



INDIAN DRUG MANUFACTURERS' ASSOCIATION ^{ole}

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Delivered in Secretary's office on 27/2/2015

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

18 February 2015

Dr. V.K. Subburaj, IAS,
Secretary to the Government of India,
Department of Pharmaceuticals,
Shastri Bhavan, New Delhi.

**Re: NPPA Office Memorandum F No. 19(81)/2015/NPPA/Div. II
dated 13-02-2015**

Dear Sir,

We refer to the Office Memorandum of National Pharmaceutical Pricing Authority (NPPA) published in their website for collecting price information of Ceiling Prices of 17 NLEM formulations under provisions of DPCO 2013 and requesting for PTR and MAT of September 2014.

Sir, as you will be aware, the Bulk Drug prices of many of these formulations were announced in November 2012 after a delay of over one year. Our Members had applied for formulation price revision in the month of November 2012. The application for formulation price increase was kept in abeyance by NPPA.

Since DPCO 2013 was announced on 15th May, 2013, it has superseded DPCO 1995. However, NPPA has continued announcing prices of those formulations under DPCO 1995. Due to this, manufacturers had already suffered losses as they could not revise the price as per the provisions of Para 10 (1 & 2), i.e. avail of revision in prices to reflect increase in WPI. Further prices of these formulations which were notified on 10th June 2013 under DPCO 1995 (even after DPCO 2013 was notified) without considering 100% MAPE i.e. the prices notified were also not as per the provisions of DPCO 1995. Due to this our Member- manufacturers were unable to take price increase as per the provisions of Para 10(1) of DPCO 2013 on 1st June 2013.

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Our Members dutifully implemented the price as notified and appealed to the Department of Pharmaceuticals for review. After considering the review appeal, the Department issued a Review Order in November 2013, directing NPPA to consider 100% MAPE while fixing Ceiling Price as per the provisions of DPCO 1995.

NPPA subsequently revised the prices of the formulations on 20 December 2013. As per the provision of Para 10(2), these manufacturers were eligible for price increase as per WPI only after one year from the date of gazette notification. As the revised prices were notified in December 2013, they could not avail of the WPI increase in the month of April 2014. We had submitted a representation dated 9 July 2014 to your office (copy enclosed) on this issue and also discussed the same in our meetings.

The 17 formulations listed in the OM dated 13-02-2015 which were in DPCO 1995 as referred above continue to be a part of the NELM list. Hence there is no need for NPPA to fix the prices for these products under any other provision of the DPCO 2013.

Para 10(2) under DPCO 2013 provides that:

"The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order, 1995 after 31st May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations."

Hence, as provided under para 10(2) of DPCO 2013, as quoted in the NPPA OM as above, the manufacturers have taken a price increase in the month of December 2014 or January 2015 only after over 2 years.

Sir, we may further reiterate that Para 9(6) of DPCO 2013 clearly indicates that for prices fixed under DPCO 1995, **the reference date** would be as per Para 10 of DPCO 2013.

The said Para 9(6) is reproduced below for ready reference:

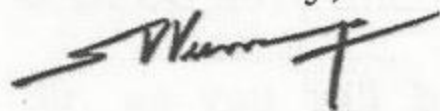
“Notwithstanding anything contained in this order, the reference date for the formulations which are part of the Drugs (Price Control) Order, 1995 shall be as per the provision of paragraph 10 of this order”

Therefore in light of the above, and since the methodology for fixing price for these 17 items that were under DPCO 1995 is clearly defined in DPCO 2013, we request you to intervene in the matter to keep the OM dated 13-02-2015 as referred above in abeyance and allow the manufacturers to implement the prices as per the provisions of DPCO 2013.

We seek your indulgence and look forward to your prompt action to avoid confusion amongst the manufacturers, the public and the Government authorities.

Thanking you,

Yours sincerely,



S V Veerramani
President

Encl: IDMA submission dated 9 July 2014