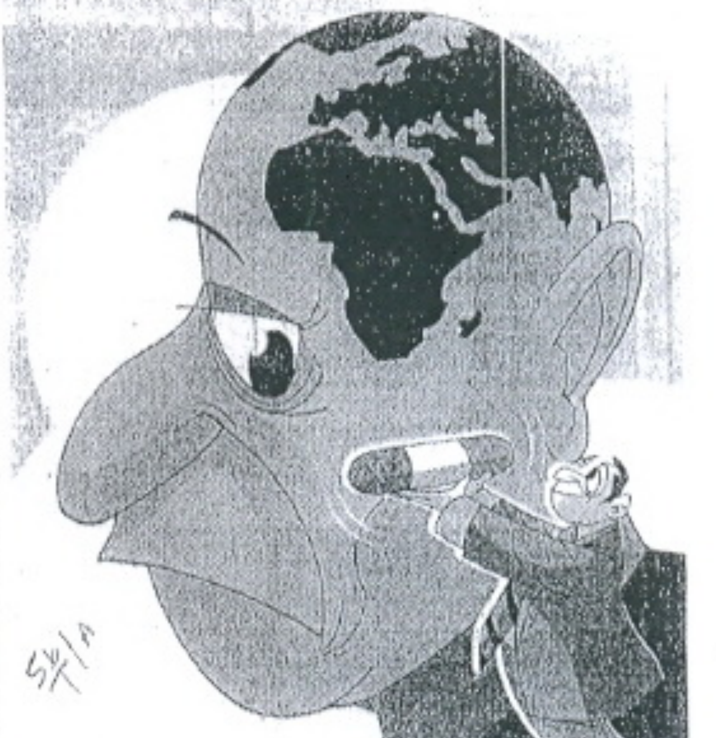
Getting back pharma growth

While the domestic industry needs to increase its R&D spending quite dramatically, price controls will only cripple the sector, says RAMESH ADIGE



India is emerging as a force to reckon with in the global pharmaceutical space. The Indian pharmaceutical industry is globally ranked as fourth by volume and thirteenth in value terms. India is one of the top five manufacturers of bulk drugs in the world and ranks amongst the top 20 pharmaceutical exporters in the world. Every fifth application for marketing a generic drug in the US, the world's largest pharmaceutical market, is filed by an Indian company. The Indian pharmaceutical industry valued at approximately Rs 27,000 crore (domestic market), has almost doubled its annual exports in the last five years to over Rs 20,000 crore. Call it the Indian dosage effect, the pharmaceutical sector is today offering stiff competition to its global competitors and is poised to excel in this area.

Genesis of growth

The domestic pharmaceutical industry has seen phenomenal growth after the government brought in the Patents Act 1970 allowing process patents. The overall policy and environment succeeded in lowering market entry barriers. Indian pharmaceutical companies used the reverse engineering route to make and sell generic drugs (a biological equivalent of an originator pharmaceutical product).

The wave of liberalisation and structural reforms introduced by the government in the 1990s further spurred growth providing the much needed pace for technological advancement. It was in this era that companies with global aspirations started investing more in R&D with an eye to develop value added proprietary products. The early 90s also witnessed India's alignment with the WTO (erstwhile GATT) regulations. All through this period, Indian industry was clamouring for protectionism and shying away from Intellectual Property (IP) rights.

> The domestic pharmaceutical prices have been rising just 1-2 per cent a year, much lower than the rate of inflation

Thrive or strive

The new patent regime that came into existence on January 1, 2005 presents both challenges and opportunities for the pharmaceutical industry. The domestic market is gradually moving towards consolidation and only players with strong technical and research capabilities and a global vision are likely to survive. The same scenario is playing out internationally. There is intense competition, price erosion and a squeeze on margins. In spite of this, in the last few years, several Indian pharmaceutical companies are beginning to take some steps to encourage the domestic production of drugs. Experts however feel that it is about time the government announced substantial policy initiatives, particularly towards encouraging R&D. It is well known that R&D in pharmaceutical is expensive and time consuming with long gestation periods and uncertain outcomes. Therefore, fiscal incentives and grants are a must and need to be scaled up.

Expenses incurred on clinical trials, bioequivalence studies, regulatory approvals and patent filings, made outside India (necessitated by regulation) are legitimate R&D expenses and should be recognised and accorded the same preferential treatment as other forms of R&D expenditure by the government. This will ensure that capital is directed to this important area critical for long-term success.

To give an impetus to innovation efforts, the government should allow data protection for new chemical entities and phyto products for a period of three-five years, subject to safeguards. Capacity building in the area of patent examination and patent office infrastructure needs immediate attention. The creation of an independent regulator with administrative and financial autonomy to monitor and safeguard the interests of the consumer and the industry, is a crying need. Therefore, the setting up of a Central Drug Authority is an imperative.

Price control — a boon or bane?

In the past, the government has made extensive use of the ... try is home to over 20,000 manufacturers of medicines. There is intense competition and this in itself has made medicines in India very affordable. Therefore, the most recent move by the government to re-assert price control on a wider category of drugs seems retrograde and is inconsistent with the government's longer term direction to progressively unshackle the industry to enable its growth. Any move to bring intrusive price control measures will stymie the much needed effort and capital required to augment crucial R&D efforts. The industry already has a lot on its plate and grappling with such unproductive diversions consumes a lot of energy and time. Hopefully, reason will prevail.

Make the right moves

The outlook for the global generic pharmaceutical industry, including India, is positive. It is expected that the years 2006-2010 will see a strong global generics market opportunity unfold with an estimated $60-70 billion worth of branded products expected to go off patent. If the industry and government work out a symbiotic relationship keeping the interest of the consumers in mind, I have no doubt that the Indian pharmaceutical industry can become the preferred global supplier for the manufacture of bulk drugs, dosage forms, CROs, CRAMS, R&D and the entire slew of upstream and downstream activities in the business. We are at the cross-roads and the whole world is looking at us with great interest.

Shakespeare wrote: "There is a tide in the affairs of men, which, taken at the flood, leads on to fortune, omitted, all the voyage of their life is bound in