PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

MINT, Delhi

Tuesday, 29th March 2011, Page: 31

Width: 28.83 cms Height: 26.42 cms, Ref: pmin.2011-03-29.50.65

A pill for generic troubles

Despite positive signals, recent trends in the generic pharmaceuticals industry have been most disheartening

Biswajit Dhar
is director general at Research and Information System for Developing Countries, New Delhi.

In his budget speech, finance minister Pranab Mukherjee announced the government's intention to formulate a manufacturing policy to help increase the share of manufacturing in gross domestic product (GDP) from about 16% at present to 25% within a decade. While the focus of this policy—reducing the compliance burden through self-regulation on the industry, and to make it globally competitive—is a necessary step, this may not be sufficient for infusing the enthusiasm that the industry requires. For this to happen, the government must take initiatives for addressing the specific requirements of the key sectors.

One of the most prominent sectors whose specific needs require prompt attention is the generic pharmaceutical industry. Over the past several decades, this industry has developed into a global powerhouse, supplying affordable drugs not only to the large Indian market, but also to several countries in Africa and Latin America. Among its more remarkable contributions was the support it lent to the Global Fund to Fight AIDS, Tuberculosis and Malaria, which was set up in 2002 following a resolution passed by the United Nations General Assembly. In the initial years of its functioning, the fund procured from Indian generic firms almost 25% of the anti-AIDS medicines it had supplied to the most affected countries.

What made this contribution more remarkable is that it came in the midst of growing challenges for the industry from the policy regime. On the one hand, the level of tariff protection enjoyed by the industry was rapidly coming down. On the other, the impending introduction of a product patent regime following India's acceptance of the commitments under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) had cast its long shadow on the future of the industry. The nature of the patent regime was a critical factor for the generic industry—its growth can be almost entirely ascribed to the introduction of the Patents Act 1970, a regime that did not permit patenting of pharmaceutical products but allowed only process patents.

In the face of these challenges, the Indian generic industry came up with its best performance ever. Since the late 1990s, all the key indicators of industry performance had showed tremendous improvement. Particularly noteworthy was the large investments in research and development (R&D) made by most of the major firms. This forward-looking strategy helped the industry not only to produce more effective generics, which were marketed in both the US and Europe after overcoming stiff regulatory barriers, but initial steps were also taken to develop new molecules. Yet another positive arising from improvements in R&D intensity of the pharmaceutical industry was the emergence of India as a major hub for contract research.

What made the generic industry so upbeat? The critical factor was the strong backing it received from developing country governments and a wide variety of civil society groups for providing cheap medicines to those who could not afford the costly proprietary medicines. A measure of effectiveness of this support was the agreement among World Trade Organization (WTO) members to provide flexibilities in the TRIPS regime that the generic industry could take advantage of. Importantly, these flexibilities were also adopted by India while amending the Patents Act and bringing it in line with the country's commitments under TRIPS.

JAYACHANDRAN/MINT

Lately, news from the global industry, too, has been encouraging for the generic industry. Over the next few years, a number of blockbuster drugs are coming off-patent. This would have a profound impact on the global pharmaceutical industry: its major firms could suffer substantial erosion in their sales arising from the competition they would face from generic producers. Industry estimates indicate that in 2010, 68% of the sales of market leader Pfizer included products whose patents would expire within the next three years. Similarly, for another leading firm, Eli Lilly, the risk from generic competition in the next three years would be as high as 66% of total sales in 2010.

Despite these positive signals, recent developments in the Indian generic industry have been most disheartening. A spate of takeovers has rocked the industry, involving some of the largest in the business. In 2008, two large takeovers occurred—the largest firm in the Indian industry, Ranbaxy, was taken over by Daiichi Sankyo of Japan, and Dabur Pharma was acquired by Germany's Fresenius Kabi. Yet another mega takeover took place in 2010, when Piramal's health formulation business was acquired by Abbott Laboratories. Besides these, two promising firms, Shantha Biotech and Matrix Laboratories, were also taken over—the former by Sanofi Aventis, the world's fourth largest firm by sales.

The slew of takeovers seems to suggest that the sentiment among generic pharmaceutical firms in India has turned bearish. To revive the sentiments in an industry as critical as this, the government should pull out all stops to intervene at two levels. First, it has to adopt policy measures necessary for putting in place a business environment in which the industry can be assured of its long term viability. Second, serious attention needs to be given to devising effective instruments to prevent takeovers that undermine competition in the market for pharmaceutical products in India.

Comments are welcome at theirview@livemint.com