

CONFEDERATION OF INDIAN PHARMACEUTICALS INDUSTRIES (ssi)

Circular No. 16

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Pharmaceutical Policy 2006 : We have made enquiries at the Ministry level in this matter. A note has already been prepared by the Ministry of Chemicals & Fertilizers and has been circulated to the Cabinet Ministers. It is clear that all the essential drugs as per the list will be brought under some kind of price control. This may be a combination of the following:

- freezing the prices at the current level based on the average price of 5 leading brands.
- ceiling on the trade margins
- cost study by NPPA of the leading brands and fixation of prices taking into consideration profit and trade margins.

This will be in addition to the fixation or ceiling prices of the scheduled bulk drugs and their formulations. The list of scheduled drugs may also be revised.

We also understand that the note circulated by the Ministry seeks approval for reduction of excised duty on medicines from 16% to 8% and also for increase in the limit for excise free clearances from Rs. 1 crore to Rs. 5 crore.

The note in final shape will be placed before the Cabinet Committee and if approved, will be implemented. There is no need to go to the Parliament, as informed by the Ministry. In such an event no scope will be left for the Finance Ministry to resist the proposed changes in the central excise on medicines.

The provision for printing of prices inclusive of all the taxes has also been made a part of the note circulated to the Cabinet Ministers.

5% Interest Subsidy : In the draft pharma policy, it was declared that a subsidy of 5% on the interest rate shall be provided to small scale manufactures for technology up gradation and for requirement of funds for schedule "M" compliance. This scheme has not been announced by the Ministry of Chemicals and Fertilizers so far. CIPI has taken up the matter with the Ministry and has also sought the support of the Ministry of Small Scale Industries in this matter.

Problems faced by small scale manufacturers in pharmaceutical sector:

Mr. Jawhar Sircar, IAS has taken over as the Additional Secretary-cum-Development Commissioner in the Ministry of Small Scale Industries. CIPI has made a comprehensive representation to the Development Commissioner highlighting the problems being faced by this sector and has sought his active support for resolving the issues being faced by the manufactures. The text of the letter is being circulated to the Members.

Reduction in excise duty and increase in the limit of excise free clearances for Small Scale manufacturers : CIPI has made an other representation to the Union Finance Minister for:

- (i) reduction of excise duty on medicines from 16% at present to 8%
- (ii) increase in excise free clearance from Rs.one crore at present to Rs.5 crores.

These relief were originally recommended for the small scale manufacturers by the Task Force constituted by the Prime Minister of India.

Complete text of the letter addressed to the Finance Minister is being circulated to the Members.

Industry News :

- US FDA has cleared Merck's Cervical Cancer vaccine called "Gardasil Vaccine". The vaccine blocks infection caused by certain types of HPV (Human Papilloma Virus). HPV induces development of planter and genital warts on the skin and mucous membranes and also causes cervical cancer. Merck's vaccine targets four types of HPV which, it is believed, causes 70% of the cervical cancer cases and 90% of the genital warts. The approval is for use in girls and women of age group of 9 to 26 years. The treatment requires three doses of the vaccine over a period of 6 months. Each does costs US \$ 120.
- Indian pharmaceutical companies are looking to opportunities in biogeneric products which have gone off patent in EU and which are expected to follow suit in USA. These products are r erythropoietin, r insulin, r HGH and r growth colony stimulating factor. Wockhardt, Biocon and Dr. Reddy are likely to be benefited. The process of approval of biogeneric has already started in USA by approval of new version of the growth hormone omnitrope by US FDA.
- The Department of Technology has launched a scheme known as Small Business Innovation Research Initiative (SBIRI) Scheme. The aim of the scheme is to provide early stage funding to industries for high risk, innovative and / or commercializable product proposals. The members may get full details of the scheme at DBT website www.dbtindia.gov.in.
- In the years 2006 and 2007, Pfizer will lose earnings to the extent of US \$ 14 billions on yearly basis as a number of its products will go off patent during this period. Pfizer is also planning to launch about 10 new prescription drugs during this period. In order to meet its requirement of funds for prescription drugs, it has decided to sell-off its OTC business to the prospective buyers.

Legal :

FICCI view on local taxes : In reply to a communication from the Ministry of Finance inviting suggestion / views of FICCI of the competitiveness of the manufacturing sector, the chamber has suggested that all the local taxes in the country such as 'octroi' and entry taxes should be

made variable. The chamber wants that combined impact of all the indirect taxes shall not be more than 20%. The chamber has also suggested that state value added tax should be harmonized across all the sectors.

Spurious Drugs : The Bill on Spurious Drugs which was drafted by the previous Government got lapsed when the Govt. got unseated in the last elections. The new Government is now planning to re-introduce the Bill in which death penalty has been reduced to life imprisonment. Other changes proposed to be incorporated are amendment to D & C Act, 1940 and Rules which will result in higher amount of fines and to make the offences cognizable and non-bailable.

Taxability of REP Licenses / Duty Free Import – Authorization: The Constitution Bench of the Supreme Court has pronounced an important judgment in April, 2006 in the matter of Sunrise Associates Vs Government of NCT of Delhi and others. The court held that sale of lottery tickets did not involve sale of goods within the meaning of the Sales Tax Act, but at the highest end, a transfer of an actionable claim.

This will have a favorable implication for the exporting community as at present sales tax is applicable on transfer of Exim-scrips arising out of Export – Import Policy which were freely transferable. Now in the Export – Import Policy supplement, a Duty Free Import Authorization Scheme has been introduced effective from May, 2006 to allow duty free import of inputs used in the manufacture of the export products including fuel and energy. Such DFIA are transferable under para 4.4.6 of the Foreign Trade Policy once export obligation has been fulfilled. In view of the aforesaid ruling of the Apex Court, there should be no sales tax liability on such transfer of DFIA licenses. The development is being watched by the Industry.

Entry Tax : The constitution Bench of the Apex Court has pronounced the judgment recently against a petition filed by Jindal Stainless Steel Ltd. challenging the levy of entry tax by the State of Haryana on the goods entering the State and local areas in which State has been divided for the purpose of levy of the tax. The tax was levied in the month of Mar, 2000 under the Haryana Local Area Development Tax Act. The Act not only covers the vehicles bringing goods into the State but also carrying goods from one local area to another. Jindal Stainless Steel Ltd., challenged the Act pleading in their petition that the same was in violation of Article 301 and could not be saved under Article 304 of the Constitution.

Article 301 states that any tax that hinders the free movement of trade and goods between the States will be violative.

Article 304 contains exception for State Taxes if levied to recover the cost of facilities provided by the State and the quantum of tax be based on a reasonable relationship to the actual or projected expenditure on the cost of services or facilities. A state tax levied to boost the State revenue cannot be saved by Article 304 and is not good in law. The Trade & Industry is watching this development particularly the reaction of the State Governments which have levied such taxes to boost their revenue.