CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (SSI) (Regd.)

(Registered Office : A-3/314, First Floor, Paschim Vihar, New Delhi-110063)

Chairman Office : **BELCO PHARMA** 515, MIE, Bahadurgarh-124507, Haryana E-mail : pkgupta_cipi@yahoo.in Website:www.cipi.in

Chairman :
P. K. Gupta
Cell : 09811106606

Secretary General :
R.K. Jain
Cell : 09927900920

Constituent Members

All India Small Scale Pharmaceutical Mfrs. Association, New Delhi-110054

All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

Himachal Drug Mfrs. Association, Baddi -173205

J&K Smal Scale Drug Mfrs. Association, Jammu - 180010

Kerala Pharmaceuticals Mfrs. Association, Kerala - 679322

Organisation of Pharmaceutical Mfrs., Hyderabad - 500038 (A.P.)

Ludhiana Drug Mfrs. Association, Ludhiana - 141001

Rajasthan Pharmaceutical Mfrs. Association, Jaipur - 302006

The Pharmaceutical Mfrs. Association of Tamilnadu, Chennai - 600015

Pharmaceutical Mfrs. Association (Kanpur), Kanpur, U.P.

West Bengal Small Scale Pharmaceutical Mfrs. Association, Kolkata - 700033

Baghat Pharmaceutical Mfrs. Association, Solan - 173212

BBN Industries Association, Baddi - 173205

Federation of Pharma Entrepreneurs, Gurgaon - 122015

Association of Pharmaceutical Mfrs., Haridwar - 249403

Devbhoomi Association of Pharmaceutical Mfrs., Dehradun - 248002

Karnataka Drugs & Pharmaceutical Mfrs. Association, Bangalore - 560001

Sirmour Pharma Mfrs. Association, Paonta Sahib - 173025

Ambala Pharmaceutical Mfrs. Association, Ambala City - 134003

Gurgaon Pharmaceuticals Mfrs. Association, Gurgaon - 122001

Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

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To,
All CIPI Office Bearers, CIPI Members & Pharmaceutical Manufacturers

Dear Members,

Greetings of the Day,

We are please to mention below the latest developments and amendments made by the Ministry of Health, NPPA and other government agencies.

As you are aware that in the past meetings held with DCGI in his office at FDA Bhawan, DCGI has given directions on many issues which are as follows:-

1. The storage conditions of the drugs to be maintained by the manufacturer to end user as mentioned on the label or mentioned in the Schedule P of Drugs & Cosmetic Act. All the drugs should be stored as per the label condition in your manufacturing plant and further sent to the wholesaler on the same storage conditions as mentioned. The same conditions should be adhered by the retailers. Storage condition in the country is worst and hence effects our medicines and when the sample fails the whole liability is of the manufacturer.
   Therefore we must start this practice immediately.

2. DCGI pointed out that all the drugs which are already manufactured or to be manufactured stability studies must be carried out both accelerated and real time. Earlier it was applicable on the patent and proprietary medicines only. Now the word patent and proprietary has been removed and inserted the word drugs i.e. all drugs whether pharmacopeial, patent and proprietary stability studies must be carried out.

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