

Confederation of Indian Pharmaceutical Industry (SSI)

Circular No.: 11

Date: November 2005

- 1. Pre-Budget Memorandum:** A pre-budget memorandum drafted by the Sub-committee headed by Mr. P.K. Gupta has been handed over to the Ministry of Finance, Ministry of Chemicals & Fertilizers and Ministry of Small Scale Industries. The comprehensive memorandum which covers CIPI's views / proposals for the Union Budget 2006-2007, has already been circulated to the members.
- 2. S.S. Industry Performa :** The proforma received from the Ministry of Industries seeking information from CIPI has been submitted to them in which CIPI has asked for reduction in duty from 16% to 8 % and raising excise free limit to Rs.5 crores. The Ministry has sent their recommendations to the Ministry of Finance.
- 3. Subordinate Legislation Committee on schedule "M":** The Committee, as already informed to the members, soon shall be calling MOH, MOC & F and MOSSI for discussion. CIPI has already sent a circular to all the members to send inputs / suggestions needed in this matter. All the Members are once again requested to send the details asked for by 7th of Nov., 2005.
- 4. Representation of CIPI on the Governing Board of NIPER:** A representation has been prepared to be sent to the Ministry of Chemicals & Fertilizers so that CIPI may get representation on the Governing Board of NIPER. IDMA and OPPI already have their members on the Board as per information with CIPI.
- 5. Bird Flu Drug - Tami flue:** The Government is considering to invoke compulsory licensing provisions under patent rules, if need be, to allow Indian manufacturers to manufacture copy Tamiflu. Roche of Switzerland is the present patent holder of this drug which is used to treat human cases of bird flu. The drug is manufactured from a raw material which is available in China. There are fears that the avian flue may turn into an epidemic. The current strain which causes avian flue is H5N1 (influenza A virus) for which birds are the carriers and travels through air and can infect human. The pathogenic virus can kill upto 90% of the affected people if not treated in time.
- 6. New Labeling Norms for Herbal Medicines:** Union Health Ministry has issued a notification which requires every exporter of ayurvedic, unani and sidha medicines to test every batch of products for level of heavy metals like arsenic, lead, mercury and cadmium. The label on the products exported shall contain a declaration that levels of contents in the products for these metal compounds are within the permissible limits.

The permissible limit for mercury is 1 ppm. The permissible limit for arsenic, lead and cadmium will be as recommended by WHOP in their publication "Quality Control Methods for Medicinal Plants and Materials". The notification says that those who do not have in-house testing facility, may get the products tested at Government approved

testing laboratories. These provisions shall soon be made applicable for products sold in the domestic market.

7. **Sterile Devices are drugs:** The Ministry of Health & Family Welfare by a notification dated 6th Oct., 2005 has specified the following sterile devices intended for external or internal use in human as drugs :

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|--------------------------|---------------------------------------|
| (i) Cardiac stents | (ii) Drug Eluting Stents |
| (iii) Catheters | (iv) Intra Ocular Lenses |
| (v) I.V. Cannulae | (vi) Bone cements |
| (vii) Heart Valves | (viii) Scalp Vein sets |
| (ix) Orthopedic Implants | (x) Internal Prosthetic Replacements. |

A notification issued on 7th Oct., 2005 specifies that these drugs will be licensed for manufacture, for sale or distribution by the Central Licensing Approving Authority appointed by the Central Government - DCGI

8. **Image Building – S.S. Pharma Sector:** MIMS in their recent issue has published a list of drugs showing wide disparity between the prices of NMCs and Indian manufacturers. The list is re produced below for the reference of the members :

Amlodipine 50 mg

Zydus Cadila	Rs.15.10 / 10 tablets
Pfizer	Rs.60.00 / "

Levofloxacin 500 mg

Cipla	Rs.68.25 / 10 Tabs.
Aventis	Rs.950.00 / "

Ciprofloxacin 500 mg

FDC	Rs.36.00 / "
Ranbaxy	Rs.89.60 / "

Ramipril 50 mg

Novartis	Rs.55.00 / "
Aventis	Rs.97.02 / "

Gliclazide 80 mg

Jagsanpal	Rs.31.00 / "
Serdia	Rs.63.64 / "

Risperidone 2 mg

Torrent	Rs.16.94
Ethnor	Rs.270.00

Glimepiride 1 mg

Zydus Codial	Rs.9.87 / "
Aventis	Rs.55.76 / "

Letrozole 2.5 mg

Biochem	Rs.99.00 / "
Novartis	Rs.1815.00 / "

This price disparity can be effectively used by S.S. Pharma Sector to its advantage in image building process. My suggestions are as under for the comments from the members:-

- (i) The members should examine their cost structure for these drugs to match the lowest price and also work out any further discount which may be offered at the lowest price.
- (ii) CIPI after the above exercise is completed may write to the Ministry of Chemicals & Fertilizers and also to the Ministry of Small Scale Industries of their willingness to supply these medicines at lower prices.
- (iii) CIPI, in its letter to these Ministries, shall categorically state that these medicines offered by SS Pharma Manufacturers will match the safety, quality and efficacy parameters of MNC / large manufacturers.
- (iv) Further, CIPI in its letter may offer to the Government that the claim of S S Pharma manufacturers about the quality, safety and efficacy may be got substantiated by performing such tests as may be desired such as BE/BA etc.

I am sure, this will give a boost to the image of small scale manufacturers.

FBT: The Constitutional validity of FBT has been challenged by tax payers in their respective High Courts. The Central Board of Direct Taxes is now considering to refer the matter to the Supreme Court for opinion. Thus a request will be made to the court so that all the cases pending at High Courts may transferred to the Supreme Court.