



INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, POONAM CHAMBERS, 'A-WINGS' DR. A.B. ROAD, WORLI, MUMBAI-400 018, INDIA

Delivered on 30/01/2013 -

Phone : 91 - 22 - 24974308
91 - 22 - 24944624
Fax : 91 - 22 - 24950723

E-mail : idma@vsnl.com
Website : www.idma-assn.org

PARTNERS IN GLOBAL HEALTHCARE

14 January 2013

The Secretary,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
Government of India,
Shastri Bhavan,
New Delhi.

Subject:-Withholding price revisions/fixation of bulk drugs and formulations in general and in particular after the announcement of National Pharmaceutical Pricing Policy-2012

Dear Sir,

We understand from our Members that a number of price applications are pending with the NPPA for fixation/ revision in prices of bulk drugs and formulations based thereon for a period varying from six months to over one and half years. We request you to take up the matter with NPPA to clear all pending applications before the announcement of the new Drugs Prices Control Order based on NPPP-2012. You will agree that DPCO 1995 continues to be in operation till it is repealed by the New Order and the manufacturers should be free to submit applications and NPPA needs to function as per the existing DPCO 1995.

2. In the Drug Policy 1994, vide paragraph 22.7.4(ii) it is prescribed that *"the time frame for granting price approvals will be 2 months for formulations and 4 months for bulk drugs from the date of receipt of the complete prescribed information."* However, we understand that NPPA has invariably not been able to adhere to this time frame. NPPA has also been seeking information from industry beyond what is prescribed for such approvals/revisions in the formats, which the industry has been complying with.

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3. When the new Policy provides for freeze on ceiling prices of formulations notified under DPCO, 1995, normally all ceiling prices should have been up to date based on increase in prices of bulk drugs contained in fixed dose combinations. Keeping such requests for revisions pending for a long time could lead to shortage of vital drugs which cannot be the objective of any Policy. It is only mass production which can help to bring down costs and prices of drugs in the country. New policy also records that such prices are already the lowest in the world.

4. There should have been provision in the policy for updating current prices of bulk drugs and formulations before applying freeze of one year as envisaged. This would have enabled the producers of bulk drugs and formulations based thereon to bear the brunt of price increases for one year only for which compensation would have become available later. Therefore under situations where there is regular inflation, prices of bulk drugs are bound to increase and this aspect cannot be lost sight of as the main aim of the Government is to give fillip to production of bulk drugs and formulations. Production of scheduled bulk drugs declined substantially under DPCO,1995 and those bulk drugs which are in the NLEM -2011 and are presently under DPCO,1995 would be the worst sufferers. Since prices of these bulk drugs and formulations have not been updated, they would be frozen at such levels that it would not be viable to produce them at all. One year freeze on ceiling prices of such formulations would virtually cripple the producers financially. As it is already known and acknowledged that 47 out of the 74 drugs under DPCO are not being produced in the country anymore due to unremunerative prices, any delay in announcing the price revision will further bring down the production of current scheduled drugs due to unviable production.

5. We further understand from our Members that price fixation/revision of bulk drugs and formulations based thereon like Levosalbutamol, Pheniramine Maleate, Chloroquin Phosphate etc have been pending with NPPA for a substantially long time. Besides there are applications for revision in prices of formulations which have been kept pending as they involved increases in prices. Since DPCO based on NPPP-2012 is yet to be announced, the process of revising prices of bulk drugs and formulations should have been continued. Since the concept is to fix a single price for specified pack, the composition prices fixed for individual manufacturers also need to be factored in the ceiling prices which would

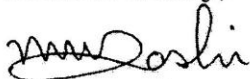
be frozen. All these aspects merit consideration before taking effective steps to implement new Policy.

6. We urge you that the disposal of pending applications for revision in prices of bulk drugs and formulations with the NPPA be expedited in a time bound manner and the receipt and disposal of such applications be continued till the new DPCO based on NPPP-2012 is notified as also the notification for applying freeze on prices for one year.

Kindly keep us apprised of the decisions taken in the matter so that we can inform our members.

Thanking you,

Yours faithfully,

A handwritten signature in black ink, appearing to read 'M U Doshi', written in a cursive style.

M U Doshi
President