



# INDIAN DRUG MANUFACTURERS' ASSOCIATION

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## INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

May 20, 2015

**Dr. G.N. Singh,**

Drugs Controller General (India)  
Central Drugs Director General of Health Services,  
FDA Bhavan, Kotla Road,  
New Delhi - 110 002

### **Sub: Labeling of Topical Products**

Dear Sir,

### **Greetings from Indian Drug Manufacturers' Association.**

We refer to the labeling requirements of medicines as described in part IX of Drugs & Cosmetics Rules 1945. As per the rule 96, manner of labeling the following particulars shall be either printed or written in indelible ink on the label of the innermost container of any drug and on every other covering:

- I) The name of the drug.
- II) Net Contents
- III) The strength of active ingredients
- IV) The name of the manufacturer and the address of the premises of the manufacture.
- V) A distinctive batch number
- VI) Manufacturing license number
- VII) Date of manufacture and date of expiry

The rule 96(B) (iv) provides for certain exemptions if the drug is in an ampoule or a similar small container.

In India, many drugs are marketed in various topical dosage forms like ointments, gel & creams which are packed in tubes. These tubes can be of various sizes. The prevailing industrial practice world-wide as well as in India is batch number and either date of manufacture or date of expiry is printed or embossed on the crimp of the tube. Most of the time, "Date of Manufacture" is printed on the crimp with a statement on the tube explaining that "Date of Expiry will be X years from the Date of Manufacture". This practice is followed as the space available on the crimp of the tube is limited and hence either "Date of Manufacture" or "Date of Expiry" is printed / embossed on the tube.

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**INDIAN DRUG MANUFACTURERS' ASSOCIATION**

We draw your kind attention that this practice is being followed almost from the commencement of pharmaceutical manufacturing and packaging of the tubes in India. Please also note that this practice is followed by all the manufacturers including multi-nationals as well as small scale manufacturers. We also would like to mention that all the required information is being provided in the manner of labeling and it is being observed without any inconvenience to the patients for last many decades.

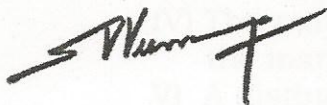
Some of our manufacturer members have brought to our notice that in the recent past, objection is being raised by Drug Inspectors who are asking to print / emboss "Manufacturing Date" as well as "Expiry Date" on the tube. As most of the tubes marketed in India has only one date, these products are being declared as misbranded.

We request you to kindly look into the matter and issue necessary guidelines so as not to declare such drugs as misbranded and amend the drug rule as necessary so as to regularize the practice.

We are confident that you would consider our request at your earliest convenience and issue the necessary guidelines so as to avoid unnecessary hardship faced by our members. It would be our pleasure to let you know for any further information, if required, in the matter.

Thanking you.

Yours sincerely,



S.V. Veerramani  
President