

## **Confederation of Indian Pharmaceutical Industry (SSI)**

### **Circular No. 20**

**Central Drugs Regulatory Authority:** This is a part of the Drug Policy -2006 as drafted by the Ministry of Chemicals & Fertilizers. The Ministry of Health & Family Welfare was also working on this subject separately and the draft prepared by the said Ministry has been approved by the Cabinet Committee to establish a CDRA of the Country. The Authority will work within the framework of D&C Rules which will be suitably amended. When established, CDRA will oversee and regulate all the aspects of the manufacture and marketing of drugs and pharmaceuticals in the country including medical devices, diagnostic kits, food supplements; will also be responsible for issue of manufacturing licenses to the units in the Country, for clinical trials, PMS, pharmacovigilance and approval of FDC of the active ingredients. CDRA will have linkage with the Patent and Trade Mark offices in the country and will play an active part in grant of patents and trade marks for pharmaceuticals.

**Exempted by Products to attract Excise Duty:** In a recent ruling the Customs, Central Excise and Service Tax Tribunal has said that exempted by-products which are produced during the course of the manufacture of a dutiable product will attract duty at tariff rate when sold, if the manufacturer has taken credit of duty on common inputs used in the manufacture of these products. The earlier provision was that such exempted goods shall be subjected to a duty of 8% (half of the rate of dutiable principal product).

**Price Control Mechanism for Patented Drugs:** The Ministry of Chemicals & Fertilizer is working on a proposal to bring patented drugs under some kind of price control mechanism. A committee has been formed in the Ministry to submit a report on this aspect. The mechanism being considered is that the Government will buy patented drugs from the manufacturers at discounted prices as compared to the market price. The drugs so purchased will be distributed by the Government to the patients BPL free of cost and to senior citizens at subsidized prices.

**Essential Commodities Act:** The Government by an amendment to the Essential Commodities Act has included drugs in the Schedule to the said act thus classifying drugs as essential commodity. The text of the amendment order is available at CIPI website [www.cipi.in](http://www.cipi.in).

The Essential Commodities Act was enacted by an act of the Parliament of India and was placed in the Ninth Schedule to the Constitution of India. Any act enacted by the Central Government or a State Government and placed in the Ninth Schedule carries an immunity and cannot be subjected to any legal scrutiny or can not be challenged in any court of law.

However in a recent judgment (12.01.07) the full Constitution Bench of the Supreme Court struck down the validity of the amendment of the Ninth Schedule and of such enactments placed in the said schedule on the ground that the subject amendment results

in taking away the Fundamental Rights of individuals. This ruling of the apex court will have far reaching impact on several laws enacted by the Central and State Governments and placed in the Ninth Schedule. The Constitution provides that no act can take away the Fundamental Rights.

**Budget Expectations:** The Ministry of Finance is holding discussion with the Industry as its pre-budget exercise. From the news items appearing in the print media, we expect the following changes in the budget:

1. peak rate of customs duty may be reduced to 10%,
2. several exemptions available under direct and indirect taxes may be re-visited
3. CST shall be reduced to 3%
4. State Governments may be allowed to tax several services in addition to the services being taxed by the Center
5. States may be empowered to levy VAT on imported goods
6. EET system of taxation may be introduced resulting in payment of tax on maturity or withdrawal of PPF and NSC
7. exemption limit for TDS on interest payments on bank deposits may be raised to Rs. 10,000.00 from the present limit of Rs. 5,000.00
8. FEMA may be further liberalized
9. biotechnology and clinical trials may get recognition in the form of tax incentives
10. limit for excise free clearances for small scale sector may be raised (not to the extent demanded by the industry)
11. there is tremendous pressure from the Ministry of Chemicals & Fertilizers for reduction of duty on drugs from 16% to 8%. It now depends on the report of the GOM to whom the matter has been referred to by the Prime Minister
12. service tax exemption may be raised to Rs. 8 lacs from present limit of Rs. 4 lacs.
13. service tax rates may be further hiked
14. more services may be added to the list of taxable services
15. duty drawback scheme may be replaced by some other scheme which is WTO compliant
16. income tax surcharge may be abolished or further pruned without changing the tax rates
17. age for senior citizen under income tax act may be reduced to 60 years from the present 65 years
18. with corporate sector entering in the field of agriculture, tax on agriculture income may be imposed in a limited manner