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INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

13 February 2014

Dr G N Singh,
Drugs Controller General (I),
Central Drugs Standard Control Organization,
FDA Bhawan, Kotla Road,
New Delhi.

Dear Dr Singh,

Sub: Schedule H1 - Implementation date

We thank you for inviting us to your important meeting on Streamlining the process of Regulatory Approvals on 24th January 2014 at Delhi and providing us an opportunity to discuss various issues on regulatory matters with you for resolving the same.

One key concern of our Members discussed was the Gazette Notification GSR 588(E) dated 30th August 2013 notifying certain classes of drugs under the newly created Schedule H1 with a requirement to print two warnings on the packs of the product. The notification, as specified therein, comes into force six months after the date of publication in the gazette. Thus it is clear that the said warnings have to be printed prospectively on the packs of the products manufactured after 1st March 2014. Despite this clear position, there is some apprehension in the industry about the implementation due to certain trade associations writing to the manufacturers to clarify whether the warning is required to be printed on the products lying in stock in the market and whether the old stocks should be sold or be returned to the manufacturers.

Such unilateral interpretation and communication by the trade associations would result in shortage of the essential medicines to the patients and cause unnecessary confusion in the minds of trade and patients.

We therefore request you to kindly issue instructions to the State FDA authorities clarifying the following:

1. The notification is effective prospectively from 1st March 2014
2. The need to print warning is effective only from the batches Manufactured after 1st March 2014
3. The old stocks already in the retail market can continue to be sold till replaced with the new stocks after 1st March 2014.

We once again seek your indulgence in resolving the issue of implementation of Schedule H1 notification as above and request you to consider our suggestions in resolving the issue. It will indeed be helpful if suitable circulars are sent on this to CDSCO Zonal Offices / State Drug Controllers and through them to the Trade. This will ensure that the industry continues providing quality affordable drugs to the poor patients without any stoppage.

We are sure, your usual proactive assistance and valuable guidance will go a long way in helping us to resolve all these issues.

Thanking you,

Yours sincerely,

S V Veerramani
President