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

Shri Raj Kumar, 1st October, 2015
Under Secretary GOI,
Department of Pharmaceuticals,
New Delhi-110 001

Sub: Pre – Budget Proposals – 2016-17

Sir,

This has reference to your letter No.31019/04/2015-PI-II dated 10.08.2015 on the subject cited above.

A. Our two major and crucial proposals relating to small and medium segment of the pharmaceutical industry are as under:

(i). Central Excise small scale exemption notification no. 8/2007 -CE dated 1.3.2007 –increase in exemption limit The said exemption notification provides for small scale units for exemption from payment of central excise duty on first clearances up to an aggregate value not exceeding Rs. 1.5 crore made on or after the 1st day of April in any financial year subject to certain conditions.

Our proposal is that (i). the S. No. 1 of the Table of the said notification be changed as under:

" First clearances up to an aggregate value not exceeding three hundred lakh rupees made on or after the 1st day of April in any financial year."

(ii). Paragraph 2 (iii) of the said notification may be changed as under:

" the manufacturer shall not avail the credit of duty on inputs under rule 3 or rule 11 of the CENVAT Credit Rules 2002 (hereinafter referred to as the said rules), paid on inputs in the manufacture of the specified goods cleared for home consumption , the aggregate value of the first clearances of which, as calculated in the in the manner as specified in the said Table does not exceed three hundred lakh rupees"

(iii). the paragraph 2 (vii) of the said notification may be changed as under:

" the aggregate value of clearances of all exciseable goods for home consumption by a manufacturer from one or more factories, or froma factory by a one or more manufacturers, does not exceed rupees eight hundred lakh in the preceding financial year"

(iv). and the paragraph 3 of the said notification may be changed as under:

" For the purpose of determining the first clearances up to an aggregate value not exceeding three hundred lakh rupees made on or after the 1st day of April in any financial year, mentioned against Serial No. 1 of the said Table , the following clearances shall not be taken into account, namely:-(a), (b), (c), (d)" (where no change required)

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

Justification: The Notification under reference is dated about eight year hence and needs to be revisited now. The value of clearances of one hundred and fifty lakh rupees which was set earlier, if calculated with reference to increase in inflation in past eight years, will amount to more than three hundred lakh rupees as suggested by us. Further in the case of pharmaceuticals sector where clearance are to be valued under section 4 (a) (MRP less abatement) of the Central Excise Act the limit is reached soon at the present price levels of medicines, therefore the small scale manufacturers for whose benefit the notification was promulgated are not able to avail any exemption. The amendments suggested by us are in the interest of the small scale sector and will be of great help in their growth.

(ii).Investment limit in plant and machinery for MSME: The MSME Act prescribes investment limits in plant and machinery for units to be categorized as micro, small or medium enterprise. A unit having an investment up to Rs. 5 crore in plant and machinery is categorized as a small scale unit.

In this matter our submission is that for pharmaceuticals segment of industry the amount of Rs, 5 crore is not adequate to establish a small scale units taking in to consideration present regulatory requirements such as revised schedule M, GLP and up gradation of the unit by installation of modern and up dated machinery and equipments to ensure the quality of the medicines to be manufactured. The compliance with these requirements results in higher investment in plant and machinery but does not necessarily result in increase in the production capacity.

B. Other proposals – Central Excise :

Ii). Central Excise Duty on drug formulations and API: The CE Duty on drug formulation is levied @ 6% whereas duty on API and other inputs used in the manufacture of formulations is levied @ 12.5%. This results in accumulation of CENVAT credit due to under utilization resulting in losses.
Suggestion: (a). Accumulated credit may be refunded by a simple and transparent self declaration by manufacturers and (b) may be allowed to be utilized for payment of service tax.

(ii). Abatement of medicaments: An abatement of 35 % is allowed on MRP for calculating assessable value for payment of CE duty vide notification 49/2008 C.E. (N.T.). The same is not sufficient considering the peculiar nature of the industry – the only industry to operate under GDP (Good Distribution Practices). Even much higher abatement is allowed to other industries such as:

- Paan Masala containing tobacco: 55%
- Mineral Water: 45%
- Glazed tiles: 45%

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

Suggestion: the abatement may be increased to 50% on MRP of the drug formulations so to address the issues relating to GDP and cold chain requirements.

(iii). Control samples and physicians' samples: At present CE duty is levied on such samples under section 4 A in the same manner as are sold in the market. Control samples are never sold and are required to be preserved throughout their shelf life. Similarly physicians' samples are not for sale but to be given to the needy patients by doctors free of cost.
Suggestion: Control samples and physicians' samples may be granted exemption from payment of CE duty.

(iv). Government supplies / institution sale to be assessed under Section 4 instead of section 4A of the Act at present: These types of sales are not governed by MRP as the prices are on the basis of competitive bidding which are much lower than the MRP. However CE duty is levied on the basis of MRP less abatement.
Suggestion: Medicines supplied to the Government / Government institutions should be assessed for payment of duty under Section 4 of CE Act. Further a suitable provision may be made for exemption of the medicines from payment of CE duty when supplied free of cost during national calamities.

(v). Expired Medicines: Rule 12 of CE Rules, 2002 requires for advance permission for destruction of expired medicines for duty remission.
Suggestion: The requirement of advance permission which is given in writing by CE Department may be replaced by advance intimation by manufacturers and a representative of CE may be present to supervise destruction of expired medicine.

C. Other Proposals – Customs:

(i).Exemption from execution of Bank Guarantee for imports against advance authorization shall not be denied even when the matter sub-judice.

(ii). Import of capital goods, raw materials, reference standards, consumables imported for R&D may be exempted from basic customs duty and other duties. The list of exempted goods may be updated keeping in line with the international developments.

D. Direct Taxes:

(i). Section 35 (2AB) grants weighted average deduction of 2 times of the expenditure on R&D activities as specified in Eleventh Schedule. This does not

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

cover expenditure on filing ANDA, product registration in foreign countries, consultation fee for patent registration overseas and cost of land and building for establishing R&D Centre.

Suggestion: (i).The expenses listed above should also be covered under section 35(2 AB) to be eligible for weighted deduction.

(ii). the weighted deduction may be increased to 2.5 times from 2 times at present for drugs and pharmaceutical sector.

(ii). **Profit from export turn-over**: Earlier under Section 80 HHC income tax on profit proportionate to export turn -over was exempted. The same may be restored so that exports from the country to be competitive in international markets.

E. **Service Tax:**

(i). In the case of intermediary service provider such as commission agents or brokers etc, the place of services provided is located outside India, therefore no service tax is payable. However service tax demands are raised in such cases. This may be clarified to the field force so that disputes may be avoided.

(ii). In order to boost exports, pharmaceutical manufacturers, in many cases, need to establish foreign offices. In such case under Circular No. 180/06/2014-STdated 14.10.2014 Service Tax Department has initiated inquiry in the pharmaceutical industry and seek to levy service tax on the expenses incurred by such foreign offices which is only in the nature of reimbursement by the Indian parent. This should be kept out of purview of Service Tax.

F. **Incentivise SME Pharmaceuticals Segment:**

The Ministry of Commerce & Industry may reimburse the following expenses incurred by SME units involved in export of pharmaceuticals:

(i). Expenses for US FDA inspection for approval of their units for exports to USA or other regulated markets.

(ii). Expenses incurred for product registration in foreign countries specially regulated markets

(iii). Expenses paid for attestation of documents by the Diplomatic Missions of foreign countries in India which are required for product registration or to accompany the export consignments.

G. **Procurements from Small Scale Sector:** The MS&ME Act provides for procurement of at least 15 % of the requirement of the Government and PSUs from small scale manufacturers. The same is not being followed by PSUs. A

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

Mechanism may be put in place by the Government to monitor this provision such as asking PSUs to furnish data to the Government about their annual procurement from small scale sector.

Thanking you,

Yours truly,

(Sudesh Kumar)

Confederation of Indian

Pharmaceutical Industry