EDITORIALS

The draft national pharmaceuticals policy: concerns relating to data exclusivity and price control

S SRINIVASAN

LOCOST, First floor, Premananda Sahitya Bhavan, Dandia Bazar, Vadodara 390 001 INDIA e-mail: locost@satyam.net.in

Two predominant issues in the current pharmaceutical scenario in India are data exclusivity and the range of drugs under price control.

If the provision of "data exclusivity" is introduced, it would preclude for a certain number of years both generic manufacturers and the drug controller general of India from relying on clinical trial data submitted by an originator company to prove the safety and efficacy of a drug. Data exclusivity would guarantee additional market protection for originator pharmaceuticals by preventing the health authorities from accepting applications for generic medicines during the period of exclusivity. One of the intended side effects of this provision would be to delay the entry of affordable generic equivalents in the market. By requiring generic manufacturers to reinvent the wheel, the drug would become more costly, defeating the idea of affordable generics.

India's amended patent provisions are silent on data exclusivity. No part of the TRIPS (Trade Related [aspects of] Intellectual Property Rights) agreement requires a change in the provisions. One hand of the government of India thinks such a change is required under Article 39.3 of TRIPS. The other hand is against data exclusivity. Only clinical data relating to "new chemical entities" that require "substantial effort" to generate are to be protected from "unfair commercial uses"(1). A period of exclusivity is not mentioned in Article 39.3.

When required as a condition of approving the marketing of pharmaceutical or agricultural chemical products that utilise new chemical entities, or for the submission of undisclosed tests or other data that involve a considerable effort to originate, members are required to protect such data against unfair commercial use. In addition, members must protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Many were under the delusion that once you pass the 2005 amendments to the Patents Act 1970, things would be relatively smooth sailing. But the game has just begun. This is a wonderful time for lawyers whichever side you are arguing for. Every useful combination of a drug, especially if there is a market for it, is being contested by multinational corporations. And patents for many old drugs are being claimed, if a cursory examination of the mailbox applications is any indication. It is high time the government of India stepped in, using its powers sanctioned by the Doha agreement and the original TRIPS agreement itself, to wield its compulsory license muscle citing national interests.

Indeed, the Doha Agreement has clarified TRIPS flexibilities ("…each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted…"); and clearly says that a country's public health needs can be given primacy above all. Unfortunately this interpretation has not been used upfront, either in the recent 2005 amendments regarding more liberal grounds for compulsory license or to define which drugs can and cannot be patented. If wishes were horses…

The pharmaceuticals policy

A draft National Pharmaceuticals Policy has been in circulation since December 2005. Only Part A is in circulation; Part B containing specific proposals for price control is awaited. Trial balloons have been floated in lieu of Part B by the ministry of chemicals and fertilisers, headed by Ram Vilas Paswan. The minister has intermittently spoken against overpricing of 4,000-5,000 per cent; all committees appointed by him as well as the Pronab Sen Task Force have recommended price control of all drugs in the National Essential Medicine List, 2003. The minister has also recommended to the Cabinet that all essential drugs be put under price control.

Lobbies and plants in the media are putting forth a different story. We are told that the prime minister's office is opposed to this move, that the Planning Commission is opposed to it, the commerce and health ministries are also opposed to it, Mr Chidambaram is opposed to it, and of course the national and multinational drug industry associations are also against the move. We are warned that foreign direct investment will evaporate overnight if such a move is put in operation.

The pro-market and industry lobbies within and outside the government have won this round. A fresh committee has been

appointed in August 2006. It includes 11 representatives of industry and three government officials. This committee will now redraft the policy. No representatives of consumers are part of the committee, as if people do not matter when formulating medicine price policy.

Even the recent proposal of a cap on margins for certain generic drugs (whose total sales amount to only Rs 2,000 crore compared to the branded pharma industry sales of at least Rs 30,000 crore) is disingenuous as it leaves out many overpriced branded medicines and irrational ones at that.

At a great cost

To reiterate what is wrong with the pharmaceutical and pricing scenario in India (2):

- A lack of availability (in the public health care system) constitutes the major crisis in drugs in India, along with a lack of affordability for the poor and the middle class.
- The pharmaceutical sector is the only sector in India where government tender prices are one to three per cent of the retail market prices.
- Adequate and sensible price control is required. The government's own committees have reported that price controls operate even in the so-called free market countries.
- Our markets are full of unscientific and therapeutically useless drugs. We must immediately weed out these drugs by allowing only drugs as per the World Health Organisation's essential drug list or the government's National Essential Medicine List, 2003.
- Medicines are the only commodity for which the end-user (the paying patient) does not decide what to buy and at what cost. The doctor prescribes and the patient pays.
- Unlike with other commodities, the buyer of medicines is extremely vulnerable as s/he is seeking immediate relief from suffering. Due to this special nature of drugs, even in so-called market economies all issues related to drugs, including prices, are subject to regulation by the government. The only exception is the USA.
- In India, unlike in the developed countries, the cost of buying medicines constitutes a large proportion (more than 50 per cent) of total medical expenditure. About 80-90 per cent of this is a person's or a family's out-of-pocket expenditure; the government spends only a small proportion on medicine procurement**.** The majority of Indians live below or near the poverty line but they are forced to spend on unnecessarily expensive medicines. Along with the cost of hospital stay, this expense is an important cause of indebtedness
- Unlike in developed countries, most Indian patients are helpless individuals before the might of the drug industry because they are not covered by insurance or social security mechanisms.
- The track record of the drug industry in India in terms of pricing is reprehensible. The following examples illustrate this point: Prices of the same drug in the same strength manufactured by two known companies can vary from two to 20 times - for example, Levofloxacin is sold by CIPLA for Rs 7 per tablet while Aventis sells it for Rs 95 per tablet. Costlier drugs often sell more because of more aggressive promotion. Committees constituted by the government have clearly documented inordinate rises in prices of drugs after they were taken off the list of price-controlled drugs in 1995. After this deregulation, the price of some tuberculosis drugs rose by 250 per cent, but no action was taken.

HIV patients and AIDS activists are beholden to India for reducing the prices of AIDS-related drugs. Prime Minister Manmohan Singh should look to South Africa and Brazil, with whom the government of India is trying to make a special alliance. These countries can educate us on how they responded to the AIDS medicine crisis. We must take urgent action to reduce our drug prices.

References

1. For further discussion see: Correa Carlos. *Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS agreement*. South Centre in collaboration with the Department of Essential Drugs and Medicines Policy of the WHO. 2002 June. Available from: http:/// www.southcentre.org/publications/protection/toc.htm. See also *MFC bulletin*; 318-319. Available from: www.mfcindia.org.
2. The formulations that follow, except for the first four, are from a press release of the All-India Drug Action Network, of which the author is a member. For more detailed analysis and arguments see *Impoverishing the poor: pharmaceuticals and drug pricing in India.* Vadodara/ Bilaspur: LOCOST/JSS; Dec 2004; and *A layperson's guide to medicines: what is in them and what is behind them*. Vadodara: LOCOST; July 2006.