

**No. 31015/63/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

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

Subject: Review applications of M/s Sun Pharmaceutical Industries Ltd. and M/s Sun Pharma Laboratories Ltd. against price revision of their various products vide NPPA order No. S.O. 1039(E), dated 01.04.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

**Ref: 1) Review applications dated 27.04.2017
2) NPPA notification under review S.O. 1039(E), dated 01.04.2017
3) Record Note of discussions held in the personal hearing held in the matter on 10.10.2017.**

1. These are two petitions under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Limited and Sun Pharma Laboratories Ltd. (hereinafter called the petitioner) against notification S.O. No.1039(E), dated 01.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) revising the ceiling prices of their various products.

2. The petitioner has contended as under:-

I. Company is aggrieved by the said notification as the revision of ceiling price has not taken the legit sense and provision of DPCO, 2013; hence the revision in ceiling price does not appear appropriate. Company sought a review of the same on following grounds:-

(i) Schedule-I of DPCO 2013 was revised on account of NLEM-2015, notified by Department of Pharmaceuticals S.O. 701(E) dated 10.03.2016. There were various medicines included for the first time in the NLEM list, and hence forth in Schedule-I. And by virtue of para 4 of DPCO 2013, ceiling price calculation of all such scheduled formulations should not have been factored with WPI of calendar year 2015, i.e. - 2.7105%.

(ii) However, WPI @ -2.7105% were factored in ceiling price calculation by NPPA in all the scheduled formulations including first time added formulations, which were being notified from 10.03.2016 onwards.

(iii) Further, ceiling price notified on 01.04.2017 does not show any rollback of WPI @ -2.7105% in formulations added first time in NLEM 2015.

- II. In view of above, Company requested this Department to issue necessary directives to consider recalculate the ceiling price of the captioned formulations.

3. **Comments of NPPA:**

- I. Ceiling price notified for their products vide S.O. 1039 (E) dated 01.04.2017 are 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 for their products vide S.O. 1039 (E) dated 01.04.2017 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.	<p>Company referred to the ceiling price notification for their products, which have been notified first time upon their inclusion in NLEM 2015 vide S.O. 701 (E) dated 10.03.2016 under DPCO 2013 and consequently their price was fixed vide S.O. No. 1039(E) dated 01.04.2017. Company is of the opinion that price calculation of such scheduled formulations should not have been factored with WPI of calendar year 2015, i.e. -2.7105%.</p> <p>However, WPI @ -2.7105% were factored in ceiling price calculation by NPPA in all the scheduled formulations including first time added formulations, which were being notified in from 10.03.2016 onwards. Ceiling price notified on 01.4.2017 does not show any roll back of WPI @ -2.7105%. Company stated that they are aggrieved by the said notifications as the revision of ceiling price has not taken the legitimate sense and provision of DPCO 2013; hence the revision in ceiling price does not appear appropriate. Company pointed out that Schedule-I of DPCO 2013 was revised on account of NLEM-2015, notified by Department of Pharmaceuticals S.O. 701(E) dated 10.03.2016. There were various medicines included for the first time. As per the opinion of the company, ceiling price calculation of all such scheduled formulations should not have</p>	<p>NPPA notified the ceiling price for the products of M/s. Sun Pharma Laboratories Limited vide S.O. 1039 (E) dated 01.04.2017 to give effect of WPI as on 01.04.2017.</p> <p>In the 27th Authority meeting held on 29.03.2016 after deliberations, it was decided that price fixation of ceiling prices of all scheduled formulation in amended Schedule-I shall be done on the basis of data for August, 2015 in Pharmatrac. Since prices of August, 2015 form the basis of calculation, in order to arrive at the current prices, WPIs need to be factored in. Therefore, ceiling price was fixed and notified after giving the effect of WPI, which is reduction @ 2.7015% with effect from 01.04.2016. It was decided that this principle would be followed uniformly, while fixing the ceiling price of scheduled formulations under revised Schedule-I and the ceiling price will be effected from the date of notification. Such principle is being followed consistently for fixation of ceiling price under Schedule-I of DPCO, 2013.</p>

	been factored with WPI of calendar year 2015, i.e.-2.7105%.	
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III. Company has not challenged in any Court in respect of ceiling price fixation of their products vide S.O. 1039 (E) dated 01.04.2017.

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

- A number of formulations were included for the 1st time in Schedule – I as per NLEM 2015 as per so 701(E) on 10.03.2016. The ceiling prices for such formulations were notified for the first time under DPCO 2013. Therefore, WPI of previous calendar year should not be factored in ceiling price calculation as per Review Order no. 31015/91/2016-PI.I dated 06.03.2017 issued by the Secretary – Department of Pharmaceuticals, as attached in Review Application.
- However WPI for the calendar year 2015 and 2016 were factored in ceiling price calculation notification SO 1039(E) dated 01.04.2017. Ideally WPI of calendar year 2016 only should be factored in ceiling price calculation upon passing of 1 year after getting included in Schedule-I.
- The same is explained in the following table

Particulars	As Per NPPA	As Per Review Order Dated 06.03.2017
Average PTR	Rs. 100.0000	Rs. 100.00000
Less : WPI For 2015 @ -2.7105%	Rs. 2.7105	
Ceiling Price Notified For the 1st Time	Rs. 97.2895	Rs. 100.00000
Add : WPI For 2016 @ 1.97186%	Rs. 1.9184	Rs. 1.97186
Ceiling Price Notified on 01.04.2017	Rs. 99.2079	Rs. 101.97186

- Moreover in various formulations, product packs with less than 1% were included in ceiling price calculations which is beyond the provisions of DPCO 2013 as per various Review Order issued by the Reviewing Authority. Revised Ceiling Price of all such formulations are yet to be notified by NPPA after excluding all such formulations with less than 1% market share.
- NPPA have not implemented Review Order dated 06.03.2017 and referred the decision taken in their 27th Authority meeting held on 29.03.2016 which is much prior to issue of the said Review Order. There is no mention of Authority decision, if any, on the captioned matters post issuance of Review Order dated 06.03.2017.
- The company representative requested the authority to give necessary directives to NPPA to revise the Ceiling Price after
 - i. Rollback of WPI @ -2.7105% in formulations added for the 1st time in NLEM 2015
 - ii. Excluding all such formulations with less than 1% market share wherever included by NPPA vide their earlier Ceiling Price notification.

NPPA, in addition to the comments stated above, further stated that the SO 1039(E), dated 01.04.2017 was issued by NPPA only to give effect of Wholesale Price Index (WPI).

5. Examination:

The company's contention is that SO 1039(E), dated 1.4.2017 has been notified to give effect of WPI as on 01.04.2017 without giving any rollback of WPI minus 2.7105 in formulations added first time in NLEM, 2015.

5.2 In this regard, it is submitted that para 9(5) of DPCO, 2013 reads as under:

“The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule.”

5.3 NPPA has fixed the ceiling prices of all the products which have become scheduled medicines for the first time vide DoP's SO 701(E), dated 10.3.2016, as per para 9(5) of DPCO, 2013 and factoring WPI is in order, as the base data is of August, 2015. Hence, the grievance of the petitioner companies has got no merit and may be rejected.

6. Government Decision:

“Fixation of ceiling prices of all those formulations, which have become scheduled medicines for the first time, factoring WPI, is in accordance with para 9(5) of DPCO, 2013 and is in order, as the base data is of August, 2015 has been considered. Hence, the grievance of the petitioner companies about roll back of negative WPI has got no merit and stands rejected.”

Issued on this date, the 1st day of December, 2017.

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

To

1. M/s Sun Pharmaceutical Industries Limited,
8-C, 8th Floor, Hansalya Building,
15, Barakhamba Road, Connaught Place,
New Delhi-110001,
2. M/s. Sun Pharma Laboratories Limited,
Sun House, Plot No.201 B/1,
Western Express Highway,
Goregaon (E), Mumbai-400 063.

3. 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