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 Small Scale Drug Mfrs. Association, Jammu - 180010

Kerala Pharmaceuticals Mfrs. Association, Kerala - 679322

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Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref. No.: CIPI/2017/308
04-12-2017

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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3. As we have already informed that now Pharmacovigilance chapter shall be implemented by all the companies. Therefore it is our humble request that whenever any seminar or workshop is conducted by the Ministry of Health kindly attend. CIPI is also planning to conduct seminars on Pharmacovigilance, the exact schedule will be conveyed to you.

4. DCGI has cleared that if any unit is coating or packing the drugs of another company or doing any process which is a part of manufacturing then such companies also require to get the manufacturing license under the Drugs & Cosmetic Act.

5. We recall all of you that in the past DCG (I) issued a letter to all the SDC's of India. In that letter DCG (I) has directed that all the technical staff should take training and get certified by the LSSSDC before August 2017. This Scheme is under PM – Skill Development Program.
   We have requested to DCGI that the time period of 6 months may kindly be extended for certification under this scheme. For more information you can contact to
   Mr. Anshul Saxena
   Director- NOS and Curriculum Advisory, LSSSDC
   Email: Anshul.Saxena@lsssdc.in
   Tel: 9650433002/011-41042407/408/410

6. It is also noted that all Manufacturers who are manufacturing narcotics and psychotropic substances kindly send their yearly stock statement either to SDC or to Deputy Drug Controller of FDA Bhawan, Kotla Road, New Delhi-110002.

7. List of new drugs approved by DCGI from 01/01/2017 to till date is enclosed as **Annexure A**.

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8. Letter from DCGI dated 24th November 2017 regarding amendment in Drugs & Cosmetics Rule is enclosed as **Annexure B.** The letter is self explanatory if you have any query then you can contact us.

9. Letter issued by DCGI to all State/UT Drugs Controllers dated 27th November 2017 is enclosed as **Annexure C.**

10. List of Drugs, Medical Devices and Cosmetics declared as not of Standard quality /Spurious/Adulterated/Misbranded, for the month of October, 2017 is enclosed as **Annexure D.**

11. Draft rules have been published by the authorities. In the said rules the number of drugs has been increased in Schedule H i.e. from 538 to 551. Enclosed as **Annexure E.**

12. News published in Times of India, New Delhi dated 28th November regarding stress test is enclosed as **Annexure F.**

13. News printed in Hindi newspaper is enclosed as **Annexure G.**

14. We have received notification on draft rules regarding mentioning of Schedule to various drugs, enclosed as **Annexure H.**

15. NPPA has released order fixing the prices of more drugs enclosed as **Annexure I.**

16. We have received a letter from Ministry of Chemical and Fertilizers, Department of Pharmaceuticals in which it is requested to send your proposal for Union Budget 2018-19.
You are requested to kindly send your proposal for the Union Budget at the earliest so that we can submit it to the authorities.

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17. On the request of our Honorable member Mr. D. Parthasarathy from Dollar Company we have written a letter to various authorities taking into account his suggestions on GSTR2. The copy of the letter is enclosed as **Annexure J** for your record purpose.

18. Letter from NPPA dated 21/11/2017 is enclosed as **Annexure K**.

With regards

For Confederation of Indian Pharmaceutical Industry

P.K. Gupta
Chairman