

CONFEDERATION OF INDIAN PHARMACEUTICALS INDUSTRIES (ssi)

Circular No. 14

1. WHO Guideline on Malaria Medicines : World Health organization has issued a communiqué asking pharmaceutical companies to stop marketing and sale of single drug formulation of the drug artemisinin used in prevention of malaria. This has been done, according to communiqué, to prevent malaria parasite from developing resistance to this drug. WHO want combination therapy instead of mono-therapy with artemisinin for effective control of malaria. Indian IPCA and Cipla are the major manufacturers who are marketing the mono-therapy formulation for want of approval of combination drug from the Regulatory Authority of the Country.

2. National Drug Authority : The Ministry of Health & Family Welfare has moved a cabinet note containing a proposal for setting up National Drug Regulatory Authority. NDA shall function on the lines of US FDA for which some experts from USA are advising the Government. The Drugs Controller General (India) will head NDA as per proposal. The proposed divisions of NDA shall consist of drug safety, licensing, clinical research, medical devices, Indian system of medicines.

It is hoped that the NDA will be in the place in about one and a half years after the legislation has been passed in the Parliament.

NDA would be independent according to sources and shall have representatives from the Government, Industry and Legal. It is also understood that NPPA is expected to remain a separate entity.

3. Pharma Advisory Forum : A Pharma Advisory Forum has been formed under the Chairmanship of Mr. Ram Vilas Paswan, Union Minister for Chemicals and Fertilizers. This Forum consists of members from consumer representatives, chemists Associations and pharma industry. The first meeting of the Forum is scheduled to be held on 11th Feb., 2006. The points for discussion are pricing mechanism, consumer problems and draft pharmaceutical policy.

4. Problems of Small Scale Pharma Sector : CIPI has once again written to the Mr. Abani Roy, Mr. Prakash Karat and Mr. A.B. Bardhan about the present problems of small scale sector. The detailed letter has dwelt upon the following points:

- (i) Reduction of excised duty to 8% from present rate of 16%.
- (ii) Increase in excise free clearances for small sector from RS. One Crore to Rs. Five Crore.
- (iii) Expeditious announcement of the funding scheme for schedule 'M' compliance.
- (iv) Expeditious passage of SME bill by the parliament.
- (v) No coercive steps be taken against the units wanting time for implementation of Schedule 'M' due to lack of funds.

The representation given to the Ministry of Small Scale Industries has been examined by the Ministry and suitable recommendations sent to concerned Ministries.

CIPI has also written to the Dy. Chairman of Planning Commission pertaining to excise duty on drugs and increase in the limit.