

**No. 31015/17/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Sanofi India Limited against price fixation of "Cetirizine 10 mg Capsules" 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 20.02.2017
2) NPPA notification under review S.O. 247(E), dated 24.01.2017
3) Record Note of discussions held in the personal hearing held in the matter on 9.5.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sanofi India 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 10 mg Capsules

2. The petitioner has contended as under:-

1. Considering that there was an apparent error in the Draft Version of Proposed Price Calculation Sheet for the proposed ceiling price in respect of 'Cetirizine 10 mg Capsules displayed on NPPA website which was uploaded on 6th December 2016, they made a detailed representation to NPPA vide our letter dated 7.12.2016 justifying that CETGEL 10 mg Capsules manufactured by Universal Medicare Private Limited and marketed by Sanofi India Limited are soft-gelatin capsules as per the manufacturing license issued to the Company by the concerned drug controller and these capsules are totally different than those listed in Section 3.2 of Schedule I to the DPCO 2013. However, NPPA has notified the ceiling price of 'Cetirizine 10 mg Capsules as per S.O. 247(E) dated 24.1 2017 without considering their justifications furnished to NPPA.

2. Grounds of review:-

(i) CETGEL 10 mg Capsules manufactured by Universal Medicare Private Limited and marketed by Sanofi India Limited are soft-gelatin capsules.

(ii) The Company is manufacturing 'Cetirizine 10 mg Capsules not as a conventional hard gelatin capsule but as a soft gelatin capsule, which is very much different from conventional capsules in terms of manufacturing process.

(iii) As the product Cetgel 10 mg capsules is a soft gelatin capsules, it is not part of National List of Essential Medicines and hence its price should not be considered for the purpose of notification of price of hard gelatin capsules.

(iv) Only 'Cetirizine 10 mg tablets, and Oral liquid 5 mg / 5ml are included in the NLEM 2015/Schedule I of the DPCO 2013. The entry for Cetirizine in Schedule I of DPCO 2013 reads as follows:

Section 3-Antiallergics and medicines used in anaphylaxis

3.2 Cetirizine P,S,T Tablet 10 mg

Oral liquid 5 mg / 5ml

(v) Though Explanation 1 in Schedule I of DPCO 2013 states that any dosage form of a medicine, other than the dosage form included in the Schedule, but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety profile over the dosage form mentioned in the list shall be considered as included, yet this is applicable only to the normal hard gelatin capsules and not the Soft Gelatin capsules.

(vi) A Core Committee under the chairmanship of Dr. V. M. Katoch, former secretary of Department of Health Research was constituted by the Ministry of Health & Family Welfare for reviewing and revising the NLEM-2011. The core committee submitted its report to the Government on December 9, 2015 and after examination of the report, the Government accepted the recommendations of the committee in totality and adopted the NLEM-2015. Accordingly the Core Committee's recommendations duly accepted by the Government are binding on all including NPPA.

(vii) The Core Committee for Revision of National List of Medicines has categorically recommended that "**Unless specified, capsules mentioned in the NLEM are considered as hard gelatin capsules**". Accordingly the provisions of Explanation 1 in Schedule I apply only to the hard gelatin capsules. On page 31 of the report of said Core Committee published in November 2015 under the head 'Improved or novel drug delivery systems', the Committee has recommended as follows:

"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)"

(viii) Thus while Cetirizine 10 mg tablets and hard gelatin capsules are included in Schedule I as per Explanation I and hence subject to ceiling price fixed under DPCO, 2013, soft gelatin capsules containing Cetirizine 10 mg are not to be considered included under Schedule I of DPCO 2013 as per Core Committee recommendations and thus are not part of NLEM 2015.

(ix) Further, as soft gelatin capsules are outside the scope of NLEM and the entry for Cetirizine in Schedule I refers only to tablets, ceiling prices would not apply for Cetirizine soft-gelatin capsules.

(x) In view of above, Company submitted that there is no justification for price fixation of Cetigel 10 mg capsules is a soft gelatin capsules (Cetirizine 10 mg Capsules) in the manner as adopted by the NPPA which is against the recommendations of the above-said Core Committee and the provisions of the DPCO, 2013.

3. Company requested that the ceiling price of 'Cetirizine 10 mg Capsules notified vide S.O. 247(E) dated 24.1.2017 may be withdrawn immediately.

Comments of NPPA:

1. In this regard, it is mentioned that ceiling price of Rs. 2.21 per capsule for **Cetirizine 10mg Capsule** was notified vide S.O. 247(E) dated 24.01.2017 as per para 4, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.
2. Company has stated that correct methodology was not followed in arriving at the ceiling price for **Cetirizine 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. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	M/s Sanofi India Limited & M/s Universal Medicare Pvt. Ltd. vide their representations challenged the inclusion of their product CETGEL 10mg capsule in calculation sheet. Company's contention is that their product is soft-gelatin capsule and hence would not come under the purview of price control. Company has pointed out that CETGEL 10mg capsule manufactured by M/s Universal Medicare Pvt. Ltd. and marketed by M/s Sanofi India Limited is soft-gelatin capsule which is totally different than those listed in section 3.2 of NLEM 2015. Company has also submitted copy of manufacturing license in support of their claim. Company had also claimed that provisions of DPCO are applicable only for hard-gelatin capsule.	Reference is invited to report of Core Committee which mentions "Capsule includes hard-gelatin capsule, soft-gelatin capsule. Unless specified, capsule mentioned in NLEM are considered as hard-gelatin capsule". 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 specifically mentioned against any formulation in NLEM 2015. Therefore, the representations of M/s Sanofi India Limited & M/s Universal Medicare Pvt. Ltd. were examined but not considered by the Authority. Ceiling price of Rs. 2.21/capsule was fixed for Cetirizine 10mg Capsule in accordance with the provision of DPCO, 2013 under monopoly conditions.

4. During the personal hearing, the representatives of the company reiterated their submissions already made by them in the review petition.

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)", manufactured by M/s Universal Medicare Pvt. Ltd. and marketed by M/s Sinofi India Limited, 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 Schedule I refers only to tablets, ceiling prices would not apply for Cetirizine soft-gelatin capsules.

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.

6. Government Decision:

"The grievance of M/s Sanofi India 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 14th day of June, 2017.

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

To

1. M/s. Sanofi India Limited
Sanofi House, CTS No.117-B,
L&T Business Park,
Saki Vihar Road,
Powai, Mumbai-400 072.
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