

The Indian pharma and biotech industry has weathered a difficult FY14. It needs proactive support, the right incentives and a conducive policy environment to get back its shine

# Unleashing the pharma power



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India has successfully showcased its scientific prowess to the world through its acknowledged leadership in the global generic pharmaceuticals space. Today, one in five generics and one in two vaccines has a 'made in India' label. The ability to deliver high-quality medicines at affordable rates has earned India the sobriquet 'pharmacy of the world'. It has also positioned India's pharmaceutical and biotechnology industry to generate combined revenues of \$100 billion by 2025.

If the industry is to quintuple in size from the current \$20 billion, it will need annual investments of \$4.5 billion for the next five years. To realise this quantum of growth and absorb this level of investments, the right policy framework needs to be put in place. Successive governments have largely ignored the pharma and biotech sector in their annual Budgets. Over-regulation, over-taxation, under-incentivisation and under-investment have steadily eroded the sector's global competitiveness.

Out-of-the-box thinking and forward-looking policies are needed to revive the fortunes of this promising sector and turn it to high-growth trajectory. A reform-minded new government at the Centre is best positioned to unleash the immense potential of the pharma and biotech industry and make it a shining example of a resurgent Brand India.

**Blueprint for growth**  
Three strategic areas need immediate attention to make the Indian pharma and biotech industry globally competitive and prime it for sustained high growth.  
**Manufacturing:** To make India a

global hub for production of small molecules (chemically synthesised) and large molecules (biologicals).  
**Innovation:** To position India at the forefront of genomics, biomedicine and novel molecules (R&D).  
**Entrepreneurship:** To catalyse innovative pharma and biotech start-ups to the next level by improving access to capital.

**Boost for manufacturing**  
Manufacturing is an area where the pharma and biotech industry has leveraged India's cost-competitiveness to expand access and affordability of life-saving drugs to a global marketplace. As the world's largest producer of generic drugs with \$10 billion in annual exports, India has the necessary prowess to capture a substantial chunk of the global contract manufacturing pie that is expected to grow to \$30 billion by 2025. The right policy incentives can enable Indian players capture as much as a 50% share of this market in the next decade.

Keeping the large opportunity in mind, fiscal incentives should be provided to drive investments in creating global manufacturing scale. Here the special economic zones (SEZs) can play a crucial role.  
**Exempting pharma and biotech SEZ units from the minimum alternate tax (MAT)** will make investments attractive. Extending the five-year tax holiday for these SEZs by two additional years will factor in regulatory time lags typical to these projects.

Elimination of service tax on manufacturing services provided to international clients, interest subsidies and long-term loans will also give the industry a much-needed boost.

**Incentives for innovation**  
Although there is a huge scientific talent pool in India, R&D has not taken off in the country owing to the lack of incentives

for nurturing innovation and encouraging breakthrough research. A whopping \$4,000 crore collected as R&D cess had to be remitted to the Consolidated Fund of India because of the government's failure to deploy these much-needed funds to spur innovative research in industry or academia.

**The cost of developing biologics is high, involving major investments in clinical development, specialised manufacturing facilities and stringent regulatory protocols. To incentivise biopharma players, these drugs should be exempt from price control for five years**

Domestic pharma and biotech companies have been investing incrementally in innovation across drugs, vaccines, diagnostics, biopharmaceuticals, biotech, enzymes and agro-chemicals. The government needs to supplement these efforts by extending the current benefit of weighted tax deduction for in-house R&D expenses to spending on international patents, global clinical studies and other outsourced services.

Also, the departments of science & technology and biotechnology should allocate a substantial part of the R&D cess collected annually to support research efforts across the life sciences innovation value chain.

India's image as an attractive hub for drug innovation has taken a hit from the snowballing of the clinical trials controversy. With global sponsors exiting, Indian contract research services providers have seen revenue halve from the \$1 billion achieved in 2012.

Budget measures like elimination of MAT on SEZs and service tax exemption for export-generating research services could help reverse some of the damage.

**Push for entrepreneurship**

India's pharma and biotech industry, which has brought global recognition for the country, has been built on bold entrepreneurship. The success of the early entrepreneurs has attracted others to the space and led to the establishment of a strong small and medium enterprises (SMEs) base. This augurs well for the Modi government's proposed universal healthcare plans. Unfortunately many of these SME players do not have access to the kind of capital needed to scale up.

To enable these SME players to move to the next level, there is a need to encourage the flow of capital through seed funds, risk capital and venture funds in the sector.

There should be full tax exemption for angel in-

vestors and CSR (corporate social responsibility) funds co-investing in government-backed innovative research in partnership with the Biotechnology Industry Research Assistance Council (BIRAC).

All SEBI-registered funds as well as CSR funds investing in government-backed accelerators and incubators should be eligible for R&D-related weighted tax deduction.

The SME Exchanges of NSE and BSE have benefited Indian SMEs in general. However, few investment bankers are willing to underwrite the offerings of pharma and biotech SMEs because of the complex, risky and long gestation nature of the business. This can be addressed by creating a corpus of \$300 crore to be utilised for underwriting 50% of the valued pharma and biotech-related IPOs on the SME Exchanges.

**Impetus for industry**

The cost of developing biologics is very high, involving significant investments in clinical development, specialised manufacturing facilities and stringent regulatory protocols. To incentivise biopharma players, these drugs should be exempt from price control for a period of five years.

Also, indigenous developed drugs need to be supported through 15-20% weighted advantage in tenders for government procurement.

Tax should be exempted on all essential drugs and those for chronic diseases such as diabetes, cancer, cardiovascular, renal and pulmonary to lessen the impact from arbitrary price controls, which can potentially deter quality drug makers from manufacturing these medicines.

The Indian pharma and biotech industry had to weather a difficult FY14 on account of an unfavourable business and policy environment. It needs proactive support, the right incentives and an enlightened policy environment to get back its shine.

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