the least of the three alternatives.

- III. DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: *"NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals & Fertilizers)".* Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. **J. B. Chemicals & Pharmaceuticals Ltd. did not make any representation against the proposed ceiling price uploaded on NPPA's website.**

IV. Company has not challenged any notification in respect of **Nifedipine 10mg Capsule** in the Court.

3. During the personal hearing, the representatives of the company, in addition to their earlier submissions, stated that ceiling price as notified for the non scheduled formulations namely Nifedipine Soft Gelatin Capsules 10 Mg, must be withdrawn as the provisions of Para 4 cannot be applied.

The company representative humbly requests that the primary issue of this review hearing is regarding Explanation 1 to First Schedule of DPCO, 2013 which reads as under: ***“if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included”***. While the company interprets conventional capsules as mentioned in Explanation 1 to First Schedule of DPCO, 2013, as per The Report of the Core Committee for Revision of National List of Medicines published in November 2015, and thereby not including soft gelatin capsules, NPPA has erred to distinguish conventional capsules as mentioned in NLEM, 2015. Thus a clarification is sought from the Department of Pharmaceuticals to concur that the definition of a conventional capsule may not include soft gelatin capsules in accordance with the recommendations of the core committee headed by Dr. V.M. Katoch.

Considering soft gelatin capsules do not form a part of conventional capsules, the aforesaid formulation may be considered as non scheduled as Section 26.2.2 of Schedule 1 of DPCAO, 2016 only includes “Nifedipine tablets 10 Mg.”.

The company representative also requested that without prejudice if Nifedipine soft gelatin capsules were to be priced under the provisions of Para 4, even then SKUs with moving annual turnover lower than 1% market share cannot be considered in calculation of ceiling price. Thus, ‘Calcigard 10mg Capsule 20’ and ‘Depin 10mg Capsule 100’ need not be considered as per the provisions of Para 4 of DPCO, 2013 and in accordance with DoP Review Orders in favour of M/s. Sun Pharma Ltd and M/s. Micro Labs Limited for the same provisions. Finally, the company is also 100% compliant with the requirement and submission under IPDMS as on 06.03.2017.

4. NPPA representative submitted that the ceiling price of Nifedipine 10 mg. capsule was fixed based on the provisions of DPCO, 2013. DPCO, 2013 does not differentiate between hard gelatin and soft gelatin capsules. Inclusion/exclusion of product/brand having less than 1% market share while calculating the ceiling price is based on the policy taken by the authority in its 27th meeting.

5. **Examination:**

The petitioner company has challenged the NPPA Order S.O. 4128(E), dated 22.12.2016 for price fixation of their formulation **Nifedipine Capsules 10 mg.** on the ground that NPPA has erred by considering their formulation **“NICARDIA 10 MG CAPSULE 10”** which is a Soft Gelatin Capsule and not covered in the First Schedule of DPCO, 2013. In this connection the stand of NPPA is in order as **Nifedipine 10mg Capsule** is included under section 26.2.2 of NLEM 2015. NPPA has considered the PTR and MAT value of their formulation **Nicardia 10mg Soft Gelatin Capsule** for working out the ceiling price of this formulation, which is in conformity with the provisions of explanation to note(1) of DPCO S.O. 701(E) dated 10.3.2016. Therefore,

the soft gelatin capsules are considered to be included in Schedule I on the following grounds:-

- (i) Nifedipine tablet 10 mg are specifically included vide Section 26.2.2 in NLEM 2015 without indicating any specific type of gelatin.
- (ii) Soft gelatin capsules are considered included in the light of the Explanation (1) in Schedule I of NLEM 2015, which says that if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included.

Moreover, there is no provision in DPCO to consider gelatin coating differently.

The another contention of the company is that PTR of two formulations, namely, '**Calcigard 10mg Capsule 20**' and '**Depin 10mg Capsule 100**' have been incorrectly considered as the aforesaid two packs are having market share at less than 1% of MAT for August, 2015 and must not be considered in the calculation of ceiling pricing under the provisions of Para 4 of DPCO, 2013.

On examination, it is found that NPPA has erred in calculating ceiling price as per para 4 of DPCO, 2013. It clearly mentions that the medicines having PTR and MAT value of more than 1% market share are to be taken for calculation. In the instant case, the principles applied by NPPA go beyond what is mentioned in DPCO. Hence, NPPA may be directed to refix the ceiling price in accordance with the provisions of DPCO. On going through the calculation sheet of each of the formulations, it is observed that the number of formulations which are to be considered having more than 1% market share and number of formulations to be excluded, as per table given below:-

<u>Formulation name</u>	<u>Number of brands to be considered having more than 1% market share</u>	<u>Number of brands to be excluded</u>
Nifedipine Capsules 10 mg.	3	5

In view of the above, the contention of the petitioner company that the price of formulation "NICARDIA 10 MG CAPSULE 10" should not be considered being Soft Gelatin Capsule and not covered in Schedule I of DPCO, 2013, cannot be acceded to as Nifedipine 10mg is included under section 26.2.2 of NLEM 2015. However, NPPA may be directed to refix the ceiling prices of the formulations by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognise a company for average PTR but only medicines / formulations.

6. Government Decision:

“The grievance of M/s J.B. Chemicals & Pharmaceuticals Ltd. that the price of formulation “NICARDIA 10 MG CAPSULE 10” should not be considered being Soft Gelatin Capsule and not covered in Schedule I of DPCO, 2013, cannot be acceded to as Nifedipine 10mg is included under section 26.2.2 of NLEM 2015.

NPPA is, however, directed to refix the ceiling prices of the formulation Nifedipine Capsules 10 mg. by considering only those medicines / formulations having MAT value of more than 1% market share.”

Issued on this date, the 25th day of September, 2017.

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

To

1. M/s. J.B. Chemicals & Pharmaceuticals Ltd.
“NEELAM CENTRE”, ‘B’ Wing, 4th Floor,
Hind Cycle Road, Worli,
Mumbai-400 030.
2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department’s Website