

India: Policy reforms enables bioscience sector

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Leveraging on the back of increasing sales of generic medicines, continued growth in chronic therapies and a greater penetration in rural markets, the Indian pharmaceutical market is expected to register a strong double-digit growth of 12-to-14 percent in 2013, although the year 2012 closed with a growth of less than 10 percent, according to BioSpectrum Asia Top 20 Survey. The Indian pharmaceutical market has seen many policy initiatives, compulsory licensing, FDI policy, pricing policy, marketing code and regulatory approvals - from the regulatory agencies in 2012.

During 2012, through the Drug Price Control Order (DPCO), the National Pharmaceutical Pricing Authority (NPPA), cleared the National Pharmaceutical Pricing Policy 2012. Unlike the current cost-based pricing policy, this new policy is market-based, and seeks to control prices of all strengths and dosages of 358 drugs and their combinations that fall into the National List of Essential Medicines (NLEM). The price control will also be applicable to imported medicines, if these drugs also fall in the list of essential medicines.

Furthermore, the government is keen to promote indigenous research in the country. Original research products that have a patent in India will get exemption from price control for five years. The government is expected to come out with the new Drug Price Control Order (DPCO) in 2013.

The Controller General of Patents, Designs and Trade Marks, which is India's intellectual property office, had in March 2012, allowed Hyderabad-based Natco Pharma to make and sell the generic version of Bayer's patented cancer treatment Nexavar. This allowed Natco to sell generic version at three percent of the original medicine's price for a month's dosage. This has received mixed reaction from different state holders like industry, policy makers and NGOs.

Also, the Supreme Court in a landmark judgment ruled against Novartis in the Glivec case by rejecting its plea for the grant of a patent for its drug molecule, imatinib mesylate. Novartis had applied for a patent for the beta-crystalline version of the drug, on the basis of increased safety due to the modifications in the chemical entity, which was denied by the apex court on April 1, 2013.

Since last year, the Drug Controller General of India (DCGI) has withdrawn from its role of approving drug trials and has handed over the responsibility to a new Drug Advisory Committee (NDAC), which has approved only nine drugs for clinical trials, according to a PwC report. Due to frequent regulatory delays, rise in the costs of conducting trials, India is losing its feasibility as a cost-effective destination to conduct clinical trials as compared to many countries. According to reports, new drug approvals dropped by over 50 percent during 2011 to 98 from 224 in 2010.

Although the government is keen on attracting foreign direct investment in pharma sector, the recent acquisition of local companies by MNCs made the government to reconsider its decision. The government through the Ministry of Commerce and Industry (Department of Industrial Policy and Promotion) amended the FDI policy in November 2011 by permitting FDI up to 100 percent for investments in existing companies in the pharma sector through the Foreign Investment Promotion Board's (FIPB) approval route. At the same time, FDI was also approved for greenfield investments in the pharma sector.

Medtech lags behind

The Indian market for medical equipment and supplies ranks among the world's top 20 but, despite strong growth rates, the market remains disproportionately small with per capita spending of just \$2.4. Increased demand for medical equipment and supplies will come mainly from private sector hospitals and medical centers, according to a report from Espicom Business Intelligence.

Moreover, Government proposals to boost health insurance cover from 25 to 75 percent by 2017 will be hampered by a lack of healthcare infrastructure in India. Given the lack of healthcare infrastructure, the government's plans mark an opportunity for investors and manufacturers as new facilities are constructed and existing ones are upgraded.

Bioagri leads biotech

The Indian biotech industry registered 17 percent growth in 2012 and the total industry size stood at \$ 4.4 billion by the end of 2012. The industry is expected to increase in size to \$11.6 billion by 2017, driven by a range of factors including growing demand, intensive R&D activities and strong Government initiatives. The bio-pharmaceutical sector accounted for the largest chunk of the biotech industry, with a share of 60 percent in total revenues in 2012. In the same year, bio-services and the bio-agri segments followed the bio-pharmaceutical segment with shares of 18 percent and 15 percent, respectively. Growth was fastest in the bio-agri segment (21 percent in 2012), followed by bio-pharma (19 percent) and bio-services (13 percent).

With many government initiatives and setting up of Biotechnology Industry Research Assistance Council (BIRAC), a government of India Enterprise by Department of Biotechnology and launch of SME exchange at India's leading bourses, National Stock Exchange and Bombay Stock Exchange as their separate platforms for SMEs - Emerge and BSESME, respectively on March 13, 2012 will support the growth of the biotechnology industry. As of April 5, 2013, of the 19 companies listed on this platform three companies , including Monarch Health Services, HPC Bio-science and Esteem Bio Organic -are focused on the bioscience segment.

The Indian biotechnology sector is one of the fastest growing knowledge-based sectors and is expected to play a key role in shaping India's rapidly developing economy. With numerous comparative advantages in terms of R&D facilities, knowledge, skills, and cost effectiveness, the biotechnology industry in India has immense potential to emerge as a global key player.