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

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

Mailing Add. : 128, Lok Vihar Appts., Vikaspuri, New Delhi - 18. Fax : 011-28538801, E-mail : sk_aries2001@yahoo.co.in, Website : www.cipi.in

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

Chairman :	*Co-Chairman :*	*Secretary General :*	*Treasurer :*
P. K. Gupta	**Dr. A.M.D. Nambudiri**	**B. Sethuraman**	**R.K. Jain**
Cell : 09811106606	Cell : 09847030460	Cell : 09444083286	Cell : 09312285623

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 Small 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

Ref. No.: CIPI/2014/612
15th January 2015

Hon'ble Sh. Jagat Parkash Nada ji
Ministry of Health and Family Welfare
Govt. of India, New Delhi

Subject: **Meeting with Hon'ble Health Minister of India with vice-Chairman of CIPI on dated 17th January, 2015**

Hon'ble Sir,

We are the apex body of the manufacturers of drugs and pharmaceuticals in the Country representing small and medium scale units. All the major State level associations of the manufacturers in this segment are our federating members representing about 7000 units.

We thank you and appreciate the initiative of your esteemed office for having an interactive meeting on a short –notice. The idea of this meeting is to for streamlining in the process of regulatory approvals and enforcement from the office of Drugs Controller General India and the State Drugs Controller of each states through a transparent and accountable management.

Pharmaceuticals industry in India wants that the issue mentioned below have transparency and the jobs to be done within a a prescribed period by the office of Drugs Controller General of India.

1. **Approval of additional item for domestic market and for Export Market.**
   Pharmaceuticals industry depends its 80% business on the approval of additional items, for the approval of additional item for domestic market, export market, new drugs, & FDCs drugs. Presently, there is a dispute between Pharmaceutical Industry and Drugs Controller General India on the issue of approval of additional items and the matter is pending in Himachal Pradesh High Court and Punjab Haryana High Court.

   Our request to you Sir, kindly resolves the issue amicably. We are not interested to move into the courts.

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2. Issuance of various certificates including grant of COPP certificates

Sir, industry needs various certificates issued by the SDCs and DCGI. These certificates from both the offices are not easily issued. Lot of time consumed to complete the formalities by that time certificate needed for the purpose is failed.

Many times industry needs these certificates very urgently to participate in the hospital business in India as well as internationally. To be participated in the domestic market. We need current certificate from the SDC and DCGI whereas for export, we need COPP certificates. Due to non-availability of these certificates, we are loosing our business in the domestic as well as international trade.

If we get these documents in time our export can be jumped 20 % immediately.

Sir, we need your help in this matter.

3. As per provision of the act, inspection of the pharmaceutical industry should be done once in a year by the State and the Central.

The difficult part of such inspection is that every time, inspecting team not satisfied with the documents and is being changed on every year. Similarly, inspecting team directed us to install more machines and equipment's, there are other various issues raised by the inspecting teams. Every time whenever inspecting team changes, new issues arise. This issue does not give any effect to the quality of drug. Our request is to be detail performa of each job be prepared by the SDC or DCGI for uniform inspection throughout the country.

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4. **Prosecution done by Drugs Controller Officer**

Prosecution done by Drugs Controller Officer in case of any sample failure either defects are of a minor nature. Drugs Controller officer of respective state launch prosecution under section which have maximum penalties. State Drugs Controller and Drugs Controller Officers who launch the prosecution never study others sections whereas in these sections for such minor issues, prosecution is not recommended. There are so many issues which we will sent to your office in details.

Recently we hold a meeting of our executive members in Mumbai and it was decided that a conference be arranged and request is to made to a Hon'ble Health Minister for to become as chief Guest of the conference. This conference will be arranged in Delhi and members of the confederation shall attend the conference from all the parts of the country.

We humbly request kindly accept to be as a chief Guest of this conference, Conference can be arranged any date which is convenient to you.

Regards

P K Gupta
Chairman
Confederation of Pharmaceuticals Industry