



MAHARASHTRA BIOPHARMACEUTICAL CLUSTER

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Executive Summary

Biopharmaceuticals are produced by natural organisms or by genetically engineering proteins derived from living organisms (application of biotechnology). Major global drug companies are increasingly turning to biotechnology for new products to fuel growth. Biopharmaceuticals account for 10 of the top 50 selling drugs and 18% of all drugs in development (IMS Health, 2009).

The Western Indian State of Maharashtra has been a major base for the Indian pharmaceutical industry for over 100 years and houses leading national companies like Wockhardt, Nicholas Piramal and Intas as well a number of large international companies including GlaxoSmithKline, Novartis, Pfizer, Johnson & Johnson etc. The largest biopharmaceutical company in the country, the Serum institute of India, is based in Pune, Maharashtra's 2nd largest city. Today, over 70 companies located in Maharashtra account for 35% of India's biotech revenues (BioSpectrum India, 2009)

Maharashtra advantages include a large pool of low-cost English speaking skilled labor. The presence of one of the 6 Indian Institutes of Technology in Mumbai is the clearest example of a regular supply of local highly talented technical excellence. The challenge of 'brain drain' is however one that must be overcome if the cluster is to move up the value chain from process replication to 'original' research and development for which it is currently, overwhelmingly dependent on foreign organizations. To address these challenges, we recommend the Indian government double R&D spending and direct money to Universities. Maharashtra's government should provide matching grants, increase research programs, upgrade laboratories and provide incentives for firms to collaborate with local institutions. Companies too should widen the scope

of their relationship with academia by inviting representation from Universities to industry associations

In an environment driven by original patents¹, the central government is highly supportive of the biopharmaceutical industry with the Department of Biotech providing grants for R&D. The high density of commercial enterprises in Maharashtra is complemented by the existence of Central Research Organizations, WHO accredited institutions and foreign research collaborations. These positive dynamics partly offset the countrywide issues of bureaucracy and corruption which when allied with low enforcement of standards have meant that foreign investors have been cautious of committing large pools of capital and withheld 'high end' development R&D. To tackle the constraints posed by bureaucracy and corruption, we recommend the adoption of a single window mechanism for new Biotech companies to get clearances, apply for financing and submit documents for auditing at the Central and State level.

The legacy of import substitution and public sector demand for inexpensive mass vaccinations has sustained the cluster for most of the previous century. Large governmental demand for low cost vaccines has meant the cluster has developed the capability of process replication and high volume (though low value) production. Nevertheless the poor public health system, unsophisticated demand and high untreated population mean the cluster has limited local sophisticated demand that could drive innovation. To address this issue we recommend that government develops a plan to invest in a few diseases and set specific health targets. The government should use financial incentives that help to achieve these targets and launch educational campaigns to improve the rates of people being tested and seeking treatment. We also recommend that cluster companies target doctors directly and facilitate their exposure to biotech- based cures for diseases such as Diabetes and Cancer.

¹ India agreed to abide by International Patent Laws in 2005 marking the end of an era of 'reverse engineering' of patented products by firms

1. Country & State Analysis: India & Maharashtra

1.1 Geography, Population, Government, & Politics

India is located in South Asia and borders Burma, Pakistan, China, Nepal, Bhutan and Bangladesh. It is spread over 3.2 million sq km. and strategically located on the Indian Ocean trade routes. India's population is 1.16 billion people with an annual population growth rate of 1.15%. 26% of India's population lives below the poverty line placing the country at 128th in terms of Human Development (UNDP, 2007). India's mass poverty is also reflected in the country's high infant mortality rate -54 deaths per 1000 births, and low life expectancy- 69.59 years. The literacy rate is 61% -73.4% for men and 43.8% for women, depicting a wide gender gap in education (Census, 2001).

Located in the western region of India, Maharashtra is the third largest state in the country, stretching over 307,690 sq km and with a total population of 96.9 million. The state is highly urbanized with 42 per cent of the people living in urban areas. **Mumbai**, the capital of the state, is India's largest, most populated city (12 million population) and the financial capital of the nation. 120km away from Mumbai is **Pune** - another major city (2.5 million) and the center of Biopharmaceutical activity in the state.

India gained independence from the British in 1947 and became a federal republic with its capital in New Delhi. The partition also resulted in the creation of Pakistan in the north-west of the country; and in the sixty years of independence both countries have shared uneasy relations that have been defined by war and conflict in the region of Kashmir. The regional tensions and politics necessitate high expenditures on military programs, which have a draining effect on the economy and resources available for developmental needs.

Constitutional authority in India is executed directly through parliamentary style government at national and state level as well as elected government bodies at local levels. India's administrative structure is divided into 28 states and 7 unions. 'The constitutional assignment of specific statutory powers (Police, public health, local government, agriculture and sales tax) to the states is what makes India a federal system. Many Indian states, like Maharashtra, are quite large in terms of population with the largest dozen comparable to larger European countries.

Maharashtra's Biopharmaceutical industry is concentrated in urban areas governed by Municipal Corporations that have responsibility of large urban areas, such as Mumbai and Pune. The governance structure stands today in the same form that was inherited from the British. These structures were effective in centralizing power at federal level and administering diverse ethnic groups, but proved to be poor in terms of promoting local development and initiative leading to the phenomena of urban decay that the Central government is now trying to address through the J.N Nehru Urban Renewal Mission.

1.2 Economic Performance

Economic History & Impact of Reforms

After Independence, India's economic policies were defined by protectionism with strong emphasis on import substitution, state intervention in financial and labor markets, business regulation and central planning, and a large public sector. Business interventions during 1947-1990 were mired by red-tape in the form of complex licensing and regulatory procedure, which was commonly known as the 'License Raj'. The slow growth rate of the Indian economy during this period is referred to as the 'Hindu rate of growth' or a stagnant growth rate of 3.5%.

India's protectionist policies bankrupted the economy in 1991 and it had to be bailed out by the IMF. In order to revive the economy economic reforms were introduced, which included opening up the economy to international trade and investment, deregulation, privatization, tax reforms, and inflation controlling measures. As a result of the profound shift in economic management, the annual GDP growth rate increased from -0.7% in 1991 to 10.6% in 2008 (IMF, 2008). The economic growth trend of India is in part explained by the shift from an agrarian to a services oriented economy, with communications and transportation, financing, and trade and hotels featuring as the fastest growing sectors – 15.3%, 11.7%, and 12.1% per annum respectively (Economic Survey of India, 2008). This also manifests in the composition of GDP, as in 2008 the GDP composition was: agriculture – 17.2%; industry – 29.1%; and services – 53.7%.

The economic reforms introduced in 1991 did not produce immediate results. The Indian economy grew at 0.97% during 1990-1996; per capita GDP growth rate increased to 3.24% between 1997 and 2002, and as shown in Fig. 1 in the past six years average increase in per capita GDP is 7.8%.

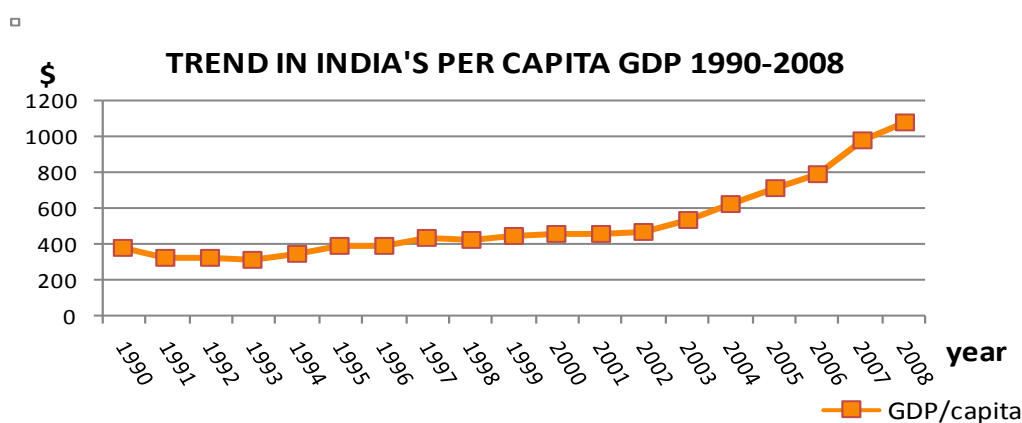


Fig 1: Source- World Economic Outlook, IMF, 2008

Maharashtra Biopharmaceutical Cluster

The growth in India's economy does not sustain luster in comparison with the other BRIC countries (Brazil, Russia, and China). As shown in Fig. 2, India has the lowest per Capita GDP growth among the BRIC countries, and the gap has increased in 2002-2008.

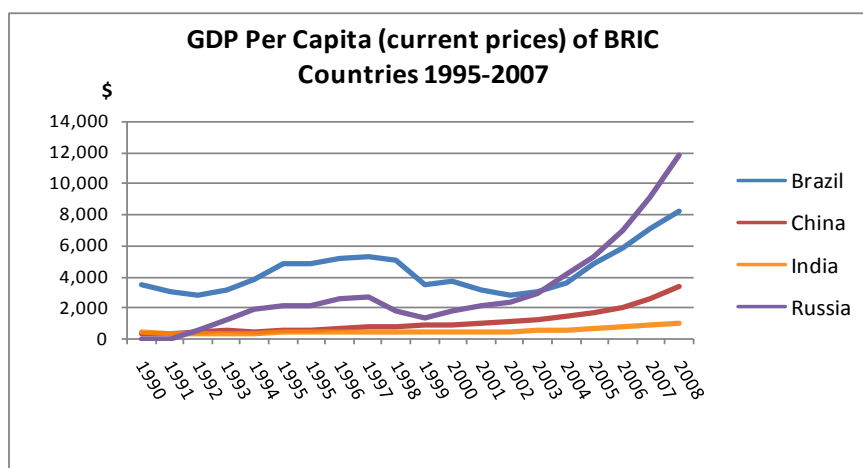


Fig. 2: Source- World Economic Outlook, IMF, 2008

Maharashtra has been a major center for trade due to its excellent harbor facilities and west-facing location. The port city of Mumbai (formerly Bombay) was critical to British trade for over 200 years. The British made significant investments in transportation infrastructure making Maharashtra the most attractive place for many years after independence.

The large volume of economic opportunities associated with trade attracted a number of migrants from arid neighboring regions. Several migrants took the lead in starting successful firms like Tata Sons, Reliance Industries, Wockhardt and the Serum Institute that today, are major players in life sciences and biopharmaceuticals. In comparison to other Indian states, Maharashtra can be described as an established state for trade and commerce; with skilled manpower, favorable policy environment and enabling infrastructure, at the helm of industrial growth. Maharashtra has grown faster than the rest of India and current GDP/capita (at constant prices) stands at 40% higher than the Indian average.

Maharashtra Biopharmaceutical Cluster

MAHARASHTRA VS INDIA: SOCIO-ECONOMIC COMPARISON

Description	Maharashtra	India
Literacy	75%	65%
Infant Mortality	34 per 1000 live births	54
Urban Population	42%	26%
Per capita value added in industries	Rs 5003	Rs 2383
Industrial consumption of electricity per capita	217.5Kwh	126.24Kwh

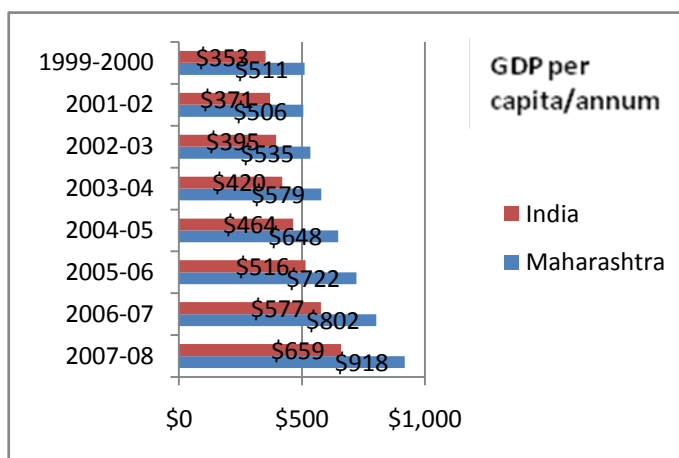


Fig 3 & 4: Source: Maharashtra Socio-Economic Survey 2007-08

Trade & FDI

India's major trade partners are US (15% exports, 7.8% imports), China (8.7% exports, 10.6% imports) and U.A.E (8.7% exports). It has made significant progress in integration with the world economy and in degree of openness; the trade to GDP ratio increased from 22.5% (2001) to 34.8% (2007). The inclusion of services trade also increases the trade to GDP ratio from 29.2% to 48%. India's fastest growing exports are petroleum products (59.3%) and engineering goods (38.1%), which reflects the world oil price, enhanced refining capacity (and increased competitiveness in engineering items (Economic Survey of India, 2008)

India also has track record of current account deficits. In 2008, India recorded a current account deficit of \$38.4billion – almost two times higher than 2007, which was due to economic slowdown, rise in the U.S rising oil prices, and appreciation of rupee against the dollar (IMF, 2008) India has been rated as the '*fourth most attractive investment destination*' in the world by Ernst & Young in June 2008. In 2007-08, in spite of the global meltdown about \$32.4 billion foreign investment poured into India, registering a 45% growth in FDI.

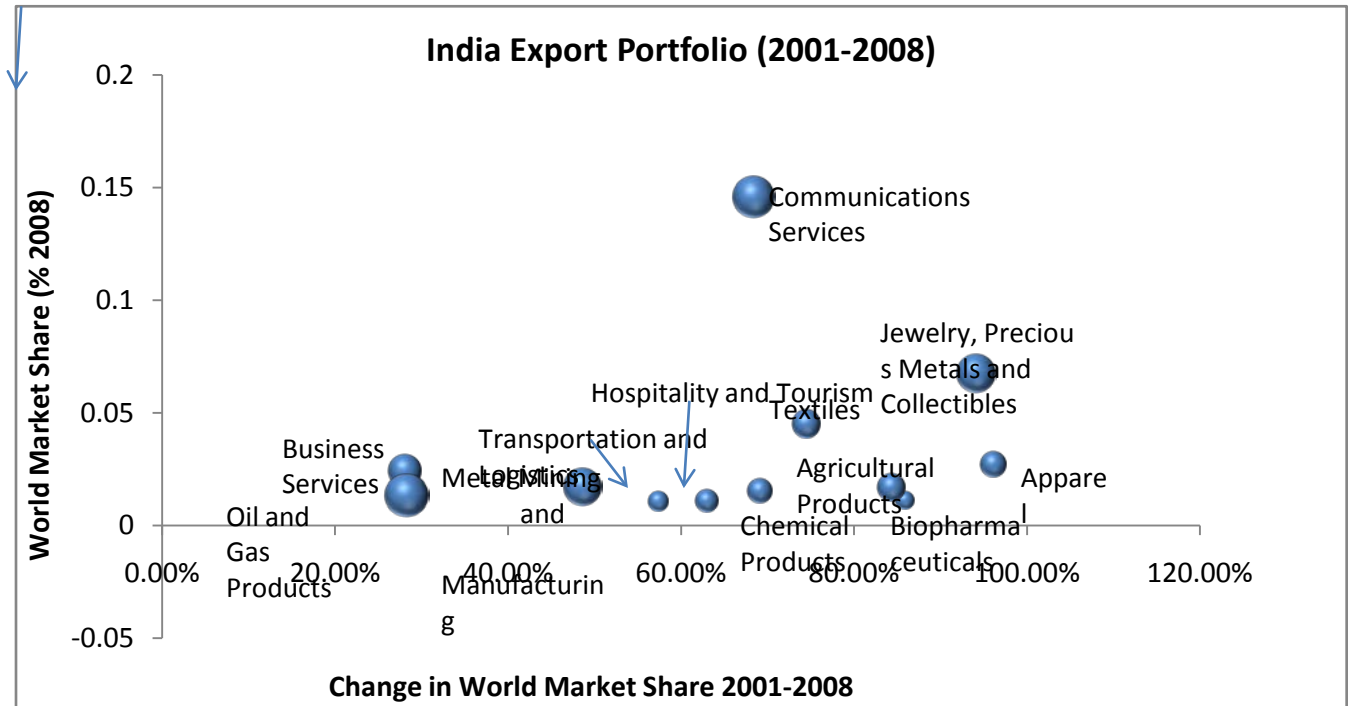


Fig 5: Source- ISC Data

India's exports are diversified and almost all exports groups, although small in terms of world market share, have achieved impressive growth in the period 2001-2008 with the jewelry, precious metals, and the apparel exports almost doubling in value and sectors such as biopharmaceuticals, chemical products, agricultural products, and textiles increasing by well over half.

Maharashtra accounts for approximately 30% of India's exports (Maharashtra Socio-Economic Survey, 2008). Key industrial clusters within the state include petrochemicals, automobiles, pharmaceuticals, financial services, media and entertainment, information technology and IT Enabled Services (outsourcing) and textiles. An important indicator of the state's competitiveness is the level of FDI inflows it has attracted over time. Maharashtra has been able to attract the largest volume of FDI in India between 1991-2000- 21% of total FDI per cent of the country's total, with nearly 4,000 projects committing over \$17 billion in investments (Center for Monitoring Indian Economy & Institute for Competitiveness, 2009)

2. National and State Competitiveness

2.1 National Competitiveness: India Country Diamond

Factor Conditions

India, the second most populous nation in the world, is struggling to lift itself out of the quagmire of poverty. In spite of a strong legal framework, its strategic position as an English speaking people and recent experience of rapid economic growth, India's challenges in terms of factor conditions are enormous. However, it should be noted that India's rankings in education have in recent years improved (77th), albeit slowly. Whilst the macro position of Indian education has been weak, India has developed a strong specialization in technology and engineering graduates- 215,000 science graduates in 2004 vs 222,000 for USA (NSTA, 2004).

A significant impediment to the Indian economy is the poor quality of infrastructure. According to the Global Competitiveness Survey 2008-09, Overall quality of infrastructure is ranked 90th, with 4.5% of the population having access to telephone mainlines and 33% of the population having access to improved sanitation and power shortages in excess of 14,500 MW (a 14% deficiency), all of which represent significant capacity constraints on the Indian economy.

Indian investment in R&D is low at 0.8% of GDP (UNDP, 2008) and this is reflected by low levels of Indian patents (ranking 57th) and that only 4.9% of its manufactured exports are high technology exports (US Patent and Trademark Office, 2008).

Context for Firm Strategy and Rivalry

Post economic liberalization, India has received significant FDI. The cumulative FDI India over the past 20 years has been in excess of \$1 trillion USD with FDI growth of in excess of 750% since 2001 (Department of Industrial Policy and Promotion, Government of India, 2009). This clearly represents a vote of confidence in India and its growth prospects.

However, India still experiences significant disadvantages in terms of red tape, corruption and government bureaucracy. India is ranked at 105th in terms of ease of starting a business with this process alone requiring a business to complete 13 different procedures (World Bank, Doing Business, 2008). The Indian Government has been working at making significant cultural changes in the administration of regulation. The World Bank notes that it currently takes 35 days to register a business in Mumbai, compared to 80 days in 2004. The performance of the Indian public sector, whilst improving remains a drag on the Indian private sector.

Another area where progress still needs to be made is that of tariffs. Tariffs currently range from 0% to 150% (for luxury items). India is ranked 131st in the trade weighted tariff index (International Trade Center, 2009). The challenge for Indian legislators is to change the tax mix away from tariffs and towards income and consumption, more in keeping with other industrialized economies.

Whilst the modern India did inherit English legal system, protection of business in terms of contracts, intellectual property and business rights are considered to be substandard. Indeed, this is a reflection of the Government's own actions internationally which did not fully recognize international law in terms of product patents until 2005 when the transition period for developing countries to abide by the Agreement of Trade-Related aspects of Intellectual Property Rights (TRIPS) expired. Further investment is needed to strengthen the commercial arm of the Indian courts. Again, this is an area where progress has been made, but more needs to be done.

It could be argued that the private sector has shown remarkable confidence in the opportunities that await in the world's second most populous nation and have done so, in spite of the weaknesses that stem from the administration and governance of that economy.

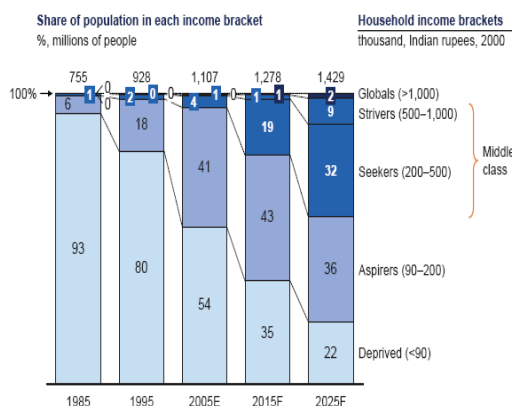
Related and Supporting Industries

India has experienced strong growth across the private sector over recent years and that has enhanced the competitive position of the wider economy. The Global Competitiveness Report ranks Local supplier quantity at 3rd in the world, the state of clusters is ranked 24th, availability of process machinery is ranked 13th and the breadth of its value chain is ranked 28th, implying a dramatic improvement in the business sophistication of Indian businesses.

Demand Conditions

The opportunities for demand in India is the classic “half empty or half full” debate. Whilst India is ranked 128th in terms of income inequality by the United Nations, it has also for many years consistently seen significant falls in its levels of poverty (UNDP, 2008) The number of Indians earning less than \$2 a day fell from 82.6% in 1990 to 75.4% in 2005 with 9.6 million people lifted out of poverty (World Bank, 2005)

INDIA WILL SEE FURTHER REDUCTION IN POVERTY AND GROWTH OF ITS MIDDLE CLASS



INDIA'S SHARE-OF-WALLET IS SHIFTING FROM BASIC NECESSITIES TO DISCRETIONARY ITEMS

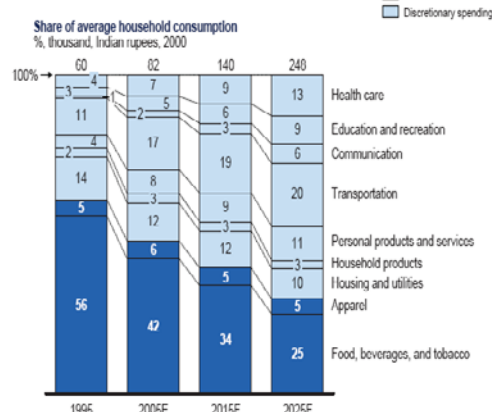


Fig 6 & Fig 7: Source – McKinsey Global Institute

As shown in figure 6 the percentage of deprived population will reduce significantly from 93% in 1985 to an estimated level of 22 % by 2025, thereby increasing the size of the middle class. Rising income levels and growing middle class will shift the consumption patterns from

basic necessities to discretionary items, with health expenditure (13% of house hold income) featuring high in the consumption basket. The India Country Diamond summarizes our analysis of India's Competitiveness.

COUNTRY DIAMOND: INDIA

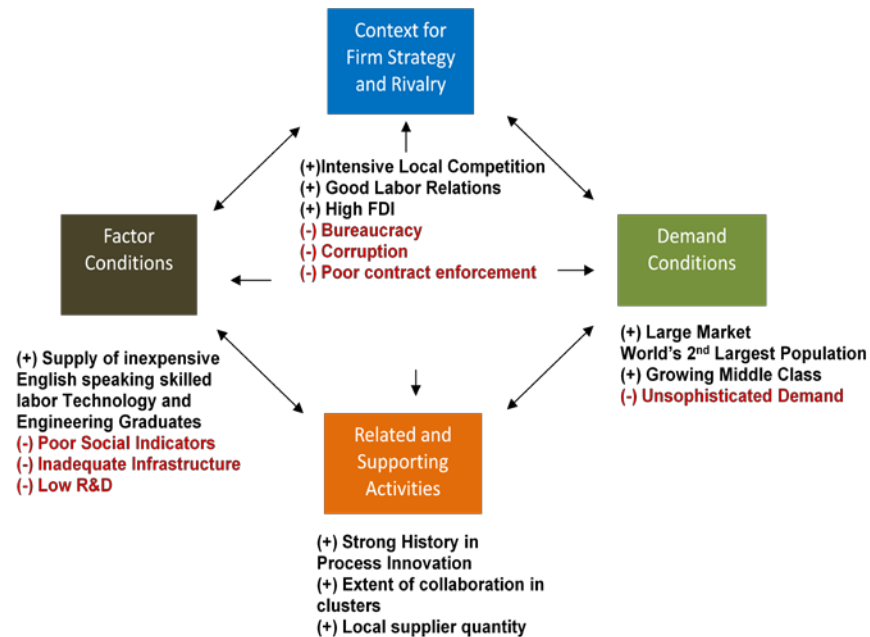


Fig 8: Source: Team Analysis

2.2 State Competitiveness: Maharashtra State Diamond

Maharashtra has long enjoyed the reputation of being one the best states for business in India. In 2006, Maharashtra was ranked at 37th in the World Competitiveness Yearbook. The Indian States Competitiveness Survey in 2009 ranked Maharashtra as No. 1 in terms of business competitiveness. The same survey gives credit to the fact that Maharashtra produces the second highest number of engineering graduates per year (173,894) and has the best road network in India. Even though it doesn't rank on top on a single indicator, all factors combined, Maharashtra provides the most enabling atmosphere for business in India.

Maharashtra Biopharmaceutical Cluster

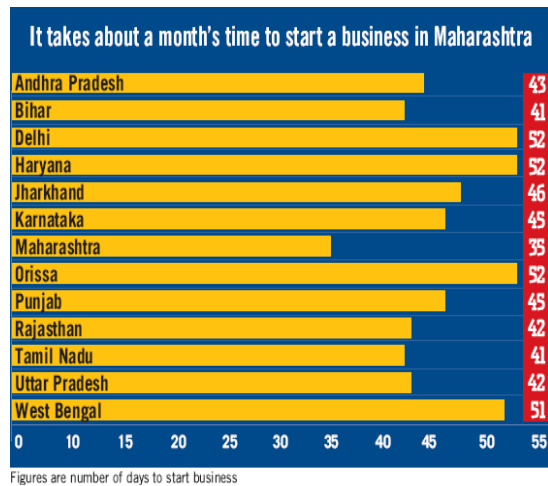


Fig 9: Source- Businessworld, 2009

When viewed using the Diamond framework, Maharashtra's strengths clearly lie in the Factor Conditions and Related and Supporting Industries corners relative to other Indian states.

MAHARASHTRA STATE DIAMOND

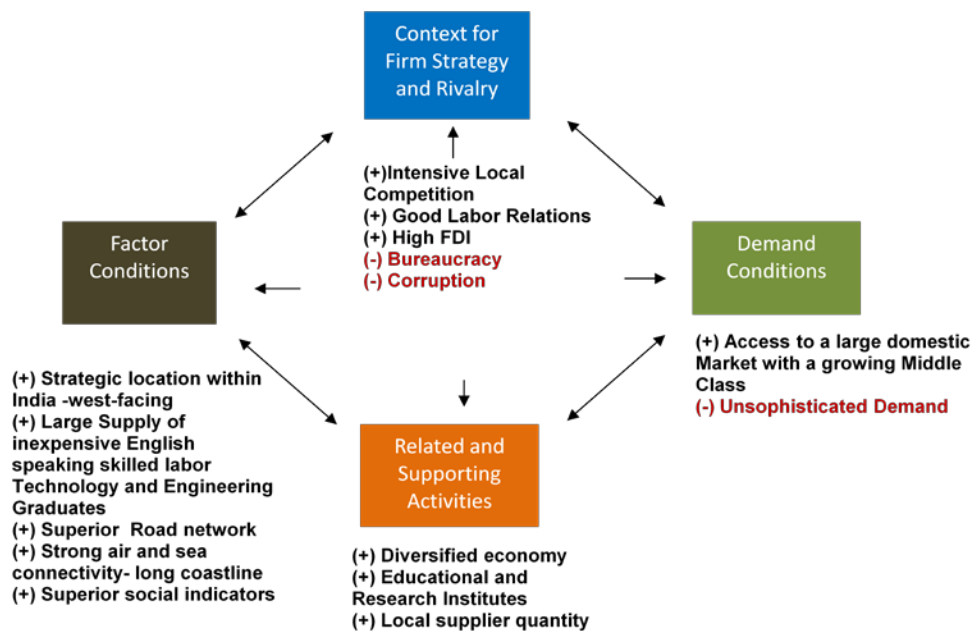


Fig 10: Source- Team Analysis

3. Global Biopharmaceutical Industry

3.1 Definition of Biopharmaceuticals

Biopharmaceuticals are produced by natural organisms or by genetically engineering proteins derived from living organisms. Biopharmaceutical production is the application of biotechnology.

The first FDA approved biopharmaceutical was recombinant human insulin developed by Genentech in 1982. Advantages over conventional chemical drugs include: therapies that generally require shorter development times, greater efficacy, reduced side effects and much better patent protection.

3.2 The Global Biopharmaceutical Market

Major global drug companies are increasingly turning to biotechnology for new products to fuel growth. According to IMS Health, specialty therapy sales, which includes most biologics, should grow 14%–15% in 2008, compared with 5%–6% for the global pharmaceutical market overall. The US represents 48% of the biopharmaceutical market, compared to 36% for conventional drugs, due to a combination of earlier regulatory approval, easier market acceptance and greater pricing flexibility than other countries. Although biopharmaceuticals comprise only 12% of world prescription drug sales, they account for 10 of the top 50 selling drugs and 18% of all drugs in development.

4. Biopharmaceuticals in Maharashtra

Cluster History & Development

The Western region has been a major base for the Indian pharmaceutical industry for more than a hundred years and houses leading national companies like Wockhardt, Nicholas and Intas as well a number of large international companies including GlaxoSmithKline, Novartis, Pfizer, Johnson & Johnson, Abbott, Aventis Novo Nordisk, etc. Almost all the traditional pharmaceutical companies are now engaged in research and production of biopharmaceuticals mirroring global trends. One of the oldest Indian firms and largest biopharmaceutical company in the country, the Serum institute of India, is based in Pune. The Institute is the largest manufacturer of vaccines and sera in the world and claims to reach one fourth of the world's children² Today companies located in Maharashtra account for 35% of India's biotech revenues with Pune and Mumbai as the combined center of the industry in the state.

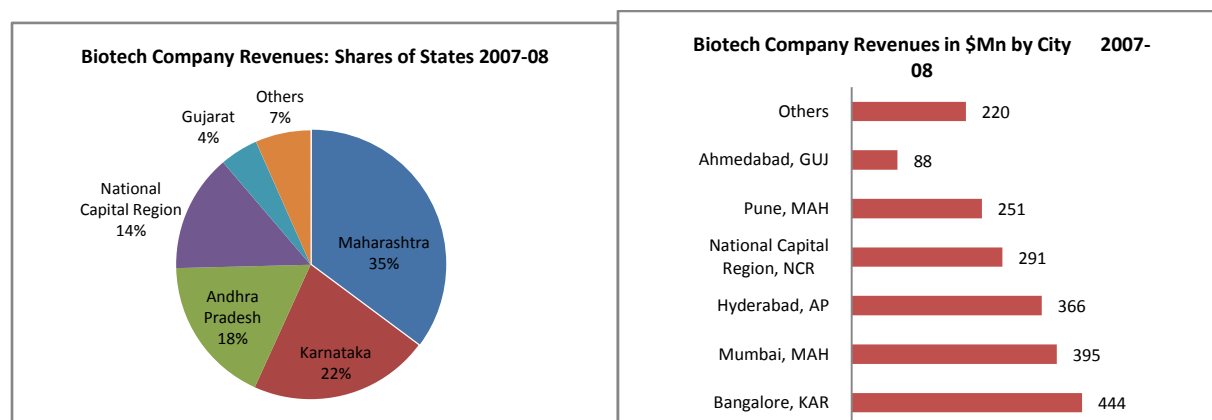


Fig 11&12: Source-BioSpectrum India, August 2008

The development of the biopharmaceutical cluster in Maharashtra can be broken up into three stages- 1) Pre-independence, 2) 1947 to 1990, 3) 1991 to current corresponding to major political events such as India's independence (1947), Balance of Payment Crisis (1990).

² <http://www.seruminstitute.com/>

The Maharashtra Biopharma cluster Timeline

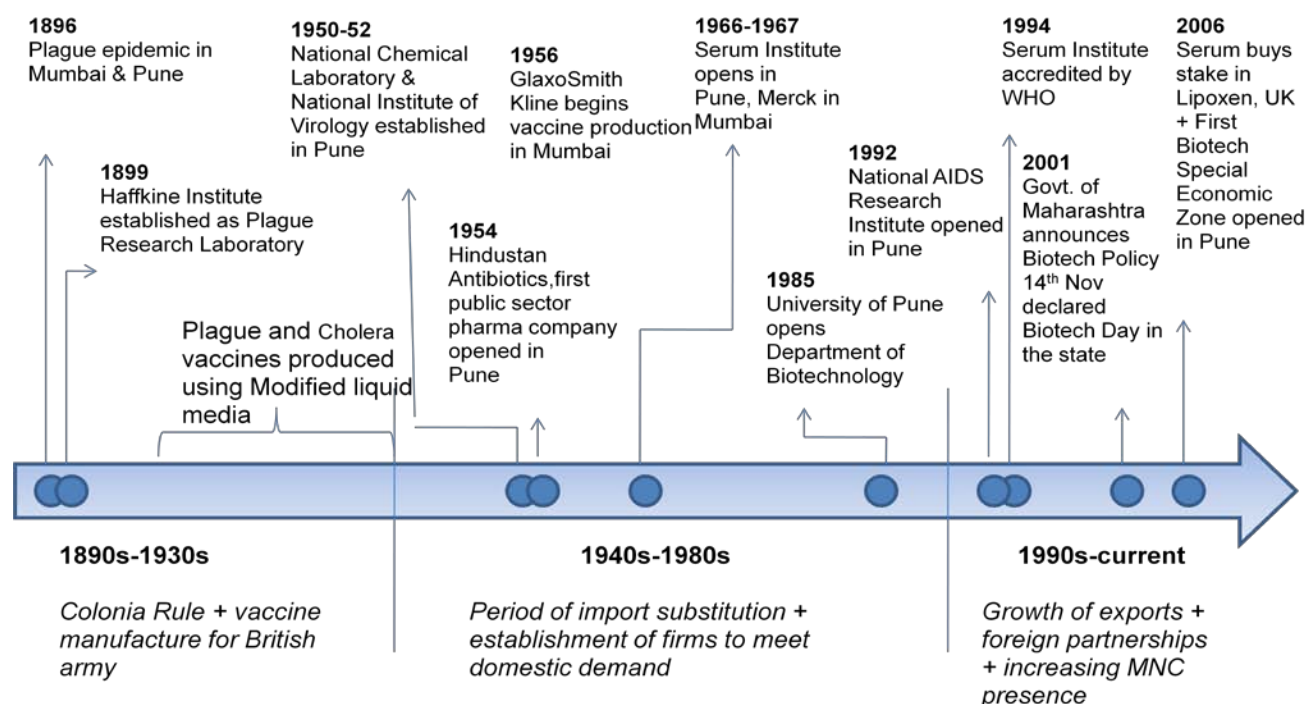


Fig. 13: Source-Team Analysis

The pre-independence production of biopharmaceuticals was mainly oriented to serving the needs of British soldiers stationed in India. In the years that followed independence, the Central Government followed a policy of import-substitution to reduce India's dependence on costly foreign drugs. During this period a number of public sector firms (Hindustan Antibiotics Limited, 1954) and Central Scientific Research Organizations were established in Maharashtra, laying the ground for the development of the pharmaceutical and biotech clusters in the state. The government's policy also benefited firms like the Serum institute (1966) that was started by horse-trader Cyrus Poonawalla with 10 scientists from the Haffkine Institute. Post liberalization, the playing field for foreign and domestic firms became more level. This period has been characterized by an increase in exports, research partnerships, mergers and acquisitions.

5. Maharashtra Biopharmaceutical Cluster Diamond

Factor Conditions

Maharashtra has a large pool (173,894 engineering graduates per annum) of low cost English speaking skilled labor. The presence of one of the 6 Indian Institutes of Technology in Mumbai is the clearest example of a regular supply of local highly talented technical excellence. The challenge of ‘brain drain’ is however one that must be overcome if the cluster is to move up the value chain from process replication to ‘original’ research and development.

Whilst the focus of the cluster is Pune, the importance of Mumbai for both its international airport and its role as a center of the Indian financial community is important to the evolution of the biopharmaceutical cluster. The nature of biopharmaceutical as a high risk endeavor means that the proximity to the venture capital in Mumbai is a crucial factor for the long term investment required. In addition to the existence of the airport, the lack of restrictions on biological imports allows the biopharmaceutical companies to source supplies that cannot be easily obtained locally.

These positive factors offset the deficient general infrastructure notably hazardous roads and unreliable electricity supply. The existence of over 3 biotech parks, encouraged by both the state and central governments, is critically important as these provide the independent electricity generators that ensure the consistency of supply that is critical to biopharmaceutical production. The superior amenities of the parks allied to local low cost equipment fabrication translate to a cost advantage for the producers. Without these amenities producers would not be able to maintain the sterile environments required for manufacture, as the general urban environment in India continues to suffer from low levels of sanitation and sewerage collection & treatment and poorly managed water resources.

Context for Firm Rivalry and Strategy

The most important piece of legislation that has impacted the competitive behavior of biopharmaceutical firms in the cluster and across the country is India's decision to sign onto TRIPS in 1995 and complete the transition process in 2005 with the 3rd Amendment to the Indian Patent Act of 1970 -fully recognizing product patents³. This has limited the ability of firms to produce generic versions of drugs patented elsewhere. The impact of the new patent regime can be seen in the shift of the business strategy of Indian firms. Two major trends:

- 1) Shift from pure manufacturing and marketing of generics to R&D through tie ups with Central Institutes and foreign firms** (e.g.: Lupin Laboratories, Mumbai ties up with Central Drug Research Institute Lucknow and Indian Institute of Chemical Technology, Hyderabad)
- 2) Investments and agreements to capitalize on outsourcing opportunities.** McKinsey projects that the market for Clinical Trials alone in India is expected to be \$1.5 Billion by 2010 and growing at a rate of 30-35% per annum with Pfizer, Johnson& Johnson, GlaxoSmithKline and AstraZeneca already conducting trials in India (5% of global trials in 2012)

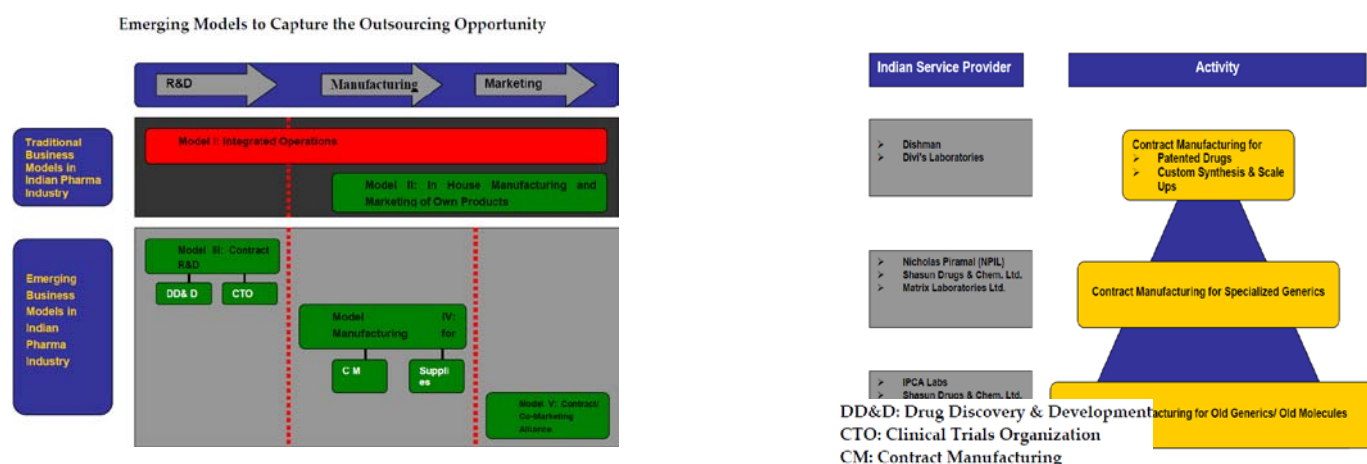


Fig 14: -Source-Federation of Indian Chambers of Commerce & Industry

³ Prior to 2005, the Indian government only recognized 'process patents' that allowed firms to manufacture products patented outside India using different processes and legally market them in India. As a result of this policy, India has among the lowest prices for drugs in the world.

Given the size of the opportunity presented by a rising middle class eager to access patented drugs, **Indian drug companies have accepted the new patent regime as an opportunity to shift their business model away from mass therapies to more specialized, patented drugs that can be sold at a higher price.**

In this new environment, the central government is highly supportive of the biopharmaceutical industry with the Department of Biotech providing grants for R&D and overseeing a flexible regulatory environment.

Demand Conditions

The legacy of import substitution and public sector demand for inexpensive mass vaccinations has sustained the cluster for most of the previous century. Large governmental demand for low cost vaccines has meant the cluster has developed the capability of process replication and high volume (though low value) production. The growing middle class means there is some initial demand for the higher value items that the cluster currently only produces for export. The increasing disease burden means there is significant focus on the biopharmaceutical solutions for cost effective results. Allied to a wave of drugs coming off patent and the active IGO sector, the cluster has some attractive demand dynamics.

India's biopharmaceutical industry has achieved impressive levels of growth; the average growth rate of biopharmaceuticals in India 2002-05 has been 34% and accounts for 76% of total revenues in the biotech sector. With sales valued at US\$2.86 billion in 2007-2008, it is expected that based on current growth trends the industry will hit US\$ 5.7 billion by 2012-13 (McKinsey, 2008) As domestic demand for improved healthcare, and international opportunities for biologics increase, India will continue to expand its presence on the world biopharmaceutical stage.

Diagnostics, vaccines and recombinant therapeutic proteins are the three main segments in the Indian biopharmaceutical industry. Recombinant therapeutics and vaccines jointly make up almost \$500 million of the domestic market. The vaccines market in India is growing at a rate of 38% and comprises 17 domestic and international players that market 50 brands of 15 different vaccines (Pharmabiz Magazine, 2009).

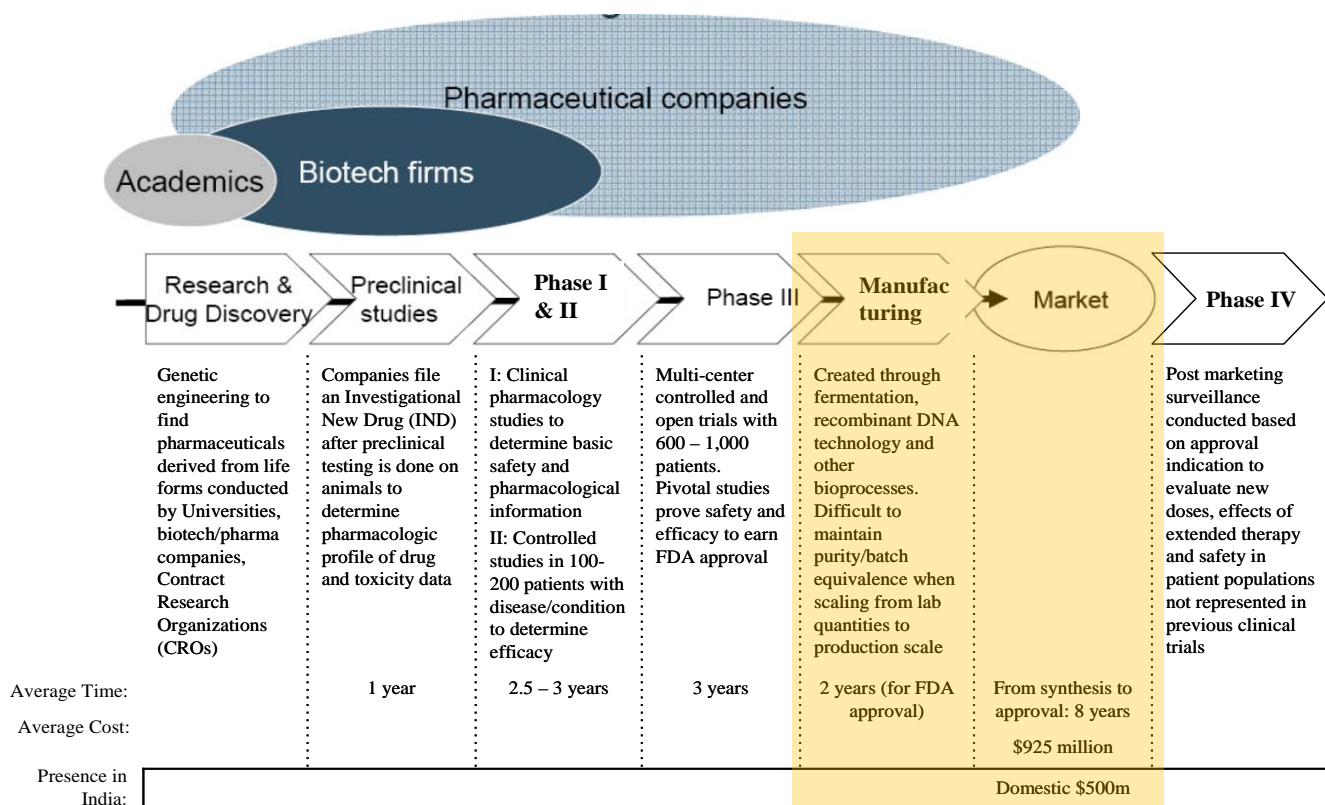
On the other hand, a major area of opportunity lies in the highly competitive Indian market for recombinant Insulin for treating diabetes. The present insulin market in India approximates 300 million (including high end vaccines introduced by the private sector), with the human insulin market is growing at the rate of 40.5%. The launch of Insulin by Indian companies has resulted in drastic downward revision in prices. Earlier, such therapies were restricted to a small category of patients who could afford the drug. Products showing good potential are Erythropoietin, Streptokinase and Interferon. The market for Hepatitis B vaccine alone accounts for revenues to the tune of US\$ 22 million, which is a critical local requirement as 8.7% of the global incidence of Hepatitis B occurs in India (Pharmabiz Magazine, 2009).

Nevertheless, the poor public health system, unsophisticated demand and high untreated population mean the cluster has limited local demand sophistication that could drive innovation. The high reliance on governmental purchases means the industry cannot allocate investment based purely on financial considerations. Additionally the largely unorganized retail environment means that demand is difficult to understand precisely, and thereby results in inadequate marketing to audience that have strong influence on direct demand for drugs.

Related and Supporting Industries

To better understand Maharashtra's strength in biopharmaceutical we first examine the value chain. The biopharmaceutical value chain is similar in structure to the pharmaceutical value chain and is composed of four main parts: research & drug discovery, preclinical studies, Phase I, II & III trials and manufacturing/distribution, as shown in Figure 15

Fig 15: **Biopharmaceutical Value Chain**



Source: Sabatier, Rousselle, Mangematin (2008); Kalorama (2008); team analysis

Of these various phases, Indian companies and multinationals based in India have been focused on Manufacturing and Marketing (see shaded area above). R&D investments by Indian and multinationals have increased since India signed TRIPS. India is now considered a serious contender in the market for outsourcing Clinical Research (Phases 1, 2 & 3). In 2009, the USFDA opened offices in Mumbai (Maharashtra) and Delhi to facilitate speedy approvals of patent applications from India.

Maharashtra Biopharmaceutical Cluster Map

The cluster map reflects strengths in manufacturing and marketing in line with our value chain analysis. There are over 4100 registered pharmaceutical firms and 70 biotech firms in Maharashtra. Initially dependent on the availability of horse blood for plasma to produce anti-toxins like tetanus, firms were located close to animal farms in Mumbai and Pune. Later, the Indian government allowed duty free imports of biological material for export purposes and it was less important to be located near animal farms. Other key cluster inputs:

Skilled manpower: Typically, workers in biotech need a Masters or a PhD to gain employment. The University of Mumbai, the Indian Institute of Technology and Pune University are educational institutions that have dedicated Biotechnology departments. Pune, once known as the ‘Oxford of the East’ has over 100 institutes and 9 universities lending substantially to Maharashtra’s pool of technical graduates. For the biopharmaceutical industry in particular, there are threats to the supply of talent from two sources: 1) Students who pursue a PhD in countries like the U.S. and U.K. often choose to stay abroad aided by immigration policies that favor highly skilled people and 2) Competition for graduates from companies in other Indian states. While figures for the second category of brain drain are not available, it is safe to say that Brain Drain from India to developed countries does impact the work of Biopharmaceutical companies by creating a scarcity of specialists.

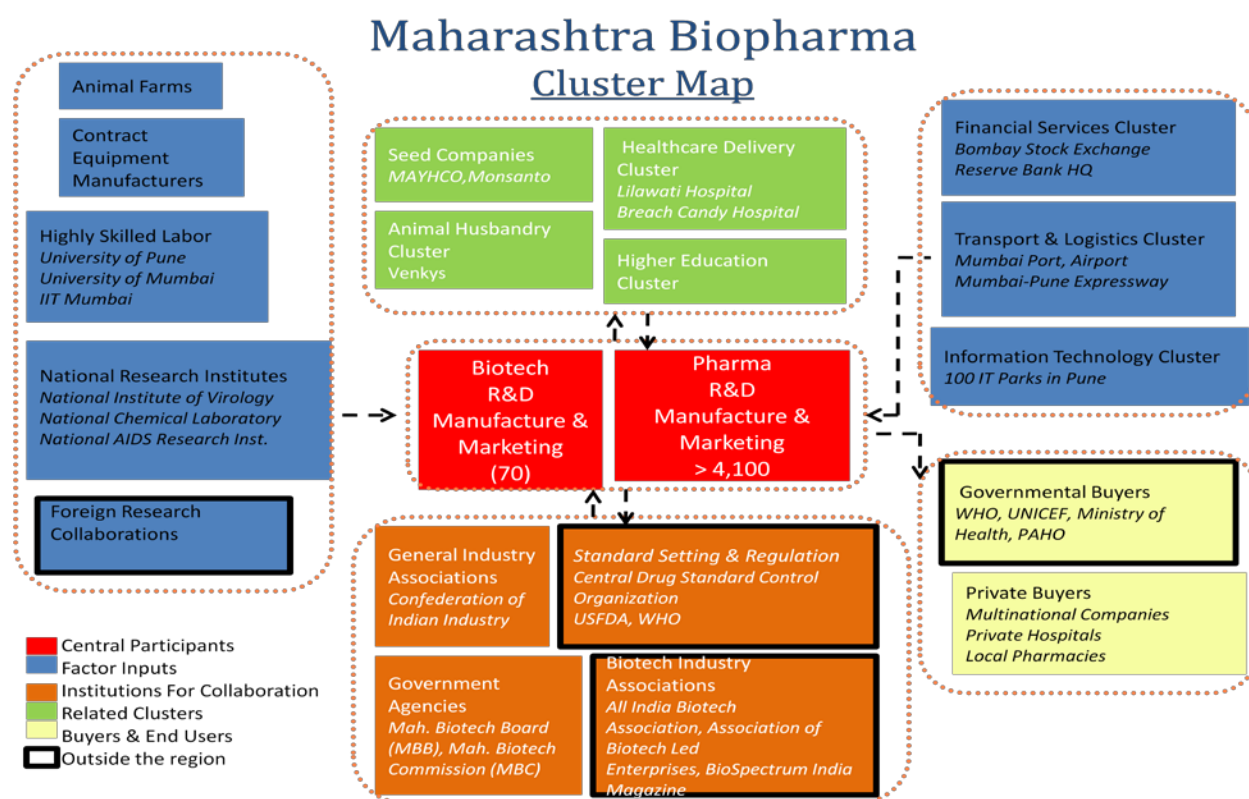
Research centers: There are over 10 National research organizations that make Maharashtra and Pune in particular, a hub for the exchange of scientific ideas and provide University students access to the latest Indian biotech research⁴. Government investments in

⁴ In India, University Professors are exempt from conducting research and most research takes place outside of Universities in Central Research Organizations

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these institutes provide opportunities for collaborative research with the biotech industry though formal partnerships are very few.

The bulk of original research continues to take place outside of the cluster. For most diseases with economic potential, researchers work for companies and universities located in developed western countries and the number of collaborations has increased manifold in the last few years



(e.g. Serum Institute and Syracuse University tie-up to develop oral insulin).

Fig 16: Source-Team Analysis

The presence of a large IT industry (over 1200 units in the state accounting for over 30% of India's software exports), a strong financial services cluster, (Over 90 per cent of merchant banking transactions are structured in Mumbai, which also accounts for 14 per cent of national

bank deposits) large healthcare delivery cluster (private and public hospital network) and an established agri-business and animal husbandry clusters (MAHYCO⁵ is the largest supplier of hybrid seeds in India and Venky's is the largest integrated poultry farming group in Asia) further support the growth of biopharma in Maharashtra. Venkys has recently diversified from producing only animal biopharmaceuticals to human biopharmaceuticals. Equipment for biotech labs is largely designed by firms and fabricated by contract manufacturers within the state. Specialized equipment is typically imported by air or ship.

In terms of Institutions for Collaboration, Maharashtra lacks sector-specific private organizations such as those located in other Biotech states like Karnataka (Association of Biotech Led Enterprises) and Andhra Pradesh (All India Biotech Association). The Maharashtra Government however, has been extremely pro active in setting up the Maharashtra Biotech Board and Maharashtra Biotech Commission to implement the state's Biotech Policy (2001) and utilizes the funds allocated under a special Biotech Fund to finance new ventures. The Fund (initially \$10 million) was developed through contributions from all state departments such as Agriculture, Commerce and Health.

Companies within the cluster adhere to standards set by the Central Drug Standard Control Organization, Maharashtra's own Food and Drug Authority, the US FDA (for exports to the developed world) and WHO (for exports of vaccines to developing countries).

Finally, Maharashtra's Biopharma cluster benefits from the presence of an active International government sector in the form of UNICEF, WHO, PAHO⁶- key buyers of vaccines for developing countries. Most international organizations have state offices that coordinate with

⁵ Maharashtra Hybrid Seed Corporation

⁶ Pan American Health Organization

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international procurement offices based in Geneva. India's Ministry of Health is also a major buyer of vaccines for its 'Extended Program of Immunization', though its Vaccine Procurement Cell is located in New Delhi.

To conclude, Maharashtra's Biopharmaceutical cluster is **very strong in the Factor Conditions and Related and Supported Activities corners** of the Cluster Diamond. These are also the areas where the Maharashtra government has the most leverage with the other two corners largely dependent on Central Government policies and macroeconomic conditions.

MAHARASHTRA BIOPHARMACEUTICAL CLUSTER DIAMOND

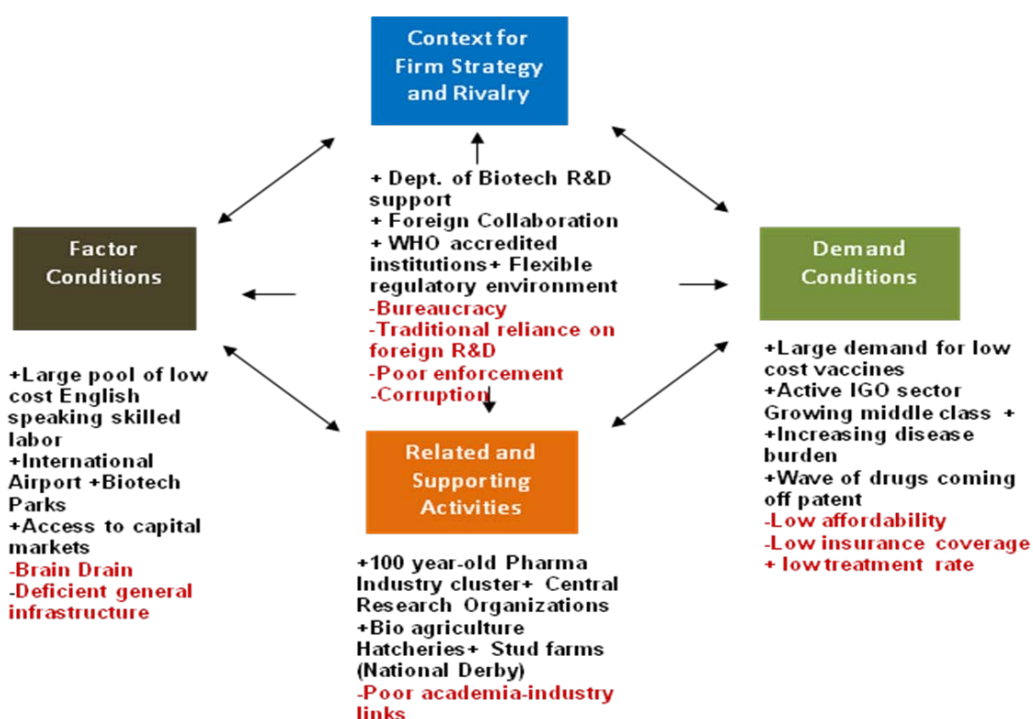


Fig 17: Source-Team Analysis

6. Recommendations to Improve Cluster Competitiveness

6.1 Country-level Recommendations

*a) Double spending on R&D, direct money to universities and research institutes (**Factor Conditions & Related and Supporting Industries**)*

Competitiveness in the Biopharmaceutical industry is driven by original Research and Development. Companies in the United States are supported by a strong university system that produces original research with potential for commercialization. The Biotech Cluster in Massachusetts draws on research produced by scientists in MIT, Boston University and Harvard. India's spending on R&D must increase from 0.8% of GDP to at least 1.5% in the next 2 years and must be directed towards R&D at the University level. Universities should enjoy the freedom to decide what research to fund maintaining a balance between funding questions of basic science and research with potential for commercialization. The Central Indian Department of Biotechnology should push for legislation like the US Bayh-Dole Act of 1980, giving Universities a right to earn royalties from the output of federally funded research.

*b) Adopt single-window mechanism for clearances, regulation and financing with higher automation (**Context for Firm Strategy and Rivalry**)*

India is ranked 105th in terms of ease of starting a new business. This is especially troubling given that the biopharmaceutical sector thrives on innovative, high risk activities of small firms rather than the research undertaken by a few large firms. To encourage the formation of new companies, the Indian Government should adopt a single-window mechanism i.e. one department or one agency for clearances, regulation and financing to save entrepreneurs the time

and money to deal with 13 different procedures administered by multiple agencies. To improve efficiency and reduce the scope for corruption, the process should be automated to the farthest extent possible.

*c) Adopt medium to long-term focus on a few key diseases to send signals to companies concerning priorities (**Demand Conditions**)*

Companies engaged in finding cures for diseases would benefit from a stable domestic policy and strategy to focus on a few diseases backed by investments large enough to make a difference. For example, a policy to control and cure for Diabetes by 2015. This calls for budgetary and organizational coordination between various ministries such as the Ministry of Health and Family Welfare, Ministry of Education (health awareness) and the Ministry of Science and Commerce. The policy should be backed with funding for public and private research and development, health awareness campaigns and healthcare facility expansion related to the diagnosis & treatment of diabetes for companies to focus on upgrading their facilities to meet the more sophisticated domestic demand.

6.2 State-Level Recommendations

*a) Address Brain Drain through incentives and changes in the state's education system (**Factor Conditions**)*

Brain Drain is a concern for the future of Biopharmaceuticals in Maharashtra since competitiveness depends on original R&D coming out of companies and universities in the state. To tackle the phenomena of graduates receiving their undergraduate science or engineering degree in Maharashtra and then leaving to the US or US to pursue their Masters and PhD, the

state must introduce legislation to make it possible for existing universities to expand PhD programs, provide good stipends to PhD students in sciences, expand the laboratory facilities and number of researchers on staff with the objective of creating equally attractive, if not equally remunerative career opportunities within the State.

*b) Foster closer ties between local industry and academia (**Related and Supporting Industries**)*

Maharashtra's government must take a proactive stance in promoting ties between industry and academia. To address the gap that is being filled by foreign collaborations such as the tie up between the Serum Institute and the University of Syracuse to develop oral insulin, the state should provide companies matching grants for R&D that takes place in institutes in Maharashtra. Industry Associations such as the Western Regional Council of the Confederation of Indian Industry and Government bodies such as the Maharashtra Biotech Commission should expand their membership to include representatives from academia to facilitate regular exchange on cluster developments.

*c) Create single-window mechanisms for clearances, regulation, auditing and financing (**Context for Firm Strategy and Rivalry**)*

Maharashtra is the best performing state in terms of time required to start a business. However, given the relative simplicity of improving this parameter, the state should streamline the clearance processes for a new company by adopting a single-window or one-stop shop mechanism. The aim should be to reduce the number of days it takes to set up a business from 35 days to less than 25 days in order to compete with other important biotech countries like Korea (17 days) and Japan (23 days).

*d) Adopt a focused strategy to tackle a few diseases backed by large investments (**Demand Conditions**)*

We recommend close coordination between the State and Central Ministries to select a few major diseases to focus spending for a direction that will galvanize industry, academia and civil society towards finding a cure and getting people to seek treatment for a particular disease thus stimulating local demand for biopharmaceuticals.

6.3 Company-Level Recommendations

*a) Influence academic curricula through closer ties (**Factor Conditions**)*

For the long term viability of Maharashtra's cluster, there needs to be a close relationship between the skills student gain at the University level and those that the industry requires. Companies within the cluster must expand membership of industry-wide associations to representatives from the University and National Research Institutes.

*b) Form a local association of biotech companies(**Related and Supporting Industries**)*

Currently, Maharashtra lacks a strong local biotech association. Both the All-India Associations are located outside of the state. Given the role of regional policies in determining competitiveness, we recommend that the Biotech firms in Maharashtra launch their own association. The Association should evolve into a resource for the growth of cluster through fee-based services rather than entity that only lobbies for tax breaks from the Maharashtra government although liaising with State and Central Governments will be a major role.

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*c) Support educational campaigns and national conferences for medical practitioners (**Demand Conditions**)*

As India's and Maharashtra's middle class grows there is bound to be an increase in doctors prescribing biopharmaceuticals to patients. Companies can accelerate this process by collaborating with the government to launch educational campaigns on diseases. The Wockhardt group based in Mumbai could take the initiative in coordinating and supporting a National Diabetes Conference in the state drawing doctors from around India to discuss and debate relative strengths and weaknesses of various approaches to Diabetes treatment.

Summary of Recommendations

Strategic Issue	Recommendations		
	Country level- Government	State level- Government and IFC	Company Level
Overwhelming reliance on Foreign R&D	Double R&D investment to at least 1.6% of GDP from 0.8%. Direct money to Universities for research in both basic science and research with commercial potential. Pass legislation allowing universities to earn royalties from licensing the outputs of central funded research.	Address Brain Drain by restructuring incentives for PhDs in the state University system. Raise PhD stipends, expand research programs and upgrade laboratory facilities. Foster close ties between local academia and industry through matching grants for in state R&D collaborations.	Widen membership of industry associations to include representatives from academia. Increase collaboration with local institutes with a long term focus of influencing curriculum and ensuring a steady supply of graduates that meet industry requirements.
Bureaucracy and Corruption	Adopt Single-window mechanism for National level clearance, regulation, auditing and financing of the Biotech Industry	Reduce days to start a business from 35 to at least 20-25. Adopt Single-window mechanism for State Level clearances, regulation, auditing and financing of the Biotech Industry with close coordination with National counterparts.	Form a local Biotech Industry Association that becomes a resource for the industry's growth through fee-based services in addition liaising with central and state governments.
Lack of Sophisticated Demand	Focus on a few diseases to control and cure in the medium term with specific health targets. Use financial incentives that help to achieve these targets. Launch educational campaigns to improve the rate of people being tested and seeking treatment	Align state health strategy with central strategy to increase funds available for research, awareness generation and expansion of health facilities.	Support National and State health-related initiatives through funding for campaigns. Initiate National Conferences for medical practitioners to facilitate exposure to biotech based cures for diseases such as Diabetes and Cancer.

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