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Quo Vadis, Indian Pharma?

The government needs to think out of the box to help pharma grow while keeping medicines affordable

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Having watched from the ringside for many years now, I have no doubt in advising that the steering wheel must be firmly grasped by the government and direction given to policies that should be stable for at least the medium term. This is crucial for the growth of Indian pharma, a $20-billion industry growing at an average of 12% considering both domestic and export arenas.

● **Price control:** The biggest and most contentious issue is eluding a solution. The extant price control is over 20% of the market for pharmaceuticals. Different methodologies are being suggested that can extend price control to 60% or even 80% of the domestic market. Which is the right formula? Nobody is certain. It is being said that the National List of Essential Medicines should form the basis for price control. Some would like cost-based controls while others suggest market-based non-intrusive methods.

I have a different take on this. What is important is to improve the delivery system for medicines and make it targeted. For all essential commodities, particularly like food, the government has opened fair-price shops under the public distribution system (PDS) for the poor and needy. Is it such a difficult task for each of the 640 districts in India to have at least two PDS outlets, which can dispense unbranded, goodquality, low-priced generic medicines? Members of Parliament are always talking about prices of medicines being high and outside the reach of the aam aadmi.

Why not set up an efficient government procurement body under the health ministry to buy under a transparent tendering process, unbranded generic medicines and then have the systems in place to distribute to different states both for the public health system and for the PDS? The Drugs & Cosmetics Act can be amended to make it possible for only PDS shops to substitute unbranded generics in place of branded ones. A public-private partnership model can be selected. Such a move will help mitigate the misery of the millions of poor in the country for whom none of the three As, affordability, accessibility and availability of medicines, are within reach.

● **Foreign direct investment (FDI):** The government has issued a notification that all FDI in brownfield cases would be referred to the FIBP and later from May 7, 2012, all such cases would be referred to the Competition Commission of India (CCI). Therefore, it is imminent that the CCI will soon be in-charge of giving the go-no-go signal for FDI in pharma brownfield cases. However, the CCI has clearly stated recently that it cannot go beyond the test criterion of 'appreciable adverse effect on competition' under the Competition Act. India has over 10,000 companies registered with the Drug Controller General of India.

The market is highly fragmented with the leader having a little over 8% market share. Hence, for many years from now, all proposals will get the green signal from CCI even if the threshold limit for the pharma industry is reduced drastically for M&A cases, thereby introducing only an unnecessary hassle for foreign investors.

The way out could be the method adopted by the government for the auto industry in the early 1990s. The fear then was the drastic outflow of foreign exchange used for import of kits by foreign auto companies. Government suggested that memorandums of understanding (MoUs) must be signed by foreign auto companies with the DGFT, indicating to the government their intentions for investment and indigenisation. The method worked. India is today a manufacturing hub for not only components but also for the manufacture and export of fully-built cars.

The government can issue such a morally-binding MoU to be signed by foreign pharma companies for M&A proposals, and areas of concern such as India's public health needs, affordable pharmaceuticals and other concerns regarding generic medicines can be addressed making the route quick and easy while at the same time getting a commitment from foreign pharma companies in their statement of intent as mentioned in the MoU.

• **Compulsory licensing and intellectual property:** A recent CL granted under Section 84 of the Patents Act by the CG of Patents to an Indian pharma company for Bayer's Nexavar (Sorafenib tosylate) for liver and kidney cancer is a case in point.

The matter will go up the appeal and judicial route. Other intellectual property (IP) matters in the pharma industry are also in Indian courts. Our judiciary will need to address such cases quickly so that case laws can be built up.

Clarity will emerge only on the basis of case laws. This will show the way: when cases get decided, the patent-holder, say, can come out victorious and the infringer can be fined. Or, the patent-holder can be told that the patent has been wrongly granted and the so-called 'infringer' has not violated IP law.

IP cases have serious commercial implications and need independent fast-track courts with expertise in such matters. It is nice to note that our courts are rising to the occasion, but much more needs to be done to speed up matters in the IP office for examining and disposing off-patents, and in our courts.

It is time for us to break the crusty exterior and not get described by that Churchillian phrase that India's pharma and IP policy is "a riddle wrapped in a mystery inside an enigma, but perhaps there is a key". There is no doubt that the key is the country's public health needs. However, even as the country's national interest should be paramount, taking a balanced approach towards all stakeholders is essential.