National Pharmaceutical Pricing Authority

NPPA invites comments of all the stakeholders / Industry Associations within a period of three weeks on the following draft guidelines for dealing with the cases of price revision of scheduled formulations under para 19 of DPCO, 2013

21/08/2014

(Jagdish Kumar)
Director (M&E)

Draft Internal Guidelines for dealing with cases of price revision under para 19 of DPCO, 2013.

In exercise of the powers conferred by paragraph 19 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394 (E) dated the 30th May, 2013, NPPA is empowered to fix/revise the ceiling or retail prices of both scheduled and non-scheduled formulations under certain circumstances, in public interest. Accordingly, ceiling prices / retail prices of formulations shall have to be fixed / revised by the NPPA in pursuance of paragraph 19 of DPCO, 2013. In this connection, NPPA could also cause enquiry, call for information as the case may be and fix / revise the prices of scheduled formulations, non-scheduled formulations and 'new drugs' if considered necessary so to do in public interest.

2. The 1st guideline related to inter - brand price difference and launch price of the non-scheduled single ingredient formulations used for anti-cancer, HIV medicines, anti-tuberculosis, anti-malaria, cardiovascular, anti-diabetics, anti-asthmatic; Immunologicals (sera/vaccines) etc was issued by the NPPA on 25.06.2014 under para 19 of DPCO, 2013, with the approval of the authority in its 147th meeting held on 16.05.2014.

3. In respect of ceiling price of scheduled formulations fixed based on market data under DPCO, 2013, it has been brought to the notice of NPPA that subsequent to price fixation, the prices of some of the APIs / drugs used in scheduled formulations have gone up substantially thereby rendering the production / sale of scheduled formulations totally unviable. The net effects of

significant increase in the input material cost / APIs is much beyond the level of price increase permissible based on WPI for the previous calendar year as provided in para 16 of DPCO, 2013. In cases of such scheduled formulations, short supply / non-availability of the drugs in some part of the country has also been reported during recent past. However, to deal with such kind of situation, there is no specific provision in DPCO, 2013 to revise the ceiling price based on price increase in input material / APIs except the price revision in public interest under para 19 of the said Order. As a result it has been decided to draft guideline for revision of prices of scheduled formulations under Para 19 of DPCO, 2013.

4. In this regard, it is mentioned that a meeting held in NPPA on 24.2.2014 with Pharmaceutical Industry Associations, the members also suggested for developing a mechanism to factor and compensate for abnormal rise in the price of raw material / APIs. Chairman, NPPA suggested that a background note may be prepared by the Industry suggesting various possible modalities, action points that could be considered and given to NPPA. The Industry, agreed to make workable suggestions and modalities in this regard but the same are still awaited.

5. The issue raised by the industry to revise the ceiling prices considering the abnormal price hike in the price of APIs has been examined in respect of scheduled formulations which are common to DPCO, 1995 and DPCO, 2013 keeping in view that (i) prices of these common drugs were earlier fixed under cost based mechanism prescribed in the DPCO, 1995 and are continued to be under price control under DPCO, 2013, (ii) prices of such formulations remains unchanged for a period of one year or so after announcement of DPCO, 2013, (iii) supply of such essential drugs should not be affected in the domestic market, (iv) mostly these low cost formulations are based on old molecules but are widely used drug, and (v) many instances have come to the notice of NPPA that these formulations were found is short supply in domestic market. Therefore, the following guidelines are proposed to carry out price revision in respect of common drugs under Para 19 in order to tackle such an extraordinary circumstances with a view to obviating the possibility of shortages etc and to make these drugs continue to be available in the domestic market in public interest.

(i) Price revision under Para19 shall be initiated only if the weighted average price of any API used in scheduled formulations based on the immediate last six month purchases goes up by more than 25% as compared to previous six months. The concerned company / companies having market share more than 50% may submit relevant purchase data to NPPA duly supported with evidences for revision of ceiling price, clearly demonstrating the impact of increase in price of API on the ceiling price of the scheduled formulation with specified dosage and strength.

(ii) NPPA shall examine the request / submission of the company and suitable recommendations for price revision based on the following formula.

Formula:

Increase in CP = [(R2 – R1) X DC X CF]

Where

R1 = Weighted average price of API based on six month purchases made prior to last six months.

R2 = Weighted average price of API based on purchases made during last six months.

DC = Per unit drug content as per label.

CF = Conversion Factor for API, if any.

Provided that increase in CP should not be more than twice of the increase worked out for annual increase in WPI, as applicable

(iii) Where increase in ceiling price works out more than twice of the increase worked out for annual increase in WPI, the cases shall be examined on case to case basis, as deemed appropriate.

(iv) The ceiling price so fixed shall remain valid for a period of one year from the date of notification after which annual price increase not exceeding WPI increase will be permissible as per provision of DPCO, 2013.

(v) After revision of ceiling price, the concerned manufacturer / importer / marketer shall submit quarterly return along with documentary evidences in respect of purchases of the API.

(vi) If the concerned company / companies fails to submit quarterly return or fails to satisfy NPPA for non-submission of quarterly return, NPPA may review the case for withdrawal of notification even within a period of one year.

21/08/2014.
(Jagdish Kumar)
Director (M&E)