

No. 31015/62/2015-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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B Wing, Janpath Bhawan, New Delhi

O R D E R BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO, 2013

Subject: Review application of M/s. Sun Pharmaceutical Industries Ltd. against fixation of ceiling price of “Volini Duo (Acetaminophen 650 mg extended release tablets)” vide NPPA notification S.O. No. 1253(E) dated 29.03.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO, 2013) and NPPA letter No.F.No.19(778)/2016/NPPA/Div.II, dated 23.5.2016.

- Ref.
- 1) Review application dated 22.06.2016
 - 2) NPPA notification under review S.O. No. 1253(E) dated 29.03.2016 and NPPA letter No.F.No.19(778)/2016/NPPA/Div.II, dated 23.5.2016.
 - 3) Record Note of discussions held in the personal hearing held in the matter on 15.07.2016

This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Ltd. (hereinafter called the petitioner) against notification S.O. No.1253(E) dated 29.03.2016 and letter No. F.No.19(778)/2016/NPPA/Div.II, dated 23.5.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of “Acetaminophen 650 mg tablet”.

2. The main grievance of the company is that as the captioned product is not included in NLEM 2015, instead of fixing a separate retail price for Volini Duo, NPPA directed the company to follow the ceiling price notified for paracetamol plain tablet 650 mg vide SO No.1253(E) dated 29.3.2016. Company has submitted further justifications for the need of fixing a separate retail price for Volini Duo on 26th May, 2016, referring to Explanation of No.2 of amended DPCO 2013, notified vide SO 701(E), dated 10th March, 2016. However, NPPA did not respond to the company’s submission and, therefore, company has filed a review application with Deptt. of Pharmaceuticals on 22nd June, 2016.

3. NPPA representative submitted that NLEM 2015 does not mention different variants of paracetamol 650 mg tablet. Hence, all variants of Paracetamol 650 mg tablet has been taken into calculation while fixing its ceiling price. Accordingly, the company was directed to follow the ceiling price. While applying for price fixation of new drug in Form I the company submitted the PTR of 4 brands available having identical composition, which were already considered in the ceiling price fixation. The companies of those four brands did not file any representation / review against the ceiling price. M/s GSK also manufacturing and marketing Crocin Advance and following the ceiling price fixed by NPPA.

5. **Examination:**

NLEM 2015 does not mention different variants of paracetamol 650 mg tablet. Hence, all variants of Paracetamol 650 mg tablet have been taken into calculation by NPPA while fixing its ceiling price. While applying for price fixation of new drug in Form I, the company submitted the PTR of 4 brands available having identical composition, which were already considered in the ceiling price fixation. The companies of those four brands did not file any representation / review against the ceiling price. M/s GSK also manufacturing and marketing Crocin Advance and following the ceiling price fixed by NPPA. Hence, the Hearing Authority is of the opinion that the contention of the petitioner company has got no merit and the review petition may be rejected.

6. **Government Decision:**

“The points raised by the petitioner company in their review petition have got no merit and stand rejected.”

Issued on this date, the 22nd day of December, 2016.

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

To

1. **M/s. Sun Pharmaceutical Industries Ltd.,
8-C, 8th Floor, Hansalaya Building,
16, Barakhamba Road, Connaught Place,
New Delhi-110 001.**
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. **Sr. PPS to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **Technical Director, NIC with the request to upload the review order on the Department's website**