

CONFEDERATION OF INDIAN PHARMACEUTICALS INDUSTRIES (ssi)

CIRCULAR No. – 3

Drug Regulatory: There are news that the Ministry of Health is going ahead to establish an independent National Drug Authority. There is a proposal to hire US FDA to advise the Government on how to modernize and overhaul the system for an effective drug control mechanism including training the personal. US FDA is also contemplating to have a proper office in India as more and more products are being sourced from India and US FDA want to keep a close watch on the manufacturers from whom the products are being sourced. With clinical research outsourcing from India becoming a destination for NCA, Government is tightening control on clinical research organization with making inspection mandatory. USFDA is also carrying out inspection of certain CROS before certifying such organizations for out sourcing.

Irrational Combinations: Discussion on irrational combinations is hoting up once again. The state of Kerala is carrying out a study on irrational combinations being marketed in the state. This could be a move to put a ban on sale of such combinations in the state.

Impotence Drugs: USFDA is examining 42 reports of blindness among some men using impotence drugs Viagra and cialis manufactured by Pfizer and Eli Lilly respectively. Among 42 cases, 38 are users of Viagra and 4 are users of Cialis. This type of blindness is called non – arteritic anterior ischemic optic neuropathy (NAION). It can occur in men who are diabetic or have heart disease and use Viagra or Cialis. There are no such reports of blindness among the users of third impotence drug Levitra. Prescribing information of Cialis refers to vision problems as an uncommon side effect. Pfizer is in discussion with USFDA to add a disclosure to Viagra's label to state that in rare cases, men taking Viagra had developed blindness.

Schedule 'H': Ministry of Health has issued notification containing a revised list of drugs which have been included in schedule 'H' to D & C, Rules, 1945 : The list contains 517 entries. A note in the notification states that preparations exempted under note to schedule 'X' shall also be covered under schedule 'H' and that preparations containing substances of schedule 'H' even ophthalmic and ear / nose preparations containing antibiotics and / or steroids are also covered. Preparations intended for topical or external use have been excluded.

Sale of Medicines in cut strips : FDA, Maharashtra has issued circular asking the manufacturers to prepare the labels with manufacturing date, expiry date, batch No. in such a way so that in the event of sale of product in cut strip the information remains intact.

CIPI activities: The confederating members of CIPI went on all India strike on 30-05-05 as a solidarity move against MRP based excise duty, the strike / bandh was a grand success. The event was covered widely by print media in respective states.

MRP based CE Duty: To further press their view points, CIPI had sent communications to Secretary, Ministry of small scale Industries, Dr. Montek Singh Ahluwalia, Mr. L.K. Advani against the levy of excise duty on maximum retail price of the medicines. Punjab small drug

manufacturer thru Members of Parliament from the state and thru C.M. Punjab had mounted pressure on the Government for seeking relief on MRP based Central Excise. The Ministry of Small Scale Industries has taken up the matter with the Ministry of Finance. A communication has sent to the Revenue Secretary containing the following proposal:-

- i) Limit for excise free clearances for small units may be raised to three crores, or
- ii) Excise duty on medicines may be reduced to 8% from 16% at present.

Schedule 'M' - CIPI had written to Union Health Minister drawing his attention to the fact that Ministry of Health has not responded to objections / suggestions submitted by CIPI on behalf of more than 5000 units in the country. Further in the representation to Union Health Minister, it was stated that the Government has not invited us for discussion so far and the time left for implementation of Schedule 'M' is very little.

West Bengal Small Drug Manufacturers had mounted pressure on the Government for setting up a review committee for schedule 'M'. Their office bearers were camping in Delhi for more than a week.

Ministry of Health notified on 30.06.05 Drugs & Cosmetics (Amendment) Rules confirming the draft schedule 'M' Rules. CIPI once again forcefully presented the matter to Small Scale Industries Ministry with clipping of news items of notices issued to small scale units by their respective licensing authorities on the basis of CIPI's representation. Small Scale Industries Minister has written to Health Minister to constitute a committee to look into the grievances of small scale manufactures.

New Drug Policy: The Ministry of Chemicals and Fertilizers has invited suggestions from all the Associations of manufacturers of Drugs and Pharmaceuticals including CIPI for drafting new drug policy of the country. CIPI has sent circular to all its federating members for sending their suggestions for which replies are awaited.

Price Control Mechanism: The Government is exploring alternative to DPCO for price control on drugs. On this subject a meeting was called by Ministry of Chemicals and Fertilizers. In this matter, Small Scale Industries Ministry has asked CIPI to express their views on:

1. Control on prices of drugs other than schedule drugs under DPCO.
2. Control on trade margins on distribution of drugs.

Members are requested to send in their views.

Lack of communication: There is very poor response from the federating members on various issues particularly suggestions about the new drug policy. Similarly the Chairman has circulated a questionnaire for updating the details which has not been responded by the members. On annual subscription payment front the response is very poor.

CIPI must send in their suggestions to the ministry on new drug policy. If we do not reply, it will reflect lack of vision in CIPI.