

CONFEDERATION OF INDIAN PHARMACEUTICALS INDUSTRIES (ssi)

CIRCULAR No. -12

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Indirect Tax Rates : Ernst & Young in its world wide survey has found that among 68 countries, India has the highest indirect tax rate. According to the figures published by the Agency under the report titled “The Growing Burden”, the cumulative indirect tax burden in India works out to over 30% due to 12.5% VAT and 16.32% CE assuming that there is no cascading VAT or excise duty. The data reeled out in the report, in brief, is as below for 62 countries :

i)	Range of indirect tax burden	5% to 25%
ii)	Average VAT rate in 62 countries	16.4%
iii)	Highest Standard VAT Rate (Denmark, Hungary, Norway & Sweden)	25%
iv)	Lowest Standard VAT Rate (Panama, Singapore & Japan)	5%
v)	Standard VAT Rate in Europe	18.7%
vi)	Lowest Average Rate – Asia Pacific Region	10.5%
vii)	Other regional rates lower than average rates	
	- Africa	14.5%
	- America	14.8%

CST Amendment Bill : A CST (Amendment) Bill 2005 has been moved by the Ministry of Finance. The amendment bill contains the following important proposals:

- i) Constitution of an independent CST Appellate Authority (CSTAA). At present this function is done by the Income Tax AAR.
- ii) Appeals to the CST AA can be filed by an aggrieved person only against any order passed by the highest appellate authority of a State such as a Tribunal or a Court other than High Court.
- iii) It increases the time limit for filing an appeal from 45 days at present to 90 days with a further grace period of 60 days.

Health Care Cess : It is reported that the Ministry of Chemicals & Fertilizers is to propose to the Finance Ministry to levy a 1% cess on all Central taxes and levies. This cess will generate about Rs.3,200 crore which are proposed to be made available to health care sector.

Cancer Drugs : The Ministry of Chemicals and Fertilizers is targeting 28 anti-cancer drugs for price reduction. This list of such drugs has been prepared by All India Institute of Medical Sciences. The major drug manufacturers making these drugs have volunteered to cut prices of some of the anti-cancer drugs by 10% to 15%.

Some of the costliest drugs are (i) Glive (Novartis chronic myeloid leukaemia), (ii) Mabthera (non-Hodking lymphoma – Roche), (iii) Herceptin (breast cancer –Roche),

(iv) Paclitael (breast cancer – Eli Lilly), (v) Viraferan (blood cancer –fulford India), (vi) Campto (colorectal cancer-Pfizer).

Regulatory System : At an annual entrepreneurs meet, Dr. Kiran Mazumdar Shaw, President of the Association of Biotechnology-Led Enterprises (ABLE) said that country's regulatory system for clinical research is impeding early drug development. She was for implementation of the Mashelkar Committee report on the regulatory system and for removal of lacunae in the regulatory regime. She said that there is lack of adequate knowledge of pre-clinical research in India.

Medi City : Dr. Naresh Trehan, leading Cardiac Surgeon is setting up a multi-specialty Med City in healthcare sector in Gurgaon. Medi City will be built on a 43 acre campus on the lines of facilities such as Mayo Clinic and Johns Hopkins in the U.S.A. The Medi City is expected to be operational by 2007. It will have a teaching hospital and research institute, will offer nursing degree, will have 1800 bed facility for cardiac care and 19 other medical specialties.

GE India out of its US \$145 million India Development Fund, would provide to Medi City high-end diagnostic tools, clinical R & D and utility services. This is GE's first collaborative venture worldwide. According to GE, by 2012 India will need to add over 7,50,000 beds to meet the demand for improved healthcare infrastructure.

Export Promotion for Pharmaceuticals : Ministry of Chemicals and Fertilizers is drawing plans so that USFDA approved manufacturing plants in India get support in securing entry in big international markets like Japan. The Government shall take up the matter with these nations so that import registration norms for such manufacturing units in other countries may be eased. India has more 70 USFDA – approved units in the country which is largest in numbers outside USA. In order to boost export of pharmaceuticals, the Government is helping Pharmaceuticals Export Promotion Council to set up their offices in these countries.

Clinical Research : Institute of Clinical Research (I) has tied up with U.K. based Synexus Clinical Research, the largest patient recruitment organization in Europe. ICR (I) and Synexus will undertake clinical trials for pharmaceutical companies and CROS on global basis in phase II to IV and will have country's first Site Management Organization (SMO) for recruitment of patients. The trials by synexus are conducted on patients and not on healthy individuals. ICR (I) has campus at Dehradun, Mumbai and Bangalore where courses are conducted for medical professionals or individuals having qualifications in the field of pharmacy in all the aspects of clinical trials on pharmaceutical products. Dr. S.K. Gupta, ex-Head, Department of Pharmacology, AIIMS, New Delhi is the Dean of ICR (I).

SAIL Tender : Steel Authority of India Ltd. Has been floating tenders where eligibility was restricted to top 100 ORG ranking firms. Subsequently on the basis of representation from the Industry, this criteria was revised and all those units which adhere to schedule 'M' were made eligible to participate in tender.

However, in the Tender floated by Rourkela Hospital, the eligibility criteria was again for 100 TOP Ranking ORG firms. CIPI has taken up the matter with SAIL for revision of the conditions of the tender.

It is believed that a trend is emerging with the bulk buyers to invite tenders from units adhering to Schedule 'M'.

Industry News:

- (1) A new generation anti-fungal drug Vorizol (Voriconazole) has been launched by Natco Pharma. It has been claimed that Vorizol is effective against amphotericin B, itraconazole and fluconazole-resistant pathogens. It is available in the form of 200 mg tablets and 200 mg injections and may be of use to patients suffering from cancer and AIDS and in patients who have undergone organ transplant.
- (2) Indian pharma companies are visualizing opportunity in R & D in drugs for neglected diseases. Details of some such research projects are :

Companies

Research Projects

(i) Ranbaxy	Synthetic peroxide – a potential anti-malarial agent.
(ii.)Gland Pharma	Paromomycin –for Kala Azar.
(iii)Lupin	Gatifloxacin – a fixed dose combination for TB.
(iv)German Remedies	Miltefosine – for Kala Azar
(v) Bharat Biotech	Malaria Vaccine.

- (3) Dr. Reddy has sold its formulations plant at Pondicherry to a USA based company. This plant was put on block after Dr. Reddy commissioned its new plant in excise free zone.
- (4) SIP Pharma, a US based company providing formulation solutions to the Industry has set up a testing facility at Bangalore. It will cater to Asian-Pacific market and will provide know-how at the formulation stage of drug delivery, will tap into intellectual property available in the country and will set up a production facility catering to the requirement of contract research organizations.
- (5) Merck has selected India as one of the countries for conducting phase-III clinical trials of its Rotavirus Vaccine. Rotavirus causes severe diarrhea and dehydration in infants and is cause of death of about six lac infants every year globally of which about 1.5 lac deaths are in India.

This vaccine has been developed by Merck with funding assistance by Global Alliances for Vaccines and Immunizations (GAVI) and advanced clinical trials will be conducted in collaboration with Programmes for Appropriate Technologies in Health (PATH).

Merck may also select India to conduct advanced clinical trials for two more vaccines developed by it which are for human papiloma virus (cause of cervical cancer) and Shingles.

- (6) Natco Pharma has launched in India its product Alphalan in the form of 2 mg and 5 mg tablets. Alphalan is used in treating a type of blood cancer known as Multiple Myelonia which affects the plasma cell. These malignant plasma cells in

the diseased persons accumulate and damage the bone marrow in the spine, pelvis, rib cage and skull.

- (7) Ranbaxy has again lost its Lipitor case before US Federal Court. This appears to be a major set back to India's largest pharmaceuticals manufacturing company in recent times.
- (8) **CIPI Progress Report:**
 - (a) In order to expedite the registration process, CIPI has hired the services of a Chartered Accountant expert in this field .
 - (b) A representation has been made to the Ministry of Chemical & Fertilizers so that CIPI gets a presentation on the Board of NIPER,
 - (c) A bank account of CIPI shall be opened with UTI Bank at Delhi for which all the formalities have been completed
 - (d) We are marinating pressure on the Government for reduction of excise duty on medicines from 16% at present to 8%
 - (e) The proposal for increase in the excise free clearance is also with the Ministry of Finance. These proposals have been strongly recommended by the Ministry of Small Scale Industries and Ministry of C&F.
- (9) **Annual Subscription:** As demanded by the Members at the meeting at Indore, invoices have been sent to all the members for annual subscription of Rs. 15,000. Members who have not paid so far, are requested to clear their dues for the year 2005-06
- (10) **Other CIPI matters:** As per Chairman's circular to the members, the matters referred to in his communication are being taken up on priority specially starting function of CIPI from Paschim Vihar Office.