

CONFEDERATION OF INDIAN PHARMACEUTICALS INDUSTRIES (ssi)

Circular No. 13

Date : 14.01.2006

(1) **Ayurvedic Drugs:** Health Science Authority, Singapore has issued warning to the public to not to consume four traditional Indian medicines – Rheuma-7 capsules, Diabecon tablets, Diabecs capsules and diabet Guard Granules as these, according to the warning, contained excessive amount of lead and mercury. The Government of India has asked for full details of tests carried out so that the results may be crossed checked in the country. Ayurvedic Drugs of Indian origin are facing similar problems in USA also. Recently the Department of Ayurveda, Yoga & naturopathy, Unani, Siddha and Homoeopathy (AYUSH) has made it mandatory to test every export batch of purely herbal ayurveda, siddha and unani drugs for heavy metals. The permissible limit for arsenic, lead and cadmium will be as recommended by WHO publication “Quality Control Methods of Medicinal Plants & Materials”. In case of mercury, the permissible limit will be one ppm. These conditions shall soon be made applicable to the products sold in India also.

(2) **Cough Syrups:** A clarification has been issued by the Drugs Controller General (I) that cough syrups that contain codeine within permissible limits do not fall under the purview of Narcotic Drugs and Psychotropic Substances Act and Rules 1985. These products according to the clarification fall under the schedule ‘H’ of the Drugs & Cosmetics Rules, 1945 and do not attract the provisions of NDPS Act. The permissible limit for the codeine is 2.5% per dose unit. Corex marketed by Pfizer and Phensedyl marketed by Nicholas Piramal are the leading brands.

(3) **Merck –ICMR Collaboration :** Merck & Co. and Indian Council for Medical Research (ICMR) are to collaborate to study Merck’s investigational cervical cancer vaccine, GARDASI (trivalent human papillomavirus type 6, 11, 16, 18) in the Indian population. This understanding was announced jointly by Prof. N.K. Ganguly, Director General, ICMR and Merck’s Indian Managing Director Leonard Tauro.

The agreement covers designing the study, making the vaccine available by Merck for study and a joint after completion study to assess the role of the vaccine on Indian population. Cervical cancer is caused by Human Papillomavirus (HPO). This is the most common type of cancer in India with more than 1,30,000 new cases reported every year – mostly women.

(4) **Generic Market :** In the next three years drugs worth US\$ 65 billion will go off patent in US and Europe. A study report prepared by Assochem visualizes tremendous scope for Indian pharmaceutical exporters and expects a 18% growth in exports from India. In terms of volume, the exports of from India may grow to Rs.30,000 crore in the year 2007-08 from Rs.16,000 crore in the year 2004-05. The report predicts that generic market may be a major growth story for the Indian pharmaceutical industry and it is expected that the growth will be around 11 % for the next 3 years by which time the volume of Rs.39,000 crores in the year 2004-05 may grow to Rs.60,000 in the year 2007-08.

5. National Manufacturing Competitiveness Council: In order to make the manufacturing sector competitive in the country and to take on the international competition, the council has recommended to the Finance Ministry as under:

- rates of excise duty may be reduced so that central and state indirect taxes on goods shall be around 20%. The present aggregate incidence is around 29%.
- the peak rate of duty of customs may be reduced to 10% and the Government should further announce a schedule of phased reduction of these rates.
- 4% counter veiling duty imposed in the budget for 2005-2006 may be extended to all import.

6. From EEE to EET : At present designated small saving schemes and instruments under section 80C of the Income Tax Act are enjoying a three step exemption i.e. EEE – these savings are exempted from payment of tax at the time of investment, the income from such scheme is also exempt and the amount payable at the time of maturity is also exempt. In the forthcoming budget, the Government is likely to amend this practice so that at the time of maturity, the amount payable shall be taxed i.e. EET. A committee constituted by the Government for this purpose has already submitted its report. The proposal may be effective from 1st April, 2006. It will have a prospective effect. Therefore, savings before the cut off date shall be exempted from tax deduction at the time of maturity.

7. Data Protection : CIPI has prepared a draft proposal on data protection to be sent to the Ministry of Chemicals & Fertilizers which is reproduced below. Suggestions, if any, from the members may be forwarded to the Chairman within a week from the date of this circular.

*The Joint Secretary,
Ministry of Chemicals & Fertilizers,
Department of Chemicals & Petrochemicals,
Shastri Bhawan,
New Delhi-110001.*

Re: Data protection to Derivatives

Dear Sir,

There are news afloat that the Government is considering to grant data protection to the variations of the same drugs which are nothing but the different salts and derivatives

launched under the garb of a new chemical entity (NCE) by the patent holder. This tactic is resorted to by MNCs to delay the entry of the generic in to the market of their drugs which are going off patent in the near future. This in medical parlance is called ever greening of a patent. These derivatives so pushed as NCE may be polymorphs, metabolites, isomers or analogues of the same drug having no therapeutic advantage.

Patentability of derivatives or ever greening of patents is opposed in several countries worldwide including Europe, Australia and Canada. Australia has stiff panel provisions in it

regulations for drug companies that resort to ever greening of patents. European Union has sent directives to the member countries that derivatives and other incremental changes to the existing active substances would not be patentable.

The Indian Patent Act also have provisions under para 3 (d) according to which derivatives which are nothing but an incremental form of an existing active substance, can not be patented.

In view of the above , we strongly feel that there should be a distinction between the patented and non patented drug as far as the data protection is concerned . A derivative of an existing drug when not patentable shall not be considered for data protection.

In addition to the above, NDDS which is a change of the drug delivery of an existing drug shall also be spared from data protection.

We trust that the views expressed by the industry shall be taken in to consideration while formulating the policy for data protection to NCEs.

Thanking you,

*T.S. Jaishankar
Chairman,
Confederation of Indian Pharmaceutical Industry (SS)*

8. Investment in small scale units : Inquiries have been received from Member Associations whether HVAC will form part of plant and machinery for the purpose of calculation of investment limit of one crore to be qualified as small scale unit.

The Ministry of Commerce & Industry under notification No. SO857 (E) dated 10.12.1999 as amended by notification SO 1109 (E) dated 13.10.04 defines a small scale industrial undertaking as an undertaking in which the investment in fixed assets in plant & machinery, whether held on ownership terms or on lease or on hire purchase, does not

exceed rupees one crore. Thus while calculating the investment of rupees one crore only plant and machinery is to be included and not all the fixed assets. Plant and machinery consists of those machines and equipments which are directly used in the manufacturing process of the goods manufactured

HVAC system has no role to play in the manufacturing / processing of goods. Therefore, does not fit into the definition of plant and machinery., Its role is to provide an environment which is conducive to manufacturing so that quality of drugs during the process is maintained. Therefore value of HVAC system cannot be included while calculating investment limit of rupees one crore.

It is further clarified that excise free clearances under central excise rules are available to all units whether small scale or large scale provided turnover does not exceed Rs.4 crore in a financial year. This concession is not related to investment limit in the unit. In other words

benefit of excise free clearances can be availed even after losing the status of small scale unit under Industrial Policy.

The members may be aware that SME Bill is awaiting to be passed by the Parliament. This Bill contains a provision by which investment limit for a small scale industrial undertaking will be raised to Rs. five crore from Rs. One crore at present.

9. Pharmaceutical Policy 2006 : The Ministry of Chemical & Fertilizers has declared a draft Pharmaceutical Policy (Part A). This part contains issues other than statutory price control. Part – B of the Pharmaceutical Policy will be issued at a later stage which shall contain provisions for price control on drugs. Some of the important features of the Pharmaceutical Policy announced by the Government, are as under :-

i) Trade Margins: 8% for wholesaler and 16 % for retailer on drugs which are under cost based price control (both for branded & generics). For drugs not under cost-based price control, margins are 10% for wholesaler and 20% for retailer in the case of branded drugs and in the case of generics 15% for wholesaler and 35% for retailer. All calculations shall be on the basis of MRP of drugs.

ii) Excise Duty : Excise Duty on Drugs to be reduced to 8% and Excise free limit for clearances to be increased to Rs.5 crores.

iii) M.R.P. : In due course all the drugs shall have M.R.P. inclusive of all the taxes.

iv) D.P.C.O.: The Government shall come out with a new D.P.C.O. to be known as 'Drugs & Therapeutics (Regulation) Act'. This Act will give appropriate powers to the Government for approval of brand-names of the drug formulations in addition to other controls on pricing of drugs.5.

- 5 -

v) Bulk Procurement by Government : In this part the system for bulk procurement has been laid down as under :-

- Procurement in the form of generics
- Schedule 'M' compliance of manufacturers
- Minimum three years track record
- Post award inspection
- Third party quality assurance
- Lower price of 65% of the price fixed by NPPA under cost based price control and 50% of MRP in other cases. This will be applicable both for generics and branded drugs

(vi) Control on Pharmaceutical Brands : Branding of drugs and therapeutics to be brought under the control of Central Drugs Regulatory System at present under the charge of Drugs Controller General of India.

(vii) Quality Certification of Drugs : The suggestion is to introduce a quality system of drugs like ISI or Agmark. Such certification will be issued by the Central Drug Regulatory Authority on submission of B.E. or B.A. data by the manufacturers.