

No. 31015/24/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

.....

A- Wing, Shastri Bhawan,
New Delhi 110 001

Subject: Review application of M/s Universal Medicare Private Limited against price fixation of “Cetirizine Capsules 10mg” vide NPPA order No. S.O. 247(E), dated 24.01.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 17.02.2017
2) NPPA notification under review S.O. 247(E), dated 24.01.2017
3) Record Note of discussions held in the personal hearing on 12.12.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Universal Medicare Private Limited (hereinafter called the petitioner) against notification S.O. No.247(E), dated 24.01.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Cetirizine Capsules 10 mg.

2. The petitioner has contended as under:-

(i) NPPA has erred by considering company’s formulation “CETGEL - CETRIZINE 10 MG SOFT GELATIN CAPSULE” 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 dosage forms 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, company’s formulation is a Non Scheduled formulation and ceiling price cannot be made applicable to company’s formulation.

(iv) AND WHEREAS, the company submitted a Letter to NPPA dated December 17, 2016, against the aforesaid Notification O.M. No. 8(34)/2016/DP/NPPA/Div.II dated 6th December, 2016 within the prescribed time of 10 working days.

(v) AND WHEREAS, NPPA has further erred by considering company's formulation CETGEL - CETRIZINE 10 MG SOFT GELATIN CAPSULE each soft gelatin capsule containing Cetirizine 10 MG as a scheduled formulation under DPCO, 2013 and notified ceiling price under the provision of PARA 6 of DPCO, 2013 despite the company's submission of documentary evidence.

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 on Page 31, Soft Gelatin Capsules are non scheduled unless specifically mentioned in the National List of Essential Medicines, 2015.

b. Company's formulations namely; "CETGEL - CETRIZINE 10 MG SOFT GELATIN CAPSULE" must not be considered in the calculation of ceiling price for aforesaid formulation for conventional Hard gelatin capsules.

c. NPPA should not notify a ceiling price for a non scheduled formulation such as CETIRIZINE SOFT GELATIN CAPSULE 10 Mg and should withdraw the ultravirus ceiling price as issued vide S.O. 247(E) Dated 24.01.2017.

(vi). In view of above company requested as under:-

a. To consider and conclude that NPPA had erred in notifying a ceiling price for company's non scheduled formulation Cetirizine Capsule 10 Mg vide Notification no. S.O 247 (E) dated 24th January, 2017.

b. To consider and conclude that Cetirizine soft gelatin capsules are not conventional capsules as covered under the First schedule of DPCO, 2013 and hence non scheduled in nature.

c. Pass a speaking order in respect hereof.

d. Any other order in interest of this manufacturer

3. Comments of NPPA:

- I. Ceiling price of **Cetirizine Capsule 10 mg** was notified as Rs. 2.21/capsule vide S.O. 247(E) dated 24.01.2017 and revised to Rs. 2.16/capsule vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
- II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Cetirizine Capsule 10 mg**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	NPPA has erred by considering their formulation "CETGEL – CETIRIZINE 10 mg Soft Gelatin Capsule" which is a soft gelatin capsule and not covered in the first schedule of DPCO, 2013.	As decided in 27 th Authority Meeting, all variants of the products are to be taken while calculating the ceiling price of formulation unless different variants of the formulation are specially mentioned against any formulation in NLEM 2015.
2.	Company referred Explanation 1 to First schedule of DPCO, 2013, where it is stated. "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 dosage forms 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". "Oral solid dosage forms include tablet, capsule, sachet, etc. Tablets include film coated, uncoated, sugarcoated, etc. Capsules include hard gelatin Capsule, soft gelatin capsule, etc. (unless specified, capsules mentioned in NLEM are considered as hard gelatin capsule).	Reference is invited to review order no. 31015/17/2017-Pricing dated 14.06.2017 where in Department of Pharmaceuticals rejected the review application filed by M/s Sanofi India Ltd. against S.O. no.247(E) dated 24.01.2017 in respect of Cetirizine 10 mg capsule. CETGEL – CETRIZINE 10 mg Soft Gelatin Capsule is manufactured by M/s Universal Medicare Pvt. Ltd. and marketed by M/s Sanofi India Ltd.
3.	Company submitted photocopy and manufacturing permission of Cetgel Capsule and claim their formulation as a non-scheduled formulation for which ceiling price fixed by NPPA is not applicable.	Company claim that their product Cetgel capsule is non-schedule is not acceptable.
4.	Company has also pointed out that they submitted a letter dated 17.12.2016 against aforesaid notification OM no. 8(34)/2016/DP/NPPA/Div.II dated 06.12.2016 within the prescribed time of 10 working days.	Company's representation was examined by NPPA and decided that there is no merit in company's representation.
5.	Company reiterated that NPPA further erred by considering their formulation as schedule formulation and notified ceiling price under provision of para 6 of DPCO, 2013 despite the company's submission of documentary evidence.	NPPA considered their formulation in fixing the ceiling price of Cetirizine 10 mg capsule as per the decision of 27 th Authority meeting held on 29.03.2016.

III. Company has not challenged in any Court in respect of ceiling price fixation for **Cetirizine Capsule 10 mg** vide S.O. No. 247(E) dated 24.01.2017.

4. During the personal hearing, the company representatives further stated that with respect to SO 701 (E) dated 10th March 2016, the Department of Pharmaceuticals was expected to follow all the provisions as mentioned under Para 17 of DPCO 2013. While DoP has notified the revised list as communicated by the Ministry of Health and Family Welfare vide Annexure III of NLEM 2015, to ensure compliance with “clearly stating reasons thereof” can be assumed to have been accepted by DoP as it formed a part of Annexure IV of NLEM 2015. The company thus assumes the well-established principle of Equity Maxim which states that “**Equity takes that as done what ought to have been done**”. In support of its view, the company quoted various court decisions.

4.2 In response to the submission made by the company during the personal hearing, the representatives of NPPA stated that SO 701(E), dated 10.3.2016 issued by DoP does not have any reference to the Report of Core Committee on revision of NLEM (regarding NLEM 2015) and its various annexure issued by the Ministry of Health & Family Welfare was not considered in price fixation.

5. **Examination:**

The petitioner company has challenged the NPPA Order S.O. 247(E), dated 24.01.2017 for price fixation of their formulation **Cetirizine 10 mg Capsules** on the ground that NPPA has erred by considering their formulation “Cetirizine 10 mg capsules (CETGEL 10mg)”, as the formulation is a **Soft Gelatin Capsule** and is totally different than those listed in section 3.2 of NLEM 2015. The company claimed that provisions of DPCO are applicable only for hard-gelatin capsule.

5.2 In this connection the stand of NPPA is in order as **Cetirizine 10 mg Capsules** is added/included under section 3 of NLEM 2015. NPPA has considered the PTR and MAT value of their formulation **Cetirizine 10 mg Capsules** 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, 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. All variants of the products are to be taken while calculating the ceiling price of formulation unless different variants of the formulation are specially mentioned against any formulation in NLEM 2015. Therefore, the claim of the company, that soft gelatin capsule be treated as non-scheduled medicine, cannot be accepted.

5.3 In view of the above, the grievance of the petitioner company has got no merit, as NPPA has rightly considered formulation “**Cetirizine 10 mg Capsules**” being scheduled medicine under section 3 of NLEM 2015. Therefore, the review petition of the petitioner may be rejected.

6. **Government Decision:**

“The grievance of M/s Universal Medicare Private Limited that the price of formulation “Cetirizine 10 mg Capsules” should not be considered being Soft Gelatin Capsule and not covered in Schedule I of DPCO, 2013, cannot be acceded to as Cetirizine 10 mg Capsules is included under section 3 of NLEM 2015 and there is no provision in DPCO to consider gelatin coating differently.”

Issued on this date, the 16th day of January, 2018.

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

To

1. M/s Universal Medicare Pvt. Ltd.,
Capsulation Premises, Sion-Trombay Road,
Mumbai-400088.
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