TABLETS AND TABLE FANS

- Drug and electricity regulations need to improve

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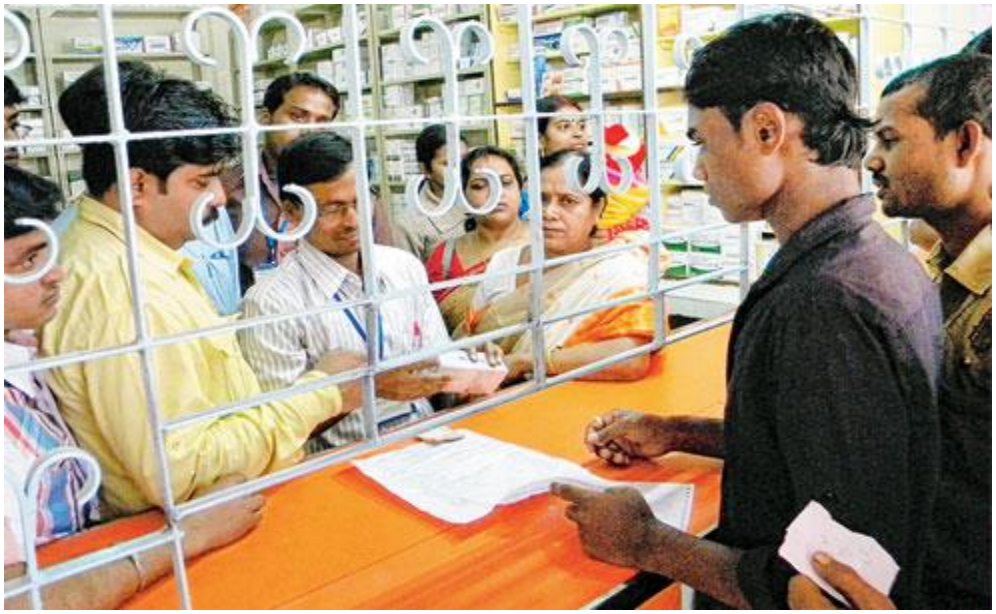

Electricity is one form of energy, along with coal, oil, gas, sun and wind. It can be generated with coal or the others, or from water flows, or nuclear reaction. As electricity, whatever the source, it travels on laws of physics, not politics. Electricity regulation in India has been inadequate — for example, the repeated failure of the northern grid last year, or the vast losses of state electricity boards.

Drug regulation has also been ineffective; witness the massive fines levied on blue chip Indian pharmaceutical companies (like Ranbaxy) by the Food and Drug Administration of the United States of America for false test claims, poor hygiene and so on. This hurts the perception of all Indian pharmaceutical manufacturers. Easy availability of dangerous drugs to anybody is another example. The poor availability of electricity in India deters fresh investments.

Drugs and other medicines are integral to healthcare. Medicines impinge and make an impact on all healthcare and should be integrated with it. Healthcare includes professional workers, managers, ministries of health at the Centre and the states, commercial interests, non-governmental organizations, community and consumer groups, legal and medical professions, agencies to prevent transmission of infectious or contagious diseases, wholesale and retail establishments, importers — amongst others.

With economic growth, markets and competition have boomed, as has the demand for natural resources. Government officials have considerable discretionary decision-making authority (licensing, clearances, tariffs and so on). This has often led to slow decisions, and enabled

corrupt officials to make sizeable illegal incomes. To speed up the process of clearances and implementation, and minimize the opportunities for corruption, a transparent, consultative and independent regulatory system was created in some sectors. This was to enable decisions to be made transparently. "Regulation occurs when a Government (at the Centre or in the states) exerts control over the activities of individuals and firms", according to Roemer, 1993. More specifically, regulation has been defined as government "action to manipulate prices, quantities (and distribution), and quality of products", by Maynard, 1982. Independent regulation seeks to ensure quality and accountability, to protect the consumers and control costs as well as the distortions created by market forces.

The Indian Constitution makes pharmaceuticals, like electricity, a concurrent subject. The Central government makes 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. Similar is the case for electricity. The Central government decides on matters like interstate transmission and trading, the national Indian Electricity Grid Code, and so on. 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. Electricity load dispatch centres (presently within state electricity boards), and state drug controllers are under the overall control of the respective ministries in the state government. State drug controllers and heads of load dispatch centres are under the secretary in the ministries. They are much lower in the hierarchy. Coordination between the Centre and the states is vital for both. 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 in practice, vary geographically and temporally. Distortions of standards of quality result when state distribution enterprises and large consumers are allowed to break the grid rules or do not maintain their equipment. Similarly the drugs controller in one state may have cleared a manufacturer or allowed a formulation. These are traded over the country. Other drugs 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 'reverse engineering'. Drugs could be made and sold cheaply in generic form. India was able to successfully compete with expensive branded drugs worldwide. Thus, low priced Indian anti-AIDS drugs reduced the spread of the disease in Africa. As an exporter of generic drugs to the US, Indian companies must follow FDA regulations. The FDA is experienced, very capable, well-staffed, and with enormous powers to prosecute and punish.

India's network of drug controllers did not have a clue about violations of US drug regulatory rules by Indian companies. These violations should have been detected by them in India, not after the FDA caught the Indian companies. Defensive pleas of victimization are preposterous and irrelevant. To sell in the US we must obey FDA rules. This could harm Indian exports

and the growth of an important industry with potential. Drug regulators must be enabled to perform their jobs completely.

Electricity has an independent regulatory commission for each state and one at the Centre, each to regulate in its jurisdictions. Most electricity enterprises are owned by governments, under electricity departments. The regulators are almost all retired bureaucrats, most of them 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 government-owned distribution enterprises, the state electricity boards. Independent electricity regulation in India has failed to ensure 100 per cent grid discipline or to keep the sector financially viable.

Our drug regulation at the Centre approves new drugs and clinical trials. The state drug regulators have to approve formulations, ensure quality in manufacturing and also that the consumer is not sold dangerous drugs unless prescribed by doctors. They report to 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 the government. The drug regulator is not independent. Decisions are taken with limited consultation with stakeholders and other drug regulators, and are not transparent. Drug regulatory authorities are grossly understaffed. It is impossible for them to oversee the more than 20,000 organized, small-scale and informal enterprises that manufacture drugs, or the almost 1,00,000 retailers who sell them, with millions of prescriptions and transactions. Coordination, sharing information and communication between regulators are weak. Use of technology is haphazard, except in some states like Gujarat. An ‘independent’ regulator, the National Pharmaceutical Pricing Authority, determines prices of drugs, again in a non-transparent way.

Self-regulation by manufacturers and retailers is poor, indeed non-existent, with few exceptions. Ranbaxy would not have falsified trials for submission to the FDA (for which they paid a huge fine in the US), if they had an honest self-regulatory mechanism, and an awake and aware board of directors committed to high standards of governance.

Thus the major issues in regulating drugs (as in electricity), are very weak self-regulation and corporate governance, low ranks of drug regulators in the government hierarchy, subservience to administrators, grossly understaffed regulatory authorities, weak penalties, poor enforcement, a long drawn out process of trial, lack of special police powers with regulators, non-use of modern technologies, and the absence of quick and full communication between regulators. There should be a national forum of drug regulators who must meet regularly for exchange of ideas and training. Drug regulators must be independent of administrators, be selected independently, have long tenures, and be accountable to legislatures. Legislation is needed, which incorporates all this and provides for severe penalties to violators.

These are issues that mean life and death for the sick, as well as for the growth of industry and the economy. This is yet another of the reforms that requires painstaking attention. They are not the ‘low-hanging fruits’ that made the 1991 reforms successful.

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