

## Sector Report

# Biotechnology & Pharmaceuticals India

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## OVERVIEW

India is a priority emerging market for UK Trade & Investment. Recent developments in the sector in India indicate increasing business opportunities for the UK's biotechnology & Pharmaceutical sector.

### Indian Biotech & Pharmaceutical Sector

#### Biotechnology

Following the phenomenal success of its information technology industry, India is fast emerging as an important player in the biotechnology sector in the Asia-Pacific Region. The large pool of scientific talent available at a reasonable cost, a wealth of R & D Institutions, a rich and varied bio-diversity, a flourishing pharmaceutical industry, strong IT skills and an English speaking population has placed India favourably in the global market.

A few years ago India had only 30 biotech companies worth talking about. Today about 325 companies are active in the modern biotechnology segment with combined revenues of about \$2.7 billion. It is expected to reach the target of \$5 billion by 2010. The heady growth achieved by the industry in the last five years dropped to 18% in 2008-09 due to appreciation of the rupee and price pressures in global markets.

#### Pharmaceutical

The Indian pharmaceutical industry is driving product development and breaking new grounds in medicine research worldwide.

The Indian domestic pharmaceutical market is estimated to be US\$ 10.76 billion in 2008 and is expected to grow at a high compound annual growth rate (CAGR) of 9.9 per cent till 2010 and thereafter at a CAGR of 9.5 per cent till 2015.

### Government Initiatives

#### Biotech

The Government of India and the UNESCO fully realising the need of training and education for generating interdisciplinary human resource relevant to biotechnology, took a joint decision to establish the Regional Centre for research, training and education in biotechnology under the auspices of UNESCO. The UNESCO Regional Centre for Biotechnology will come up in Faridabad, Haryana by next year.

Further, the Department of Biotechnology (DBT), Govt of India, has also decided to set up a unique Health Biotech Science Cluster (HBSC) at Faridabad.

The DBT is exploring avenues to fund research, focus on the opportunity of bio-similar products and create infrastructure to scale-up human resources to support a shift to high-end research in the long term. The department has recently got approvals from the Union Finance Ministry for US\$ 39.33 million fund for vaccines that would support a range of programmes including clinical trials, vector development, adjuvant development and intellectual property. Another such funding proposal from the DBT is the US\$ 68.79 million corpus, over a three-year period, where soft loans would be given at two per cent interest for bio-similar projects.

The Centre is also looking to support innovation from universities and a Bill to empower scientists and help them commercialise their innovations is expected to be passed by the end of the year.

- The Karnataka government is proposing to establish biotech parks in prominent cities to promote the biotechnology sector in the state. Chief Minister Mr B S Yeddyurappa, in his budget proposals for the year 2009-10, said that the government would take steps to establish biotech parks based on the recommendations of the Biotechnology Mission.
- The Andhra Pradesh Industrial Infrastructure Corporation (APIIC) has allotted land to 19 companies so far in the Biotech Park Phase III at Karakpatla, Medak district. The biotech companies such as Avesthagen Ltd, Indian Immunologicals Ltd, Neozene Biosciences, Parsvanath SEZ Ltd, Brinda Life Sciences and Globion India Pvt Ltd have been allotted land. Over the next five years, over US\$ 2.69 billion is likely to be invested by these companies.
- The Phase III of Genome Valley Biotech Park was inaugurated on January 28, 2009. Nineteen companies have confirmed setting up their operations here on the 600-acre facility at Karakapatla, near Shamirpet on the outskirts of Hyderabad, Andhra Pradesh.
- The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and the DBT have launched a project for establishing a platform for translational research on transgenic crops (PTTC).

#### Pharmaceuticals

The Government has taken various policy initiatives for the pharmaceutical sector

- Government has offered tax-breaks to the pharmaceutical sector. Units are eligible for weighted tax deduction at 150 per cent for the R&D expenditure incurred.
- Steps have been taken to streamline procedures covering development of new drug molecules, clinical research etc.
- Government has launched two new schemes—New Millennium Indian Technology Leadership Initiative and the Drugs and Pharmaceuticals Research Programme—specially targeted at drugs and pharmaceutical research.

#### Funding

Most funding support for Research and Development has come from Central and State Government. Biotechnology is still relatively new ground to the Indian venture capital community and this lack of understanding is seriously limiting the availability of funding for both start-ups and established companies. As a result many companies are employing a so called 'earn as you learn' model to launch and sustain their businesses. This involves revenue-generating projects, such as contract research or contract manufacturing. For established companies, Indian banks are the main source of capital. Some State Governments, such as Andhra Pradesh, have set up a separate Biotechnology Venture Capital Fund to bridge the gap. A few Venture Capital groups from USA have been visiting India in the recent past to explore investment opportunities. Some national banks such as ICICI and Small Industries Development Bank of India (SIDBI) are also offering schemes to help start-ups.

## OPPORTUNITIES

### Biotech Sector

India is also gaining importance as a clinical trial destination. The global clinical research outsourcing market is projected to touch US\$ 23 billion by 2011, with consultancy firm KPMG estimating that India will corner 15 per cent of this in two years.

A growing number of Indian biotechnology firms are now providing research and development (R&D) services to global pharmaceutical companies. The vaccines' market in India will also lead the demand growth in South-East Asian countries as many new vaccines are set to be launched in five years. Global vaccine sales were US\$ 21 billion in 2008 while the Indian market was valued at US\$ 360 million, thus, creating major opportunities for Indian biotechnology and pharmaceutical companies.

According to an industry survey, carried out by Association of Biotech Led Enterprises (ABLE), biotechnology industry in India has notched up a growth of 20 per cent during 2007–08 and the revenues earned were worth US\$ 2.56 billion as against US\$ 2.1 billion during the previous fiscal. Research services touched US\$ 500 million and bio-IT (bioinformatics) was US\$ 250 million.

Further according to the findings, going by the current trend and the new biotech policy of the central government, the sector is poised to generate US\$ 13–16 billion by 2015.

### Pharmaceutical Sector

#### Generics

According to a report by IMS Health, the Indian generic manufacturers will grow to more than US\$ 70 billion as drugs worth approximately US\$ 20 billion in annual sales faced patent expiry in 2008. With nearly US\$ 80 billion worth of patent-protected drugs to go off patent by 2012, Indian generic manufacturers are positioning themselves to offer generic versions of these drugs.

#### Diagnostics Outsourcing/ Clinical Trials

The Indian diagnostics and pathology laboratory business is presently around US\$ 864 million and is growing at a rate of 20 per cent annually.

Moreover, the US\$ 200-million Indian clinical research outsourcing market will reach up to US\$ 600 million by 2010, according to a joint study done by KPMG and the Confederation of Indian Industry (CII) in September 2008.

### Research & Development

- In a bid to boost R&D in the pharmaceutical sector, the government will provide US\$ 422.96 million for establishing six National Institutes of Pharmaceutical Education and Research over the next five years.
- Biotechnology major, Biocon, will be investing US\$ 20.11 million in the next fiscal in enhancing its R&D.

UKTI publishes international [business opportunities](#) gathered by our network of British Embassies, High Commissions and Consulates worldwide. These opportunities appear in the Opportunities portal on the relevant sector and country pages on the UKTI website. By setting a profile you can be alerted by email when relevant new opportunities are published. New or updated alert profiles can be set in My Account on the website.

## CHARACTERISTICS OF MARKET

### Definitions

The Indian definition of biotechnology used for many official figures is broader than that generally used in the UK and elsewhere. It tends to include all industries involving a biological process covering plant culture, nutraceuticals, traditional pharma and alternative medicine etc.

### Bio-Clusters in India

India finds a place amongst the top 10 biotech hubs in the world and is one of the five promising biotech markets in the Asia-Pacific region.

Being home to 200 diverse companies, the biotech cluster in Bangalore alone leads the pack, whereas other cities like Hyderabad, Chennai, Pune and Mumbai also have come up as preferred destinations to set up a biotech facility.

### Karnataka –Bangalore

India's silicon hub Bangalore dominates not only in IT, but also in biotechnology, accounting for about 60 percent of the country's exports. It is a sunrise industry, estimated to achieve the target of \$5 billion (Rs.200 billion) by 2010. With about 30 percent year-on-year growth, the sector's revenue increased to \$3 billion (Rs.120 billion) for fiscal 2008. About 50 percent (\$1.5 billion) of the total revenue is generated from exports, with Bangalore again driving the growth. In the case of investments, Bangalore accounted for 12 of the 24 biotech firms set up in the last fiscal (FY 2008). Bangalore biotech firms have maintained 35 percent growth rate with upfront investment of \$250 million in last fiscal. As the country's largest cluster, the city boasts of 200 biotech firms.

Companies like Biocon, Strides, Avestahgen, Microlabs are present in Bangalore. Dr Kiran Mazumdar Shaw a key influencer is from Biocon, Bangalore.

Government of Karnataka is investing Rs. 5,500 crore in Bangalore Helix Biotech park which is spread over 106 acres at the Electronics City, off Hosur Road in Bangalore.

Bangalore can boast of good Universities like the Indian Institute of Science, JNCASR, NCBS, University of Agricultural Sciences. ABLE the Trade association for Biotech Industry is headquartered at Bangalore.

Bangalore has opportunities in Contract Research Space and lot of potential in the Stem Cell area.

### Andhra Pradesh - Hyderabad

Biotechnology is an important industry in Andhra Pradesh. There is a high concentration of biotech companies producing recombinant therapeutics for human consumption. It also has the second largest recombinant DNA therapeutic production facility in the world, which is also being used by multi-national companies to produce their own recombinant products.

Andhra Pradesh is called "Bulk drug Capital of India". Andhra Pradesh has a dominant position in the bulk drugs and pharmaceutical sector with Hyderabad accounting for nearly one third of India's total bulk drug production.

Hyderabad has witnessed infrastructural development in the biotech domain wherein the Knowledge Park, the Biotech Park, Genome Valley and other projects have come up giving the city an advantage over others. Hyderabad is also a house for research and development Centres like Centre for Cellular and Molecular Biology (CCMB), Indian Institute of Chemical Technology (IICT), International Crop Research Institute for Semi-arid Tropics

(ICRISAT), Central Food Technology Research Institute (CFTRI) and Institute for Life sciences centre is based out of Hyderabad and have 32 laboratories and 12 research centres. (ILSC)

The Government of Andhra Pradesh offers opportunities in Therapeutics, Diagnostics, Industrial Biotechnology, Inputs to the industry (hardware suppliers - Instrumentation and Chemicals), Agricultural Biotechnology in the biotech space.

#### TamilNadu - Chennai

Tamilnadu is the first state to have introduced a separate Bio Tech policy. Tamil Nadu presents an attractive market for medical biotechnology products as it accounts for about 11% of the pharmaceutical market in the country. The Government of Tamil Nadu has also announced the establishment of Biotechnology Enterprise Zones (Bio-Valleys) along the lines of Silicon Valley to exploit the bioresources of the State. Chennai has some of the top pharma companies like Orchid Pharma, Shasun Pharma and Bafna Pharmaceuticals and few Biotech companies like ABL Biotech and Proalgen Biotech. Tamil Nadu also has research centres like Centre for Biotechnology, Anna University Centre for Plant Molecular Biology, Tamil Nadu Agricultural University, Coimbatore, Centre for Research in Medical Entomology, Madurai, Department of Biotechnology, School of Bioengineering, SRM University, Rajiv Gandhi Centre for Biotechnology, School of Biotechnology, Madurai Kamaraj University, School of Chemical and Biotechnology – Sastra University.

Tamil Nadu has opportunities in the area of Stemcell Research and Nanotechnology.

#### Western Region

##### Maharashtra

The state accounts for 40 per cent of the country' pharmaceuticals output. It has strong research capabilities and accounts for over 30 per cent of country's patents. It has a presence of reputed companies focusing on the biotech sector including Wockhardt, Nicholas Piramal, Cipla and Lupin, among others and state is setting up biotech parks at Hinjewadi, near Pune. Major opportunities have emerged in the pharmaceutical sector, primarily in the areas of contract research, contract manufacturing and clinical trials. State boasts of Low costs, strong manufacturing base, well developed laboratory and R&D infrastructure, a strong resource pool. The backward linkages with the well-developed chemicals and petrochemicals sector is an added advantage.

##### Gujarat

Gujarat accounts for 28 per cent of national pharmaceutical production (2006-2007). First state to manufacture APIs and finished dosage forms. It is a home to 902 allopathic manufacturing units and 2,122 contract manufacturing units. Gujarat accounts for exports worth US\$ 1.4 billion (2006-2007). It has number of clinical research organisations in India and over 100 companies with WHO-compliant manufacturing units, academic and research institutions providing over 4,600 technically-skilled manpower per annum. India's largest biotech park of 700 acres being developed at Savli, Vadodara. Key players are Zydus Cadila, Torrent Pharma, Sun Pharma, Intas Pharma, Alembic, Dishman Pharma.

Mumbai is home to the two major pharmaceutical associations including Indian Drug Manufacturers Association (IDMA) and Organisation of Pharmaceutical Producers of India (OPPI).

#### MNC's Scout for Alliances with Small R & D Companies

MNCs, whose drug pipelines are drying up and more blockbuster drugs going off-patent, are desperately looking for alliances for drug co-development, buying or licensing out innovative molecules which can further be developed into finished drugs. Smaller Indian firms such as Indus Biotech and Rubicon Research are set to sign multiple deals with MNCs for molecules as well as technology out-licensing.

#### Northern India

New Delhi is home to the Department of Biotechnology, Department of Science and Technology (DST), the Ministry of Health & Family Welfare, the Ministry of Agriculture and the Ministry of Environment and Forests—which are involved closely with the development of biotechnology. Two other important government agencies—the Council of Scientific and Industrial Research (CSIR) which runs a chain of 39 laboratories out of which 12 are dominant players in biotech and the Indian Council of Agricultural Research (ICAR) with its 91 laboratories out of which at least 20 do top end research in biotech, are also headquartered in the Capital. New Delhi is also home to a large number of national and international research centers. At the top of the heap is the International Center for Genetic Engineering and Biology (ICGEB). This UN funded institution has major research activities in genetics based out of New Delhi

This region is particularly strong in the area of research and education within the Biotech/pharma sector.

BioAgriculture research activities are also concentrated in the Capital. India's premier farm research center, the Indian Agricultural Research Institute (IARI). IARI's research teams are developing at least half-a-dozen GM food products.

Private sector institutes including ICRI and Cliniminds are also headquartered in North India.

Business – A number of API manufacturers are clustered in Baddi in Himachal Pradesh. Most of these have FDA approved plants and are keen to work with overseas pharma companies. Panacea Biotech, one of the two leading Indian vaccine manufacturers has about 4 manufacturing locations spread around North India. The region is also home to CROs like Ara Healthcare, Onquest and Premas Biotech providing services in niche areas of Biotechnology.

#### Size of the Market

##### Biotechnology

The BioSpectrum Biotech Industry Survey conducted with the Association of Biotech Led Enterprises (ABLE), shows that the industry's revenue grew to Rs 12,137 crore or \$2.7 billion in the fiscal ended March 31, 2009 from Rs 10,273 crore or \$ 2.56 billion in 2007-08. India's domestic market grew by just 9% large proportion of exports. The rise in dollar value has helped companies increase their topline.

In rupee terms the export business went up by almost 25% to Rs 7,152 crore, accounting for 60% of the total business in 2008-2009. However, the export growth in dollar terms is just 6% for the year. The domestic business at Rs 4,985 crore registered a 10% growth during the year, but this resulted in a negative growth of 7% in dollar terms.

The biopharma segment continued to account for the largest share of the biotech industry in terms of revenue. In 2008-2009, the sector had a 65% share with revenues at \$ 1.67 billion (Rs 7,883 crore). In dollar terms this is a negative growth. The bioservices market registered a 30% growth and continues to be the fastest growing sector.

## Pharmaceuticals

Currently, the Indian pharmaceutical industry is one of the world's largest and most developed, ranking 4th in volume terms and 13th in value terms. The country accounted for 8 per cent of global production and 2 per cent of world markets in pharmaceuticals.

The Indian pharmaceutical offshoring industry is slated to become a US\$ 2.5 billion opportunity by 2012, thanks to lower R&D costs and a high-talent pool in India.

## Growth

India's pharmaceuticals market is expected to grow by about 12-13 per cent in 2009, says a study by consulting firm IMS.

The Indian vaccine market was worth US\$ 665 million in 2007-08 and is growing at over 20 per cent. Exports contribute over US\$ 360 million, while the domestic market for vaccines is US\$ 300 million.

## Sector Dynamics

While India has long been practising conventional methods of biotechnology, the use of modern biotechnology is relatively new. It still needs to contend with vital issues such as intellectual property rights and other regulatory matters. The Government of India has taken several initiatives to change the perception of the IPR System and its implementation mechanism. However, several Indian biotech companies have managed to cross these IP hurdles to work with international partners through confidentiality and non-disclosure agreements. Though Indian companies have been impacted with credit squeeze, public funding has been on the rise and through Public Funded R&D programmes there is encouragement for researchers and academics to innovate.

The industry is optimistic and is on the path to recovery with several concerns including funding, regulatory issues, government support, industry-academia collaborations and public-private partnerships are falling in place. The vaccine industry is buoyant and the pharma sector is geared to enter the biosimilar space.

## Looking ahead

India is already being globally recognised as a manufacturer of economical, high quality bulk drugs and formulations. With a huge base of talented, skilled and cost competitive manpower, and a well-developed scientific infrastructure, India has great potential to become a leading global player in biotechnology.

### Key Methods of Doing Business

General information on doing business in India is contained in the India pages.

In the biotech sector, there are different possibilities of doing business. Some of the ways in which one can do business is as under:

1. Set up joint venture companies to locally manufacture the product
2. Collaborative research
3. Contract research
4. Contract Manufacturing
5. Technology transfer
6. Marketing arrangement for Bio-supplies (appoint distributor/agent)
7. Clinical research

As regards supplies to the biotechnology sector, equipment and instruments are dealt with by the laboratory equipment manufacturers/distributors. Most heavy machinery and equipment are either imported through agents or manufactured locally by multinational companies.

When considering potential partners, it is important to look for companies with an established track record of foreign clients. Also most promoters of biotech companies (SMEs) have strong linkages with leading research and academic institutions. It would be useful to ascertain the existence of such arrangements if any. Other good indicators are whether the company is a member of any recognised trade body or has international certification (FDA approval /ISO 9000 etc). The network of Commercial Offices of the British High Commission in India could also be contacted for guidance and reference.

### PUBLICATIONS

- Biospectrum (monthly biotech magazine)  
401, 4<sup>th</sup> Floor, MBC  
134 Infantry Road  
Bangalore 560 001  
Website: [www.biospectrumindia.com](http://www.biospectrumindia.com)
- Chronicle Pharmabiz (weekly newsletter)  
Ipharma India Ltd  
Manek Mahal,  
5<sup>th</sup> Floor,  
90 Veer Nariman Road,  
Churchgate  
Mumbai-400 020  
Website: <http://www.pharmabiz.com>
- Express Pharma Pulse  
Business Publications Division,  
Indian Express Newspapers (Bombay) Ltd.,  
Express Towers, 1st floor,  
Nariman Point, Mumbai 400 021  
Website: <http://www.expresspharmapulse.com>

Monthly Newsletter by ABLE: <http://ableindia.org/html/newslet/newslet.html>

Other background information on doing business in India can be found on UKTI's website. Simply go to the India country page where you will find information on:

- Economic background and geography
- Customs & regulations
- Selling & communications
- Contacts & setting up
- Visiting and social hints and tips

### MORE DETAILED SECTOR REPORTS

Research is critical when considering new markets. UKTI provides [market research](#) services which can help UK companies doing business overseas including:

- Overseas Market Introduction Service (OMIS). Bespoke research into potential markets, and support during your visits overseas
- Export Marketing Research Scheme. In-depth and subsidised service administered by the British chambers of Commerce on behalf of UKTI

Contact your local [International Trade Advisor](#) if you are interested in accessing these services, or for general advice in developing your export strategy.

When considering doing business in India, it is essential to obtain legal, financial and taxation advice. A useful contact list of lawyers and other relevant professional bodies as well as further information on the fire, police & security sector in the country is available from the High Commission. For further details, please contact:

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[www.ukinindia.com](http://www.ukinindia.com)

### EVENTS

- Global Value on going Programme – UKTI initiative
  - BioInvest: 5 Nov, 2009 ([www.ableindia.org](http://www.ableindia.org))
  - Inward Delegation – Stem cell focussed : Jan, 2010 (UKTI initiative)
  - BioAsia: 3 to 6 Feb, 2009 (<http://www.bioasia.in>)

UK Trade & Investment's [Tradeshaw Access Programme](#) (TAP) can help eligible UK businesses take part in overseas exhibitions. Attendance at TAP events offers significant benefits:

- possibilities for business opportunities both at the show and in the future
- a chance to assess new markets and develop useful contacts
- grants are available if you meet the criteria
- UKTI staff overseas will be available to assist delegates

Find out if you are eligible to apply to attend this event, and more about the support UKTI can offer, on the UKTI [Market Entry](#) web page.

Details of TAP events can be found in the Events portlet on the India page.

Other Market Visit Support may be available via your local International Trade Advisor.

## CONTACT LISTS

### Trade Associations

Association of Biotech Led Enterprises ( ABLE)  
123/C, 16th Main Road  
5th Cross, 4th Block  
Near Sony World showroom / Headstart school  
Koramangala  
Bangalore - 560034  
India  
Telefax : +91 80 41636853 / 2563 3853  
E-mail: [info@ableindia.org](mailto:info@ableindia.org)  
Website: [www.ableindia.org](http://www.ableindia.org)

Confederation of Indian Industry (CII)  
Plot 249 F, Sector 18  
Udyog Vihar Phase IV  
Gurgaon 122 015  
Tel: +91 124 5014060-67  
Email: [cico@ciionline.org](mailto:cico@ciionline.org)  
[www.ciionline.org](http://www.ciionline.org)

The Associated Chambers of Commerce & Industry of India  
ASSOCHAM Corporate Office  
1, Community Centre, Zamrudpur,  
Kailiash Colony, New Delhi - 110 048  
Tel: +91 11 46550514  
Website: <http://www.assochem.org/>

### National Government Bodies

Department of Biotechnology,  
Department of Biotechnology  
CGO Complex, Lodi Road,  
Block No. 2, Floor 7,  
New Delhi - 110 003.  
Website: <http://dbtindia.nic.in>

Council for Scientific and Industrial Research  
Anusandhan Bhawan, 2 Rafi Marg,  
New Delhi-110001.  
Tel: +91 80 23737889  
Email: [dyr@csir.res.in](mailto:dyr@csir.res.in)  
Website: <http://www.csir.res.in>

Department of Science & Technology,  
Technology Bhavan, New Mehrauli Road,  
New Delhi - 110016  
Tel: +91 11 26567373, 26962819

Fax: +91 11 26864570, 26862418  
Email: [dstinfo@nic.gov.in](mailto:dstinfo@nic.gov.in)  
Website: <http://www.dst.gov.in>

Intellectual Property & KnowHow Informatics (Patent) Division  
National Informatics Centre,  
Department of Information Technology  
A-Block, CGO Complex, Lodhi Road  
New Delhi - 110 003, India  
Tel: +91 11 24363239  
Fax : +91 11 24362628  
Email: [bali@nic.in](mailto:bali@nic.in)  
Website: [www.patinfo.nic.in](http://www.patinfo.nic.in)

Controller General of Patents, Designs & Trade Marks  
Bhoudhik Sampada Bhavan,  
Near Antop Hill Head Post Office, S.M. Road, Antop Hill, Mumbai-400037,  
Tel: +91 22 24123311,  
Fax : +91 22 24123322  
Website: [www.ipindia.nic.in](http://www.ipindia.nic.in)

UKTI's International Trade Advisers can provide you with essential and impartial advice on all aspects of international trade. Every UK region also has dedicated sector specialists who can provide advice tailored to your industry. You can trace your nearest advisor by entering your postcode into the [Local Office Database](#) on the homepage of our website.

For new and inexperienced exporters, our [Passport to Export](#) process will take you through the mechanics of exporting. An International Trade Adviser will provide professional advice on a range of services, including financial subsidies, export documentation, contacts in overseas markets, overseas visits, translating marketing material, e-commerce, subsidised export training and market research.