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,

Ref. No.: CIPI/2015/1215
31st January 2016

Sh. K. L. Sharma
Joint Secretary
Ministry of Health &Family Welfare,
Nirman Bhawan,
New Delhi

Sub: **Objections against Notification dated 29.12.2015, Draft Rules to amend the Drugs and Cosmetics Rules, 1945**

Dear Sir,

We are in receipt of above said notification and noted that Ministry of H&FW has decided to amend the various Rules concerning Fees for new Licenses, renewal of Licenses, various approvals, import registration under the following rules:

Rule 24A, 34, 34A, 59,62,62C, 67, 67A, 69,69A,75,75A,82,85B,85E, 85D, 90, 122A, 122B, 122D, 122DA, 122F, 122K, 129A, 138, 138A, 139AD, 150B, 151-1

We strongly object the steep hike in the fees under various rules of the Drugs and Cosmetics Act due to the following reasons:

1. We as manufacturer of Pharmaceutical formulation and bulk drugs are important stakeholders of Pharmaceutical industry in India.
2. The increase in fees for all types of approvals as suggested in the draft notification is very steep and exorbitant. It will hurt the small scale manufacturers the most. The proposed hike in fees has been made on adhoc basis and is not based on uniform formula for all the cases.
3. No rationale has been given in the draft rules for increasing the fees by 10 times of the existing fees in most of the cases.
4. We are of the opinion that this high increase in fees, may force to cut in production by the small scale industry and this share shall be in the account of Large Pharmaceutical companies and the prices of Drugs shall be so high which will become unaffordable by poor people. Whereas we are

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pledged to manufacture and supply pharmaceutical formulation on affordable price.

5. It is a well known fact that about 35% drugs are exported by small scale units and this steep hike in fees may affect the units who are in the field of exports. As a result, exports may decline and will have a negative effect on the Indian Pharmaceutical industry.
6. The purpose of present Government which is announced by Hon'ble Prime Minister of India Mr. Narendra Modi i.e. Make in India, Startup India, Jan Aushidhi, Affordability of Medicines, Availability of Medicines shall be failed.

Our Suggestion:

However, we do not mind if the Ministry of Health and Family Welfare reasonable increase the fees for various approvals, registration between 10% to 25% of the prevailing fees.

It is our humble request in view of the above facts, the proposed hike in fees may not be implemented in the interest of Pharmaceutical industry of India, Exports and for the people of this country where 70% people are under below poverty line may not be able to purchase costly drugs manufactured by Large Houses or Multinational companies.

Regards

For Confederation of Indian Pharmaceutical Industry

P. K. Gupta
Chairman

CC:

1. Dr. G.N. Singh, Drugs Controller General of India [DCGI]
2. Sh. Jagat Prakash Nadda, Health Minister, Ministry of Health and Family Welfare
3. Sh. Anant Kumar,Minister of Chemical & Fertilizer
4. Smt. Nirmala Sitharaman, Minister of State for Commerce & Industry