

Busting bottlenecks

Industry-Regulator Dialogue

India



Life Sciences
Associations in Asia

In the second part of the series of articles profiling the life sciences associations of Asia, *BioSpectrum* brings you how associations in India are accelerating the pace of Indian life sciences industry

THE publicly listed life science companies in India had revenues of \$14.85 billion in 2007 recording a 40 percent growth compared to 2006.

As per the government of India annual report 2006-07 the Indian pharma industry is worth about \$12 billion as of now, which includes \$4.5 billion in exports of drugs, pharma and fine chemicals. As per McKinsey report, by 2010 the Indian pharma market will be \$25 billion. The Indian biotechnology industry is still small as compared to the global industry. The total revenues from this sector in India are less than 10 percent of that in the US or the European Union. However, India is being increasingly recognized as an emerging player in this field.

There are many life science industry associations in India playing critical roles in the growth and development of the industry. *BioSpectrum* brings you a snapshot of how these are accelerating the pace of emerging Indian life sciences industry.

ORGANIZATION OF PHARMACEUTICAL PRODUCERS OF INDIA

The Organization of Pharmaceutical Producers of India (OPPI) established in 1965, is a premier association of research based international and large pharmaceutical companies in India and is also a scientific and professional body.

OPPI identifies itself with the country's national healthcare objectives and encourages its members to make substantial contributions to social concerns and actively promotes Corporate Social Responsibility (CSR).

PHARMA PRICING, A BIG ISSUE

Commenting on the ongoing pricing issue of Indian pharmaceutical industry Mr Tapan Ray, Director General of OPPI, said, spiraling increase in the input costs of a very large number of pharmaceutical formulations is causing a great concern to the Industry. OPPI is making representations to the National pharmaceutical Pricing Authority (NPPA) and also to the Department of Pharmaceuticals, Government of India to address this pressing issue, without further delay.

The pharmaceutical industry has been witnessing an unbridled increase in the prices of a large number of Active Pharmaceutical Ingredients (APIs). Many manufacturers were sourcing such APIs from China where the prices were competitive. However, before commencement of Beijing Olympic, export of many APIs and intermediates from China was adversely impacted due to enforcement of strict pollution control norms by the Chinese Government. As a result, many manufacturers in China had to even stop their manufacturing operations and the remaining producers had increased their prices.

It was expected that post Olympic games, prices of APIs, imported from China, will come back to normal. Unfortunately, it has not happened, so far. This is mainly because of whatever little improvement that had taken place in the supply situation, got more than neutralized by sharp increase in the rupee exchange rate.

Many APIs, like paracetamol, are non-schedule bulk drugs. However, the single ingredient manufacturers of such APIs are unable to neutralize increase in the input costs with a commensurate increase in price in view of the government guidelines in respect to prices of non-schedule formulations.

Against an average growth rate of around 13 percent, the domestic retail pharmaceutical market with

a size of about \$6.7 billion (Rs 33,000 crores) grew by a meager four percent in August 2008. One of the key reasons of such a steep decline in the growth rate of the industry is attributed to sharp increase in the prices of APIs imported from China.

In view of the above scenario, OPPI has requested the government for an appropriate upward price revision for all such formulations to help neutralize unusual increase in their input costs, without any further delay.

CHALLENGES

According to OPPI, if the government promptly addresses such issues, the future of the Indian pharmaceutical industry is indeed quite promising. To ensure that India emerges as a global powerhouse in pharmaceuticals innovating, developing and manufacturing medicines of international quality standards available at affordable prices, the following challenges of the industry must be addressed, soon:

Stringent Price Control: The long pending new pharmaceutical policy aims to bring 354 drugs featuring in the National List of Essential Medicines under price control. The pharmaceutical industry has been proposing to the government of India that instead of cost-based price control, there should be price monitoring, which as indicated by the NPPA of India, is having over 99.5 percent compliance rate. It is also worth noting that prices of medicine in India are already one of the lowest in the world.

Poor IPR enforcement system and Infrastructure: Just a patent regime is not enough. India also needs a world-class product patent enforcement system to encourage, protect and reward innovation along with



Mr Tapan Ray, Director General, OPPI

"To instill confidence in R&D based sector, the Drugs Controller General (India) should put in place appropriate guidelines to ensure that marketing approval is not granted to a generic manufacturer, if innovator already has a patent on the same molecule in India."

a robust patent infrastructure of global standard. An expedient judicial process for quick resolution of disputes is of utmost importance to ensure that fruits of innovation reach the ailing population at the shortest possible time.

Harmonization of Regulatory Process as per ICH Guidelines: This will ensure that India is 'on the same page' with the global pharmaceutical industry to fa-



Facilitate the process of reaching safe and effective medicines to the patients as quickly as possible without compromising on quality, efficacy and safety norms.

Spurious and Counterfeit Medicines: There is no reliable data available to gauge the magnitude of the menace created by counterfeit drugs in India. Recently, a survey carried out by International Pharmaceutical Federation under WHO showed that around three percent of medicines are counterfeit. This data has since then been challenged by many. Actual magnitude of the problem is commonly believed as many times higher.

However, it is reported that the Ministry of Health, Government of India, has decided to conduct a pan-Indian study to ascertain the magnitude of this problem. OPPI has also come out with anti-counterfeiting guidelines to address this menace, which is causing great harm to unsuspecting public in general.

Generic Industry – High Volume, Low Margin: Due to cutthroat competition within generic pharmaceutical market, it is gradually but surely getting transformed into a high volume and low margin business. Thus it is quite likely that in this market we shall see the 'survival for the fittest', which in turn will make all of us witness even more consolidation in the foreseeable future.

To address the above challenges, it is very important to build a consensus with various stakeholders such as, the industry, government, consumer forum (patient groups), and medical professionals. Simultaneously, the pharmaceutical industry should work very closely with the government to help bring out an industry/patient-friendly drug policy, regulatory framework of global standard and an innovation friendly business environment", states Mr Tapan Ray.

The Association of Biotechnology Led Enterprises (ABLE) is a national forum that represents the Indian biotechnology sector.

The objectives of ABLE are accelerating the pace of biotechnology in India by enabling strategic alliances between researchers, government and the global biotech industry; showcasing breakthrough technologies and cutting-edge biotech initiatives that will take the Indian biotech sector to new heights; partnering with the government in its biotech endeavors towards a more favorable environment; forging stronger links between academia and industry; and encouraging global investment in India's rapidly expanding biotechnology sector, facilitating proactive collaborations and partnerships.

ASSOCIATION OF BIOTECHNOLOGY LED ENTERPRISES

ABLE and BIOTECCanada, signed a memorandum of understanding (MoU) to strive for closer cooperation in the biotech sector between the two countries. Similar agreements have been signed with AusBio-tech, and Irish Business and Employers Confederation (IBEC).

According to Dr KK Narayanan, President of ABLE, some of the challenges that Indian biotech industry face are Infrastructure bottlenecks, availability of funds for early-stage discovery/research and trained human resources especially for higher levels of scientific jobs. There are no short-cut solutions; each problem has to be dealt with in a planned manner through project funding and policy initiatives.



Dr KK Narayanan,
President, ABLE

"The opportunities in biotech manufacturing are promising. However, there is a lot to be done in the general infrastructure and human resources front for India to catch-up with some of the global leaders"