

## CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (ssi)

### CIRCULAR No – 4 Dated 11<sup>th</sup> Aug., 2005

1. **Excise / Tax free zones:** Central Government by notification no. 27-CE dated. 19-05-2005 has extended Excise concessions to several other zones in the State of Uttaranchal in the districts of Almora, Dehradun, Nainital, Pithoragarh, Pauri Garhwal, Ydham Singh Nagar and Haridwar.

Further, these concessions have also been extended to the existing units which have undertaken substantial expansion by way of increase in installed capacity by not less than 25%.

More large companies are shifting to excise free zones. Dr. Reddy has established and commissioned their unit at Baddi. They have put their Goa unit on block.

2. **Monthly Return of Central Excise :** CBEC under notification No. 26 – CE (TN) dated 16-05-2005 has revised the Form ER-1 under rule 12 of the CE rules and under rule 9 (7) of CENVAT credit rules. Now the monthly returns shall be filed in the revised form.
3. **Service Tax :** A notification no. 7/2005-ST dated 01-03-2005 was issued under service tax rules under which date of payment of service tax has been advanced to 5<sup>th</sup> of next month. It has been clarified that service tax is payable only on receipt of the payment of bill.
4. **Cash withdrawal tax** Central Board of Direct Taxes has notified Banking cash Transaction Tax Rules. The transactions on which scheduled banks will levy the tax are :
  - Cash withdrawal exceeding Rs. 25,000 on a single day from any account ( other than saving account ) by an individual or a HUF.
  - Cash withdrawal exceeding Rs. 1 lac on a single day from any account ( other than saving account ) maintained by a person other than any individual.
  - Receipt of cash exceeding Rs. 25,000 on a single day on encashment of one or more term deposits by an individual or a HUF.
  - Receipt of cash exceeding Rs. 1 lac on a single day on encashment of one or more term deposits by a person other than on individual.

There is a three stage reporting under which banks will have to maintain transaction wise record including account number, name and address of the person and value of the transaction tax followed by monthly returns and annual returns.

5. **NPPA circular :** NPPA has issued a circular requiring all the manufacturers and importers of drugs to issue price list / supplementary price list in Form V of DPCO, 1995. This circular has been issued giving referred to para 14 and 15 of DPCO, 1995

requiring issue of price list for non- schedule formulations. The circular requires the manufacturers and importers to submit price lists / supplementary price lists / consolidated price lists in Form –V to State Drugs Controllers / Government ( i.e. Ministry of Chemicals and Fertilizers ) / NPPA.

6. **Drugs going off – patent :** List of some of the drugs which are going off patent in near future is given below. Hope it may be useful to members :

|     | <b>Drugs</b>       | <b>Patent expiry date</b> |
|-----|--------------------|---------------------------|
| 1.  | Amlodipine         | 01-08-2008                |
| 2.  | Losartan Pot.      | 11-08-2009                |
| 3.  | Valporate SemiSod. | 29-01-2008                |
| 4.  | Sumatriptan        | 28-12-2006                |
| 5.  | Tiludronate disod. | 24-10-2006                |
| 6.  | Ibadronate Sod.    | 09-07-2007                |
| 7.  | Resperidone        | 29-12-2007                |
| 8.  | Risedronate        | 10-12-2013                |
| 9.  | Pioglitazone       | 17-01-2006                |
| 10  | Rosiglitazone      | 30-08-2008                |
| 11. | Terbinafine        | 29-12-2006                |
| 12. | Natritriptan       | 12-08-2008                |
| 13. | Risperidone        | 29-12-2007                |
| 14. | Paroxetine         | 24-09-2008                |
| 15. | Budesonide         | 13-03-2007                |
| 16. | Salmeterol         | 12-02-2008                |
| 17. | Zafirlukast        | 26-09-2009                |
| 18. | Dofetilide         | 25-09-2007                |
| 19. | Azithromycin       | 01-11-2005                |
| 20. | Levofloxacin       | 01-10-2008                |

7. **Tenders:** States of Uttaranchal and Chhattisgarh have floated tender for supplies of medicines. one of the conditions of tender is that the manufacturer should be holding WHO GMP. CIPI took – up the matter with the Health Authorities of the respective States for deletion of this condition in view of Supreme Court’s orders ratifying the earlier order of the Hon’ble High Court of Uttaranchal ruling that WHO – GMP is not mandatory for domestic supply of medicines and that GMP issued by the Licensing Authority is sufficient.

CIPI has asked the respective States to amend the terms and conditions of tender notifications.

8. **Compulsory Licence – effective use by Brazil :** Brazil has asked for a steep price cut on AIDS drug Kaletra manufactured by Abbott Laboratories and has announced its intention to produce generic version if the company refused to fall in line. This step has been taken by Brazil under WTO Agreement on TRIPS against the patent holder.

Brazil has earlier also used this clause of compulsory licence effectively against Merck and Roche. In each case, the companies subsequently agreed to sell patented drugs at lower prices.