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

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All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

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Gurgaon Pharmaceuticals Mfrs. Association, Gurgaon - 122001

Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref. No: CIPI/2015/762
13th March 2016

Shri K.L. Sharma,
Joint Secretary to the GOI,
Ministry of Health & Family Welfare,
Nirman Bhawan,
New Delhi-110011

Sub: Prohibition of Fix Dose Combination Drugs for human use under section 26 A of the D&C Act 1940

Sir,

This has reference to the Gazette Notifications Nos. SO - 705 (E) to SO - 1048 (E) dated 10th March, 2016 issued under Section 26 (A) of the Drugs & Cosmetics Act, 1940 prohibiting the manufacture for sale, sale and distribution for human use of 344 drug formulations with immediate effect.

The drug formulations which have been prohibited as per the above notifications fall into two categories i.e.

(i). formulations licensed for the manufacture by State Licensing Authorities for sale and distribution in the country without approval from the Drugs Controller General (I), and

(ii). formulations which are already approved by the Drugs Controller General (I) for manufacture for sale and distribution in the country.

In this regard we would like to draw your attention to a circular dated 15.01.2013 issued by the Drugs Controller General (India) F. No. 4-01/213-DC (Misc13-PSC) addressed to All State /UTs Drugs Controllers stating as under:

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" .....

In respect of other FDCs falling under the definition of "New Drug" licensed by State Licensing Authorities before 1.10.12, without the permission of DCG(I), it has been decided that the DCG(I) will ask all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO with in a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the Country.

As regards the new FDCs, if any, licensed by the State Licensing Authorities after 01.10.2012 without approval of DCG(I), the same will be considered for being prohibited for manufacturing and marketing in the country. ....."

The aforesaid letter addressed by the DCG(I) to SLAs is the subject matter of Court Cases filed by Haryana Pharmaceutical Manufacturers Association before the Hon'ble High Court, Punjab & Haryana, Chandigarh. In this matter the Hon'ble High Court have restrained the Government from taking any coercive action against the manufacturers arising out of the contents of the aforesaid letter of DCG(I) till final disposal of the petitions. The Court Order is valid even now as the petition has not been disposed of due to lack of clarity and response from the Government.

Thus notifications issued under serial number SO-705 (E) to SO 1048 (E) dated 10.03.2016 containing products which were approved by SLAs before 1.10.2012 are under stay of Punjab & Haryana High Court order cannot be banned or prohibited.

The prohibition, as per notifications, has been exercised on the basis of the recommendation of the expert committee constituted by the Government which has opined that drugs have no therapeutic justification. The industry has not been given an opportunity to present their views before the ban was imposed and also the findings of the Expert Committee were not disclosed or put in public domain. Therefore the whole process lacks transparency.

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Further a number of formulations which are being prohibited now are already approved by DCG(I) as New Drugs. Before granting such approvals, the therapeutic justification, safety and efficacy of such formulations must have been assessed by CDSCO. Now these formulations, without citing any scientific reasons, have been prohibited for manufacture and distribution in the Country. The Industry is unaware of the causes which have prompted the Government to prohibit the formulations which are already approved by DCG(I) for the manufacture and marketing in the Country.

Further prohibition imposed on such formulations is not in lines with the contents of letter F. No. 4-01/213-DC (Misc13-PSC) dated 15.01.2013 issued by DCG(I) where safety and efficacy and also therapeutic justification of such formulations approved by CDSCO has not been questioned.

The Notifications in question prohibits the manufacture for sale, sale and distribution of the formulations. Thus the stock lying at various distribution channels and lying with the manufacturers for sale and distribution cannot be sold. Further the raw material, excipients and packing material lying with the manufacturers will go as a waste resulting huge losses.

The manufacturers have not been given a reasonable time for liquidation of the stock before prohibition comes into force which is contrary to the normal practice. This is contrary to an earlier ruling of the Hon'ble Apex Court in the matter of E-Merck vs Government of India of the year 2001 where it was held that suitable time may allowed to the manufacturer so that stock lying with the manufacturer and at distribution channels may be liquidated before the prohibition order comes into force.

The sudden and blanket ban on such formulations which are being widely prescribed and used by the patients will result in utter confusion amongst the prescribing physicians and patients.

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The FDCs in question are being manufactured under the valid manufacturing licenses from the respective licensing authorities and for prohibiting such formulations to be manufactured due notices are required to be served on the manufactures for cancellation of their licenses giving reasons for such cancellation as per procedure in the D&C Act and rules there under. Also an opportunity is to be given to them by their licensing authorities to represent their cases. Thus the laid procedure has not been followed for such a ban as per the D&C Act and Rules.

In any case, the small scale manufacturers will be the most affected because of their limited range of products which are being manufactured by them from last several years. They are holders of the valid manufacturing licenses for such formulations which were granted to them by their licensing authorities. Such licenses have been renewed from time to time on payment of the requisite fee and other documents as required by the SLAs. Such units due to prohibition orders will face closure and need to be compensated for the losses to be incurred by them with no fault on their part.

Now in view of the above, the notifications under reference may please be reconsidered and should be kept in abeyance so that a proper procedure is followed, the manufactures shall be given an opportunity to present their cases and where prohibition is considered necessary, sufficient time for liquidation of the stock may be given.

Further a suitable compensation package be announced for loss of business of the manufacturers for sudden ban on manufacturing and marketing of their products which have been licensed for manufacturing and marketing by their incensing authorities and also by CDSCO.

Thanking you,
Yours sincerely

(P.K. Gupta)
Chairman