

No. 31015/102/2016-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 Sun Pharma Laboratories Ltd. against price fixation of "Propranolol 40mg capsules" vide NPPA order No. S.O. 3180(E), dated 07.10.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review application dated 04.11.2016
2) NPPA notification under review S.O. 3180(E), dated 07.10.2016
3) Record Note of discussions held in the personal hearing held in the matter on 24.01.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharma Laboratories Ltd.(hereinafter called the petitioner) against notification S.O. No.3180(E), dated 07.10.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Propranolol 40mg capsules

2. The petitioner has contended as under:-

I. NPPA has revised the ceiling price of Propranolol Capsule 40 mg vide S.O. No. 3180(E) dated 07.10.2016. The company stated that they are aggrieved by the said notification. The company therefore sought a review of the same under paragraph 31 of DPCO 2013 on the following grounds:-

(i) NPPA uploaded the draft working sheet of 19 formulations including captioned formulation on NPPA website on 21.09.2016. The company had submitted their representation dated 30.09.2016 encompassing necessary documents within 10 working days of presentation of the draft working sheet to NPPA requesting to exclude their product BETACAP 40MG CAPSULES TR 10 and other incremental formulation from the ceiling price calculation as per Explanation Note (2) of Department of Pharmaceuticals' S.O. 701(E) dated 10.03.2016.

(ii) NPPA has notified the ceiling price of the captioned formulation via S.O. No. 3180(E) dated 07.10.2016 without giving due consideration to their representation. This has led to the ceiling price which is not as per the provision of DPCO 2013. Considering such scenario, it seems that overall purpose of bringing transparency in ceiling price calculation/fixation is being defeated.

II. In view of the above, they requested this Department to kindly issue necessary directives to NPPA to consider their representation and to recalculate the ceiling price of the above said formulation.

3. Comments of NPPA:

(i) Regarding inclusion / exclusion of different variant for calculating ceiling price NPPA observed that the representation submitted by the company had no merit. Therefore, the Company's representation was not considered by NPPA. NPPA has considered the PTR & MAT value of Betacap 40mg Capsule TR 10 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 37th Authority meeting decision held on 06.10.2016.

(ii) For SR/CR/MR/ER/DR/Entric coated etc. and DT/effervesant/soluble/MD, etc. category of tablet, the ceiling price has to be notified for such specific tablet separately, only if specifically included in NLEM 2015 and in Schedule I of DPCO, 2013.

When there are other categories of tablets, they are considered as conventional tablet only and the ceiling price computed, clubbing the data of all such categories of tablets including all variants for computation of ceiling price, unless specifically indicated in Schedule-I of DPCO, 2013. The same interpretation discussed above is also applicable for capsules.

4. During the personal hearing, the representatives of the company made following further submissions -

1. Advanced release formulation packs in addition to conventional packs were included in the draft working sheet.
2. Sun Pharma filed representation with supporting documents against inclusion of advanced release formulation in the office of NPPA dated 30.09.2016.
3. NPPA notified the ceiling price of Propranolol 40 mg Capsules as Rs. 3.53 per capsule including advanced release formulation of Sun Pharma and others via SO 3180(E) dated 07.10.2016.

5. Examination:

5.1 The petitioner company in its review application submitted that their product BETACAP 40MG CAPSULES TR 10 is a prolonged release formulation and not an immediate release formulation in Propranolol 40 mg capsule category. Hence, this product pack along with some other prolonged release formulations should not have been included in the ceiling price calculation of Propranolol 40mg capsule as per explanation note (2) of DoP's notification SO 701(E), dated 10.3.2016.

5.2 Explanation note (2) of Schedule-I of DPCO, 2013, issued vide notification SO 701(E), dated 10.3.2016, reads as under :-

“Innovation in medicine must be encouraged. The formulation developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc.”

5.3 Schedule-I of DPCO, 2013 does not specifically notify the prolonged release drug, hence, NPPA has included the subject formulation of the petitioner company along with other conventional tablets and fixed the ceiling price. As per company's submission that their product BETACAP 40MG CAPSULES TR 10 is a prolonged release formulation and not an immediate release formulation and should not be included in the ceiling price calculation of Propranolol 40mg capsules.

5.4 There is a provision in DPCO as per Para 11(2&3) that a Committee of Expert may recommend fixing of separate ceiling price of scheduled formulations or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size, or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be. In view of this, NPPA may be directed to get the claim of petitioner examined by the Committee of Experts and recommend whether the formulation BETACAP 40MG CAPSULES TR 10 is to be treated as an incremental formulation with specific therapeutic rationale. NPPA may thereafter take a decision about inclusion or exclusion of subject formulation of the petitioner company from the ceiling price fixation of Propranolol Capsule, on merit basis on the recommendation of the Expert Committee.

6. **Government Decision:**

“NPPA is directed to get the claim of the petitioner examined by the Committee of Experts and their recommendation, on whether the formulation BETACAP 40MG CAPSULES TR 10 can be treated as an incremental formulation with specific therapeutic rationale, be obtained. NPPA may thereafter take a decision about inclusion or exclusion of subject formulation of the petitioner company from the ceiling price fixation of Propranolol Capsule, on merit, based on the recommendation of the Expert Committee.”

Issued on this date, the 24th day of August, 2017.

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

To

1. M/s. Sun Pharma Laboratories Limited,
Sun House, Plot No.201 B/1,
Western Express Highway,
Goregaon (E), Mumbai-400 063.
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