

No. 31015/32/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhawan,
New Delhi 110 001

Subject: Discussions held with Indian Pharmaceuticals Alliance (IPA) on 6th June, 2016 in respect of Note (e) of NPPA's Price Fixation Notification S.O. 644(E), dated 02.03.2016.

NPPA issued price notification No.SO 644(E), dated 2nd March, 2016, revising the ceiling prices of scheduled formulations with negative Wholesale Price Index (WPI) with effect from 1st April, 2016. The notification was issued containing the following notes:-

“(c) The manufacturing/marketing company shall make corresponding reduction in the maximum retail price as per WPI under paragraph 16(4) of the DPCO 2013 and shall report to the Government in Form II of Schedule II of DPCO, 2013 within a period of 15 days of such revision. Non submission of Form II in this regard shall be construed as non-revision in maximum retail price as per WPI and the concerned manufacturers shall be liable to deposit the amount charged over and above the pre-revised/revised MRP, as the case may be, along with interest thereon from the date of overcharging.

(d) The ceiling price for the pack of the scheduled formulation shall be arrived at by the manufacturer in according with the ceiling price specified in column (5) of the above table (**table in notification SO 644(E), dt.2.3.2016**) as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V as per paragraph 24(2) of the DPCO, 2013.

(e) All the manufacturers of above mentioned scheduled formulations (**as contained in table in notification SO 644(E), dt.2.3.2016**) having MRP lower than the ceiling price specified in column (5) in the above table (**table in notification SO 644(E), dt.2.3.2016**) plus local taxes as applicable, if any, shall make corresponding reduction in the maximum retail prices as per the provision of paragraph 16(4).”

2. **Indian Pharmaceuticals Alliance (IPA) had submitted a representation cum review under para 31 of DPCO 2013 against the Note (e) of Price Fixation Notification SO 644(E) dated 02.03.2016.**

3. Being aggrieved by the said Note (e) and the directives given therein, their association submitted the following for and on behalf of all its Members with a request to take immediate remedial measure to redress their grievances

- a. The directives contained in Note (e) of the said Price Fixations Notification are an attempt to penalize those manufacturers who have already been selling their products below the respective Ceiling Price.

- b. Reduction from the existing MRP which is already below the revised notified Ceiling Price is not envisaged in the Scheme or under the provisions of DPCO, 2013. The same would be an unreasonable burden on the manufacturers; and
- c. The DPCO 2013 mandates reduction of prices only with reference to the Ceiling Price and not the MRPs.

4. They further submitted that directing the manufacturers to reduce the MRPs of their products which are lower than the respective Ceiling Prices on account of revision in WPI appears to be arbitrary and high handed and that such a directive by NPPA is in excess of the powers and authorities vested in it under DPCO, 2013.

5. **NPPA's Comments:**

Ceiling prices of 530 scheduled formulations has been notified as per provisions of the DPCO, 2013. Notes mentioned therein are integral part of notification and needs to be mandatorily complied with by all manufacturers. By said notification ceiling prices have been revised due to revision in WPI. In this connection, relevant paragraphs 16(1) & (4) of DPCO, 2013 are reproduced below-

“16. Revision of ceiling price of scheduled formulations.– (1) The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.

.....

(4) In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.”

In reply to para 3 to 8 of aforesaid review application of IPA, NPPA has stated that the contentions, interpretations and assumptions made therein are wrong, misconceived and denied. As regards Note (e) of said notification dated 02.03.2016, it is stated that it is in accordance with paragraph 13(3) and 16(4) of 2013. All manufacturers are required to reduce MRPs as per decline in WPI. Paragraph 13(3) and 16(4) of DPCO, 2013 clearly stipulates that there shall be corresponding reduction in the MRP which has to be affected by all manufacturers before the date of notification and sell all stock including pre-manufactured stock from date of notification as per revised prices.

6. **Examination:**

Para 16(4) of DPCO reads as follows :-

“In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.”

In the phrase, “**reduction in maximum retail price**”, going by the definition of **maximum retail price (MRP)** given in para 2(r), it clearly means the **ceiling price** [or the **retail price** plus local taxes plus local taxes and duties, applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack.]. Further, in this paragraph, the “**retail price**” is defined in para 2(z) as the price fixed by the Government for a new drug under para 5. As per Para 2(d) “**Ceiling Price**” means a price fixed by the Government for scheduled formulations in accordance with provisions of this Order.

Also Para 16(1) of DPCO says that “***the Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.***”

The NPPP-2012, approved by the Cabinet, clearly stipulates in its para(x) that “in case of decline in the WPI, a corresponding reduction in the **ceiling price** shall be **obligatory**. The NPPA itself will also separately **notify the revised ceiling prices** as applicable as on 1st April each year and in case any company has not fixed the prices not consistent with the **revised ceiling price**, the NPPA will take appropriate action to have these revised.”

It is evident from the foregoing read with definitions as stated above that it is the ceiling price that has to be changed in respect of a scheduled drug by NPPA, i.e. those manufacturers selling their products above ceiling price are required to bring the price to the new level of ceiling price fixed by NPPA in the light of new WPI.

Therefore, the companies already selling their scheduled formulations lower than the ceiling price may not be required to further lower the prices of their products by applicability of negative WPI as they are already well within the ceiling price fixed by NPPA in the light of new WPI. Therefore, NPPA has clearly erred in inclusion of Note(e) in the SO, dated 2.3.2016.

7. **Government Decision:**

The WPI impact, whether increase or decrease, should be given effect to by NPPA by revising the ceiling prices of the scheduled formulations.

NPPA is therefore directed to revise the Ceiling Price of Schedule I medicines each year in accordance with the WPI revision. Individual companies/ brands/ medicines which are already having a MRP below or equal to such WPI adjusted Ceiling Price shall not be required to reduce the MRPs any further vis-a-vis the WPI.

NPPA's Note (e) of the SO No.644(E), dated 2.3.2016 be deleted from the S.O. No.644(E) dated 2.3.2016 with immediate effect.

Issued on this day, the 10th day of January, 2017.

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

To

1. Indian Pharmaceutical Alliance,
A-205, Sangam, 14B, S.V. Road, Santacruz West, MUMBAI-400 054.
2. The Member Secretary,
National Pharmaceuticals Pricing Authority,
YMCA Cultural Centre Building,
New Delhi – 110 001.

Copy to:

- (i) PS to Hon'ble Minister (C&F), Shastri Bhavan, New Delhi for information.
- (ii) PSO to Secretary (Pharma), Shastri Bhavan, New Delhi for information.
- (iii) Technical Director (NIC) for uploading the order on Department's Website.