INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

Received 26.11.14

19th November 2014

Mr. Injeti Srinivas, IAS
Chairman,
National Pharmaceutical Pricing Authority,
Department of Pharmaceuticals,
1, Jai Singh Marg, New Delhi.

Dear Sir,

Sub: Inviting Comments of All Stakeholders on Draft Proposal for Display of Distinguishing Mark and Ceiling Price/ Unit in respect of Scheduled Drugs under DPCO 2013 – IDMA Representation thereof

Ref: File No. 16(1)/2013/Div-III/NPPA 14 November, 2014

We refer to your draft proposal as above and thank you for giving us an opportunity to offer our comments.

We appreciate that NPPA is making efforts to promote consumer awareness, which the Indian Pharma Industry has been supporting all along.

However, the manner in which this is being considered is not practical and implementable, as it raises many issues which would defeat the very purpose of our providing affordable efficacious medicines to the consumers.

The concerns that need to be addressed are as follows:

1. The Drugs and Cosmetics Rules under Rule 96 (xi) stipulates as follows:

> *"[(xi) In addition to the other particulars which are required to be printed or written under these Rules, the label of innermost container of the following categories of drugs and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than 1mm in width and without disturbing the other conditions printed on the label under these rules, namely: –*
>
> *Narcotic analgestics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules 'G', 'H', and 'X' whether covered or not in the above list."*

Over and above what exists in the Drugs and Cosmetics Rules as above, your proposal for a distinguishing mark (may be a bold red strip with the words "DPCO Scheduled Drug" printed on it in black ink) would mean that the scheduled drugs will need to carry two red lines which would create more confusion among the consumers.

2. For all packs which are very small, it would not be possible to add any additional field or lines. The size of the packs of ampoules, strips etc are very small and the requirements under the Drugs and Cosmetics Rules 96 and 97 regarding declarations to be made on each pack of drug is mandatory. And this 'distinguishing mark would not be able to fit in, in addition to all the declarations already required to be displayed on each such pack.

3. The draft proposal also mentions that the pack will carry the information on ceiling price per unit additionally along with the MRP already printed as per DPCO 2013 Rules. This would be totally confusing to the consumers as they are not aware of the state-wise VAT taxes (local taxes) added to the ceiling prices. This could also create ill-will and chaos among the consumers, as they naturally would prefer to pay the lesser printed price, i.e. the ceiling price and not the MRP, which they need to pay.

4. Also, when the Supreme Court has ruled that no pack should be available at two different prices at the same time to avoid confusion among the consumers, how is it mandatory to print the ceiling price and MRP on the same pack and expect the consumer to understand the working of DPCO to calculate the MRP to be paid?

5. All the packs and labels of scheduled drugs will have to be changed and artworks redesigned and printed reprinting of labels/ cartons/ foils, etc. to incorporate the new suggestions, entailing additional costs running into hundreds of crores, which are not covered under DPCO 2013.

6. In addition to preparation of art work, which is a onetime cost, the cost of packing material will also go up.

7. Regarding invoking Legal Metrology Act 2009 and the Legal Metrology (Packaged Commodities) Rules 2011, you would be aware Drugs are exempted from the provision of these Rules under Rule 26(c). And this exemption stems from the very fact that there already exists under the Drugs and Cosmetics Act more than adequate labeling provisions so that the labeling provisions under the Packaged Commodities Rules would be redundant. If the exemption is removed, then all Drugs available in the market will also have to additionally comply with these Rules and be governed by the size of fonts and principal display concepts etc. embodied in the Legal Metrology (Packaged Commodities) Rules for declarations.

8. A drug which falls under the scheduled category for one manufacturer as a 'new drug' may not necessarily be a scheduled drug for another manufacturer. This will have some drugs with red line and the same drugs without the red line and will only add to the confusion among the consumers & medical doctors.

In view of the facts and concerns mentioned above, it would be more pertinent to consider better and more practical methods of publicizing the provisions of the DPCO, of fixing ceiling prices of formulations and publicizing those prices of scheduled formulations as well as of non-scheduled formulations.

We earnestly request you to withdraw the draft proposal in the interest of the Public, the Manufacturers and the Regulatory authorities.

Thanking you,

Yours sincerely,

S V Veerramani
President