**“Financial Express”**

**“Setting Tight pharma, power sectors-coordination between the centre and states is vital” S L Rao, November 6 2013**

**With economic growth, market opportunities have increased manifold. The value of natural resources under government control has grown. Infrastructure projects are huge and require big investments. Discretionary authorities with government officials in these matters (licensing, clearances, tariffs, etc), enable the corrupt official to make sizeable illegal incomes. It is to speed up the process of project clearances and implementation, and minimize the opportunities for corruption, that a transparent, consultative and independent regulatory system was created. This takes away authority to make these decisions behind closed doors and lets the light of transparency shine on them.**

**The Indian Constitution makes pharmaceuticals like electricity, a concurrent subject. The central government makes the rules on matters that affect more than one state. The state governments rule on matters within the state. These include manufacturing, retail, preventing sub-standard drugs from reaching the consumer, as also other drugs that are inadequate. Similarly, electricity is under the central government on interstate matters (like interstate transmission rules, the national Grid Code, etc). State governments make the rules for generating plants within the state and for intra-state transmission and distribution. There are state load dispatch centres that supervise the operations of the Grid within the state. Drug Controllers in each state supervise the pharmaceutical manufacture and trade in the state. Both load dispatch centres and state drug controllers are under the overall control of the respective Ministries in the state government. Thus the state drug controllers are under the Secretary in the Health Ministry and like heads of load dispatch centres, much lower in the hierarchy. Coordination between the centre and the states**

**is vital. Electricity follows no political boundaries but flows along the wires taking the path of least resistance. Drugs are traded all over the country, irrespective of where they are made.**

**Electricity quality parameters are standard, but vary around the country and at different times. Distortions against standards of quality result when state distribution enterprises and large consumers over or under draw electricity from the Grid. Similarly the Drugs Controller in one state may have cleared a manufacturer or allowed a formulation. These are traded over the country. Other Dugs Controllers have to assume that the clearances were done correctly.**

**India for many years did not recognize product patents, allowing Indian manufacturers to develop alternative processes for making drugs that enjoyed product patents in other countries. This enabled Indian manufacturers to 'reverse engineer' the drug and offer it cheaper in generic form (without brand names). India was able to tap into a huge worldwide market, especially in the USA where branded drugs were very expensive. Thus, generic drug manufacture enabled Indian manufacturers to sell expensive AIDS drugs very cheap in Africa. This has reduced the scourge of the disease in Africa. Indian pharmaceutical industry become a major exporter of generic drugs to the large United States market. The drug regulator in the USA, the Federal Drugs Administration (FDA), is very capable, well-staffed and has enormous powers to prosecute and punish.**

**In the last one year they have punished the largest manufacturers and exporters (for example Ranbaxy), pay enormous fines for misdoings including poor hygiene, poor manufacturing standards, false trials and sub-standard quality. The FDA found faults in Indian factories of these manufacturers (admitted by the companies). This has adversely affected Indian generic drug exports, and harmed the perception of all Indian pharmaceutical manufacturers.**

**The pity is that India with its network of Drug Controllers, did not have a clue about these violations of drug regulatory rules. They learnt only after the FDA caught them. There have been defensive pleas of victimization by the US government and local manufacturers there. Highly unlikely as they are, they are irrelevant even if true. Indian pharmaceutical industry has seriously lost face overseas. This could harm Indian exports and growth of an industry in which we had potential. If drug regulators were able to their job completely, we might prevent such episodes. We have progressed with comprehensive and independent regulation of electricity, but unsatisfactorily.**

**Electricity has an independent regulatory commission for each state and one at the Centre to regulate in its jurisdictions. Most electricity enterprises are owned by governments and there are electricity departments in each government. The regulators are almost all retired bureaucrats, used to a lifetime of subservience to political and other superior authorities and inured to procedure. The Load Dispatch Centres, are electricity traffic policemen, under the government owned distribution enterprises, the state electricity boards. Independent electricity regulation in India has these and other reasons failed to ensure 100% grid discipline or to keep the sector financially viable.**

**Our drug regulation is at two levels-Centre and states. At the Centre, new drugs and clinical trials are approved. The state drug regulators approve formulations, are to ensure quality in manufacturing, and that the consumer is not sold dangerous drugs except with prescriptions from medical practitioners. They report to largely itinerant bureaucrats in the Ministries, who do not stay in the job for over three years. The level of the drug regulator in the hierarchy is well below a Secretary to government. The drug regulator is not independent. Decisions are taken with limited consultation with stakeholders, and are not transparent. All Drug Regulatory authorities are grossly understaffed. It is impossible for them to oversee the over 20,000 organized, small-**

**scale and informal enterprises that manufacture drugs, or the almost 100000 retailers who sell them. While governments attempt tp ensure coordination between regulators and to share information, coordination and communication between them are weak. Use of technology is haphazard. States like Gujarat are far in advance of others. An 'independent" regulator, the National Pharmaceutical Pricing Authority (NPPA), determines prices of drugs, again in a non-transparent way.**

**Another major problem increases the need for strong independent regulation. Self-regulation by manufacturers and retailers is poor, with very few exceptions. Ranbaxy would not have falsified trials for submission to the FDA (for which they paid a huge fine in the USA), if they had an honest self regulatory mechanism that was followed by all employees, and governance committed to high standards.**

**Thus the major issues are very weak self regulation and corporate governance, low level drug regulators, subservient to administrators, understaffed regulatory authorities, weak penalties, poor enforcement, long drawn out process of trial, lack of special police powers with regulators, fast trials, and use of modern technologies, with speedy and full communication between regulators. There should be a national forum of all drug regulators who must meet regularly to exchange ideas and for training. Drug regulators must be independent of administrators, be selected independently, have long tenures, and accountable to legislatures. Legislation which incorporates all this, and provides for severe penalties to violators, is needed.**

**These are issues of life and death for the sick, as well as for the growth of the industry. Littlre attention is being paid to them.**

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