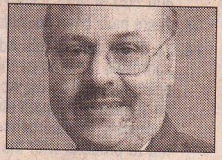
THE GLENMARK CASE

Indian Pharma: Good Pills and Bad Pills



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Over a year ago, I had written a piece, *Quo Vadis, Indian Pharma?* (ET, May 11, 2012), in this column. Some key issues were highlighted in the article. Perhaps it is time to revisit the subject and bring out some current issues.

▶ *Price control:* Hurray, the department of pharmaceuticals has come out with a new non-intrusive price control methodology, moving from the cost-based model to the average market price of brands in the market, for all products appearing in the National List of Essential Medicines. This will bring down market prices by 10-40%.

For those with chronic diseases such as hypertension, diabetes, heart ailments, rheumatoid arthritis, etc, there will be considerable savings in the long term. Antibiotics will also cost less. It is important for the government to disseminate news in the media regarding this positive development.

Pricing of patented medicines, though, continues to evade an equitable solution and discussions are ongoing. A dual pricing system, i.e., controlled price for the public health system and a free pricing mechanism for the private market can be a workable solution, helped by "patient-assistance programmes" run by the innovator.

▶ *Intellectual property:* In the case of Novartis, the Supreme Court upheld the denial of patent quoting Section 3(d) of The Patents Act. This landmark decision validates our lawmaker's intention to prevent evergreening. But India's IP law is only as good as its enforcement. What would be your reaction if a patented product, on which you have worked for years, is copied by somebody, who then says "get a court injunction if you can"?

I refer to the imbroglio caused when the Indian company Glenmark introduced Sitagliptin phosphate, a diabetes drug, in the market, even though the innovator Merck has a patent in India only for Sitagliptin and not Sitagliptin phosphate. How does India retain its credibility on IP enforcement? The answer is not difficult. In the absence of patent linkage to market authorisation, the law ministry should establish a fast-track IP bench in the Delhi High Court (to start with), and a fast-track IP bench in the Supreme Court.

If Glenmark has infringed Merck's patent, then fines and penalties will be imposed by the Delhi High Court that is hearing the matter. This will send out a message to the world that in India, one cannot take a cavalier attitude towards IP law. Quick disposal of IP cases is the key. Working around patents is a complex exercise and Indian generics companies have a formidable reputation for possessing deep knowledge of this complex exercise that helps to bring the generic version of the drug ASAP to the market.

▶ *Regulatory framework:* The ministry of health is working to improve the regulatory framework. The Standing Committee of Parliament is also breathing fire and pushing the ministry to implement plans. The ministry must place the long-awaited Bill in Parliament for the formation of the Central Drug Authority (CDA). This organisation will supersede the Central Drugs Standard Control Organisation (CDSCO). Once CDA is up and running, it will vastly improve the regulatory environment for drugs, clinical trials and medical devices.

Patient safety cannot be compromised. Pharmaceutical units must conform to cGMP and cGLP standards and regular inspections are a must. Pharmacovigilance programmes and receipt/collation of Periodic Safety Update Reports are necessary to keep a track of adverse events. It is also noticed that the DCGI and state FDAs are not always on the same page. If amendments are required in the D&C Act, the ministry should take it up forthwith in order to enhance the financial and administrative powers of the DCGI.

Another aspect: just try and visit the websites of the CDSCO and state FDAs. Almost all have archaic and incomplete information. And we talk about e-governance! Doctors, hospitals, patients, NGOs and the lay public must know details of the pharmaceutical units in the country and the products they manufacture. The CDSCO and state FDAs must, in real time, upload details of manufacturing and marketing licences they have issued. Transparency is essential.

"*Salus populi suprema lex esto,*" said Cicero in ancient Rome. It means the welfare of the people is to be the highest law. This holds true for all time.

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