

HARVARD BUSINESS SCHOOL

MICROECONOMICS OF ECONOMICS



# THE ANTIRETROVIRAL DRUG CLUSTER IN INDIA

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## **1 INDIA: PROFILE AND ENDOWMENTS**

India is one of the oldest civilizations in the world with a rich cultural heritage, ethnical and cultural diversity, and multiple religions. In the 19<sup>th</sup> century, Britain incorporated India into British empire, but resistance against English colonialism led to India's independence in 1947. Since then, India has gradually but steadily become a self-sufficient agricultural and industrialized country despite English colonial legacy.

### **1.1 GEOGRAPHY**

India is located in South Asia, occupying the most part of Indian subcontinent. The area of India is 3.3 million sq. km., making it the 7<sup>th</sup> largest country in the world. India is located to the north of the equator and stretches to the Himalayan mountains that separate India from the rest of Asia. The coastline of India is more than 7 thousand km long and flanked by the Indian Ocean from southeast and the Arabian Sea from the southwest.

### **1.2 POPULATION**

India has a population of 1.33 billion people, making it the second most populous country in the world after China. Thirty percent of the population lives in urban areas and the population density of India is one of the largest in the world (270 people / sq. km.).

Officially, the population is not divided by castes and ethnic groups. The Constitution of India establishes the equality of rights of all people in the country. But in reality, the Indian society is very differentiated by class, ethnic, caste and religious basis.

### **1.3 POLITICAL AND JUDICIAL SYSTEM**

New Delhi is the capital of India, while Mumbai is the largest financial and commercial center. India is a federation of 29 states and 7 union territories. All states and union territories are governed by elected legislatures and governments. The federal government has 3 branches: executive, legislative and judicial. The executive branch is represented by the President, with the Prime Minister heading the Council of Ministers.

The judicial system of India is the oldest judicial system in the world. It was highly influenced by English law and represents unitary three-tier judicial power, that consists of the Supreme court, the Highest Courts of India and the Subordinated Courts. The Supreme court is a legally independent and has the right to declare laws or repeal laws of the States and territories in case they contradict the Constitution.

### **1.4 ENDOWMENTS ADVANTAGES**

In classical economics theory, factor endowments are defined as land, labor and capital. India's advantageous endowments are the following:

#### **1.4.1 Distinct geographical location**

In the north, the Himalayan mountains form natural boundary that separate India from its neighbors and the rest of Asia. On the east, south and west, it is surrounded by the Indian Ocean and Arabian Sea, thus having ample access to the sea. India lies on the major crossroads from China to the Middle East and Europe.

### **1.4.2 Large territory**

India occupies the area of 3.3 million km<sup>2</sup> and it is the 7<sup>th</sup> largest country in the world. Fertile land and access to the sea make it favorable for agriculture and industrial production.

### **1.4.3 Large and young population**

Labor costs are highly inexpensive in India due to the high supply of labor. This is advantageous for industrial manufacturing and agriculture. The labor force is also young relative to similar countries; the median age in India is 27.6 years vs. 37.1 in China in 2016.<sup>1</sup>

### **1.4.4 Warm climate**

India is located to the north of equator and has the Himalayan mountains as the natural barrier to the winds from Asia, making Indian weather warmer than in similar countries. It has wet tropical, dry tropical, subtropical and mountain climate, making India favorable for biodiversity of species and plants.

### **1.4.5 Entrepreneurial Culture**

There are 48 million small businesses in India, double the number in the US.<sup>2</sup> They contribute 8% of Indian GDP, 45% of manufacturing output, and 40% of total exports.<sup>3</sup> With policies facilitating the growth of entrepreneurship, the number of small and medium enterprises (SMEs) has grown over the past few decades.

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<sup>1</sup> Statista.com - <https://www.statista.com/statistics/264727/median-age-of-the-population-in-selected-countries/>

<sup>2</sup> Business Today (India)

<sup>3</sup> Government of India statistical data on small businesses

## **1.5 ENDOWMENT DISADVANTAGES**

India has several disadvantages when it comes to endowments.

### **1.5.1 Lack of mineral resources**

Despite its large territory, India is not rich in natural resources. Its major resource is coal. Apart from coal, India has some oil, gas and metallic minerals. Yet due to India's large population size, the sparse natural resources are rapidly depleting. The country is a net importer of major mineral resources.

### **1.5.2 Poor infrastructure**

Indian roads, ports, the railway system, and airports are in relatively poor condition. This makes logistics and transportation costs high and weakens the national business environment.

### **1.5.3 Lack of Capital**

Access to capital is scarce in India, particularly due to the low number of foreign and domestic investors. Governmental regulations have created barriers for investors to fund investments to support business development.

## **2 INDIA'S ECONOMIC PERFORMANCE**

With a population of 1.3 billion people and a GDP in of 2.1 trillion GDP (8.72 trillion in PPP), India is the 8<sup>th</sup> largest economy in the world.<sup>4</sup> India's economy has been growing rapidly over the last 15 years. The growth rate of per capita GDP has consistently been above 5% (only interrupted by a slight dip in growth in 2008 due to the global financial crisis), making India one of

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<sup>4</sup> World Bank Data, 2016

the fastest growing economies in the world.

**Exhibit 1** illustrates this, comparing India to economies of similar geographic size and levels of development.

Despite exhibiting rapid growth levels during the latter 20 years, India is still a developing economy (by the definition of United Nations) with a high share of the population living in poverty. The GDP per capita (PPP-adjusted) was 5730 USD in 2015. The low average income level is similar to the average prosperity levels of countries as Kenya and Nigeria, as seen in **Exhibit 1**.

This is reflected in the similarly low average level of human and social development in India: the average level of education and human development is not much greater than that of developing nations at similar GDP-levels. The UNDP's Human Development Index measures a country's achievement in a combined index composed of health indicators, knowledge levels and a decent standard of life. In 2016, India ranked as country 131 on this index (lower scores are higher levels of human development). **Exhibit 2a** and **Exhibit 2b** contain comparisons between India and other countries.

## 2.1 EXPORT DIVERSITY

As can be seen in **Exhibit 3**, the economy is relatively well-diversified with major export sectors being in fuels, precious metals and textiles. In 2014, pharmaceutical products accounted for 4% of all of India's export amounting to 12.6 billion USD.

## 2.2 TOTAL LABOR PRODUCTIVITY

Decomposing the value added by industry, and as seen in **Exhibit 4**, we find that India is heavily reliant on the services sector. Over 50% of the total economy is generated by the service industry, where both manufacturing and agriculture accounts for between 15 – 20% of value-added to GDP. Both agricultural and manufacturing contribution to GDP has been declining slightly during the last ten years. This also means that the remarkable growth trajectory of India during the last 15 years has been driven primarily by the service sector.

## 3 INVESTMENTS IN INNOVATION AND R&D

*“When I was growing up as a kid, there were two choices: science or commerce. If the kid is not in one of these two fields, they are going to suffer.”*

*Kommana, Laurus Lab*

Although average education levels are low, India has specialized its education sector in the field most relevant to the pharmaceutical industry: higher education is focused around science and engineering. Fifty percent of all PhDs has a degree within this field. The engineering sector has enjoyed a high level of governmental support and incentives. For instance, the government has incentivized investments in R&D by giving remarkable tax deductions for companies to acquire research from approved science centers and universities. Despite these investments, India still lags behind China when it comes to overall investments in R&D: In 2011, India invested 0.82% of its GDP to Research and Development.

In the same year, China invested more than double this amount – 1.79% of GDP.

## 4 COMPOSITION OF THE ECONOMY BY CLUSTER

The top performing clusters in India are Communication Services (18.43%), Jewelry (8.42%), Textiles (5.36%), Oil & Gas (5.04%), Business Services (3.25%) and Biopharmaceutical products (1.49%). Geographically, Mumbai, Delhi and Hyderabad are the top-performing regional centers of the biopharmaceutical industry in India in terms of GDP growth and per capita income.

**Exhibit 5a** shows the relative strength of these three centers of the cluster as cities of high growth and generally high levels of GDP per capita. **Exhibit 5b** contains a graphical breakdown of India's clusters

The Indian pharmaceuticals market is the 3<sup>rd</sup> largest in the world by volume and 13<sup>th</sup> in the world by value. In volume-terms, India is the largest provider of manufactured generic drugs in the world: the Indian supply accounts for 20% of the global market.<sup>5</sup> The Indian pharma market size was \$36.7 billion<sup>6</sup> in 2016 and is expected to grow to \$55 billion in 2020 and \$100 billion in 2025 with CAGR 15.9% - which is well above pharma industry average in the world. Indian pharma exports in 2016 accounted for \$16.9 billion and is expected to reach \$40 billion by 2020.

The Indian pharmaceutical market is very fragmented, with more than 1,000 small and large

companies employing more than 4 million people.<sup>7</sup> The top five companies (Dr. Reddy, Lupin, Cipla, Aurbindo, Cadilla) account for 20% of the market share.

### 4.1 THE PHARMACEUTICAL CLUSTER'S REGIONAL CENTERS: HYDERABAD, BOMBAY, DELHI

The Antiretroviral (ARV) cluster is particularly strong within three cities of India: Hyderabad, Bombay and Delhi. Cipla, located in the Bombay region of India, is the world's largest manufacturer of ARV's. **Exhibit 6** lists some of the important factors that has made Hyderabad, Bombay and Delhi the center of generic ARV medicine production in India.

The rapid growth of the industry in these areas is a result of a higher level of per capita income relative to other parts of India, high HDI-levels, a large volume of technical universities, and a high level of political support. Furthermore, the national government's *Make in India* campaign has supported projects that will further enhance the competitiveness of the cities of the ARV cluster. One example is the initiation of the Delhi Mumbai Industrial Corridor, a \$100 billion infrastructural project aimed at improving transportation, water supply, and power plants.<sup>8</sup> It is the world's largest infrastructural project and has the potential to extensively enhance the cluster's competitiveness.

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<sup>5</sup> [https://www.ibef.org/download/Pharmaceutical\\_March\\_2017.pdf](https://www.ibef.org/download/Pharmaceutical_March_2017.pdf)

<sup>6</sup> *ibid*

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<sup>7</sup> *ibid*

<sup>8</sup> <http://www.makeinindia.com/article/-/v/fuelling-growth-delhi-mumbai-industrial-corridor>

## 5 CLUSTER MACRO-COMPETITIVENESS AND PERFORMANCE

In **Exhibit 10**, we use the framework of Porter's Diamond to assess the macroeconomic competitiveness of the Indian economy in general and the generic pharmaceutical industries in particular. We particularly assess input conditions, demand conditions, firm rivalry and strategy and the related and supporting industries.

## 6 KEY COMPETITIVENESS ISSUE FOR THE CLUSTER

### 6.1 GOVERNMENT INITIATIVES SUPPORTING THE CLUSTER

In 2010 India launched the National Innovation Council (NIC) to force innovations. It is chaired by the adviser to the Prime Minister of India, Mr. Sam Pitroda. The main objectives of the NIC are:

- Development of a road map of innovative development of India in the period of 2010-2020;
- Promoting small and medium enterprises in the innovation process;
- Creation and coordination of work of branch and regional councils on innovation;
- Creation of innovative clusters, etc.

In addition, the Indian government has invested in a vast number of government institutions involved in innovation development. Among them are the Society for Innovation and Development (SID), Council for Scientific and Industrial Research (CSIR), Technology Development Board (TDB), Council for Scientific and Technological Research (SERC).

In the framework of Indian government for conducting the cluster policy, which started in 2000, there are 24 programs, with more than 1200 clusters - these programs allocated about \$1.4 billion to industry development. Their main goals are reducing poverty, creating new jobs and strengthening the competitiveness of enterprises.

Furthermore, the *Make in India* program launched by Prime Minister Narendra Modi has provided a major impetus to the pharmaceutical sector in India. Revenues of Indian pharmaceutical producers increased by 6% in 2015 in part due to this and other similar government programs.

India's pharmaceuticals industry turnover is projected to grow by 8.8% in 2016 and sustain a CAGR of 9.8% over 2015-2020 due to continuing capital investment in the industry. The increase will also be underpinned by rising online pharmaceuticals stores, which will benefit the retail side of the market.

### 6.2 CURRENCY TRENDS

The devaluation of the Indian rupee in recent years has also led to moderate increase in the import of drugs. India's main importing partners are Germany, the US and China, the latter being the main source of India's pharmaceutical imports. China exported 5.8% more medicaments in the form of raw materials as well as finished products in 2015, mainly due to competitive prices.

### 6.3 LAX PATENT LAWS

India has a loose regulatory system for patents on drugs. It limits the ability of companies to get

patents for new versions of drugs whose active ingredients are known.<sup>9</sup> At the same time, it leads to the manufacturing of more affordable drugs that are exported to low-income countries in Africa.

## 6.4 EASE OF DOING BUSINESS

Foreign companies are also loath to invest in India because it is relatively hard to do business in the country. India ranks a pitiable 130<sup>th</sup> out of 190 countries on the *Ease of Doing Business Index* published by the World Bank Group. On the sub-indicators, India performs particularly poorly in “Starting a Business, Dealing with Construction Permits, Paying Taxes, Trading across Borders and Enforcing Contract.”<sup>10</sup>

India has made significant improvements under the current government<sup>11</sup> but they have not led to large-scale, quick reforms.

## 6.5 STRONG DEMOGRAPHIC POTENTIAL

India has a large, growing young population with gradually increasing education and income levels. With rising annual disposable incomes, an expanding middle class and rapidly growing incidence of chronic diseases, India’s healthcare services sector continues rapid growth and raises spending on pharmaceuticals by 8% in 2015.

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<sup>9</sup> Anand, G. (2015, March 19). Inside India: India’s Fight Against Big Pharma Patents Is a Just War. Retrieved from <http://blogs.wsj.com/indiarealtime/2015/03/19/inside-india-indias-fight-against-big-pharma-patents-is-a-just-war/>

<sup>10</sup> See section 7.

<sup>11</sup> Roy, R. Z. and R. (2016, October 26). Why India Isn’t Climbing Ease of Doing Business Ranking Despite Efforts. Retrieved from <https://blogs.wsj.com/indiarealtime/2016/10/26/why-india-isnt-climbing-ease-of-doing-business-ranking-despite-efforts/>

## 6.6 CHEAP LABOR

Salaries increased primarily as a result of patent expirations, increasing demand and rising popularity of generic drugs. These factors put a strain on producers to retain skillful workers, especially researchers, which in turn led to increased wages. Labor costs accounted for 21% of total expenditure in 2015.

## 6.7 GLOBAL EFFICIENCY

Exports increased by 11.2%, reaching a monetary value of Rs822.5 billion and accounted for 42.5% of total output in 2015. Main exporting partners were South Africa, the UK and the US. Trading with the latter skyrocketed by 26.2% during 2015 mainly as a result of US companies increasingly choosing to buy APIs from external sources in low-cost countries such as India, rather than producing themselves.

## 6.8 PATENTS

An ongoing issue for the industry that can impact its competitiveness has been that of Intellectual Property Rights (IPR) and patents dispute. India signed a new patent law as part of joining the WTO in 2005.<sup>12</sup> Although this allowed Indian drug manufacturers to continue selling drugs, a licensing fee was added to the sales. The amendment also grants 20-year patent monopolies to drug developers that will result in higher drug prices. The resulting rise in prices may see increased competition for India from other hubs

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<sup>12</sup> Dr, D. G. M. (2005, March 24). India Alters Law on Drug Patents. The New York Times. Retrieved from <http://www.nytimes.com/2005/03/24/world/asia/india-alters-law-on-drug-patents.html>

of generic drug manufacturing in Brazil, China and Thailand.

The Indian government has attempted to limit the repercussions of this law by declaring “emergency” and ensure that there be no sudden or unreasonable spikes in the drug prices.

It has also provided tax benefits to local drug manufacturers to improve the competitive environment both within and without the country by spurring innovation.

## 6.9 R&D

Another issue is the lack of collaboration between industry and academia. Unlike the west, where collaboration between researchers in academia and pharmaceutical industry is de rigeur, India lags behind in supporting academic research in the field.

## 6.10 CREDIBILITY ISSUES DUE TO QUALITY

India has deviated from the Good Manufacturing Practice (GMP) resulting in warning letters, product recalls and bans on the import of drugs into the US.<sup>13</sup> Companies like Wockhardt, Dr. Reddy’s Labs, Cadila and IPCA have experienced quality issues in their plants.

## 6.11 LACK OF RECOGNITION

The final issue is the lack of recognition of the Indian market – it is still considered a generic drug haven and new truly innovative R&D breakthroughs do not get the respect they may deserve globally.

## 7 NATIONAL BUSINESS ENVIRONMENT

India ranks 130th out of 190 countries according to the *World Bank’s Doing Business 2017 Report*.

India’s Prime Minister Narendra Modi has pledged to reduce the regulatory barriers that small companies in India face, but while policy changes have led to improvements in some areas, the overall national business environment is still poor. One particular achievement was in the area of electricity. Whereas it previously took a company in Delhi approximately four months to get an electricity connection, it currently takes just 45 days, bumping India’s ranking in this area from 51 in 2016 to 28 in 2017 (See **Exhibit 7**). Other areas of improvement include the introduction of an electronic system for the payment of employee insurance contributions, mechanisms for resolving commercial disputes, and a simplified procedure for exporting and importing.

Despite improvements, India slipped in some rankings. Their rankings for the ease of starting a business, dealing with construction permits, and getting credit all worsened from 2016, placing India among the lowest 25% of countries in these areas. While these areas affect the national business environment, they do not reflect some of the progress India has made in key areas, such as infrastructure improvements, increased foreign investment, and the movement to digitize registrations and approvals. India also recently signed into law a new bankruptcy code, which will consolidate existing insolvency laws. The law will also create insolvency professionals, who will manage the liquidation process for failing companies, as well as the creation of the

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<sup>13</sup> India turns to certification in pharma manufacturing quality drive

Insolvency and Bankruptcy Board of India, which will serve as a regulatory body. The law is expected to drastically shorten the time needed to resolve insolvency, from 4.3 years to 180 days.

## **8 LEGAL FRAMEWORKS AND THE ARV CLUSTER**

### **8.1 FDA (INTERNATIONAL)**

A negative setback for the industry's exports is possible as the US FDA implemented a number of regulatory actions relating to various Indian pharmaceutical companies. Large pharmaceutical producers such as Wockhardt, Sun Pharma, Lupin and Ipca are currently facing problems because of FDA letters and notices regarding product quality. Furthermore, other drug producers such as Emcure Pharmaceuticals and Dr. Reddy's Laboratories reported that their exports to the US have dropped because of US FDA intervention. From 2008 to 2015, the institution has issued around 50 warning letters to Indian companies, 40% of which led to import alerts. Increasing US FDA regulatory actions could substantially reduce Indian pharmaceutical exports to the US in the foreseeable future.

### **8.2 PRICE RELAXATION**

Prices for pharmaceutical products in India increased during 2015 in line with government's relaxation of pricing caps. In the first quarter of 2015, the government of India allowed the prices of 509 essential pharmaceuticals to increase, which resulted in a cumulative price increase of 3.8%. The medicaments that were affected by the price increases were hepatitis B and C, cancer related drugs, carboplatin injections and

fluconazole capsules which are used in treating fungal and other infections.

### **8.3 GOVERNMENT TRAINING INITIATIVES**

The Government is keen to upgrade the skills of workers in the industry. Central Drugs Standards Control Organization, a government body, has launched a certification program for workers in the pharmaceutical and biologic industries.

It aims at the completion of the certification process by all workers by Jan 1, 2018.<sup>14</sup>

### **8.4 GOVERNMENT INVESTMENTS**

The Government recognizes the potential of the industry and has planned to invest in the sector. It has also allowed pharma companies to have 100% FDI in the industry.

## **9 HISTORY OF THE ARV CLUSTER**

Antiretroviral drugs (ARVs) are part of standard antiretroviral therapy (ART) that is used to suppress the HIV virus and prevent the progression of HIV to AIDS. The emergence of the ARV sector in India can be traced back to government policies at the time of Independence from the United Kingdom. In 1947, the Indian pharmaceutical market was dominated by foreign corporations that together took around 80% to 90% of market share. This situation led to India having some of the highest prices for drugs in the world. As a response to this the national government instituted a set of economic policies meant to stimulate self-reliance and reduce the market share of MNCs; to this end, the

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<sup>14</sup> India turns to certification in pharma manufacturing quality drive

government passed laws abolishing “product patents, on food, chemicals, and drugs; the institution of process patents; the limitation of multinational equity share in Indian pharmaceutical companies, and the imposition of price controls on certain formulations and bulk drugs.”<sup>15</sup>

This change in government regulations drove MNCs out of business in India by making their business models unprofitable and “due to the absence of legal mechanism to protect their patented products;”<sup>16</sup> thus the withdrawal of MNCs from the Indian market created a vacuum in which Indian owned and operated companies could compete by focusing on reverse engineering drugs that had patent protection in other territories. The result was that “by 1990, India was self-sufficient in the production of formulations and nearly self-sufficient in the production of bulk drugs.”<sup>17</sup>

In the 1980’s, the HIV/AIDS pandemic became a major health crisis across the world. Thus, within the broader context of the emergence and growth of the Indian generic pharmaceutical cluster, there was a growing need within India for the provisions of medications for the treatment of HIV and AIDS. The first HIV patient in India was diagnosed in 1988 and since then, the disease has spread widely across reaching a total patient population of over 4.6 million by 2002. This vast

number of patients residing in predominantly poor countries, combined with the existing regulatory framework meant that fighting the HIV/AIDS pandemic by importing ARVs formulation produced by patent holders was not feasible financially or politically. In 2004, the Indian government’s health budget was around \$160 million per year with only a small fraction of the funds dedicated to combating HIV/AIDS.<sup>18</sup> The limited availability of funds for combating HIV/AIDS drove Indian generic manufacturers to reverse engineer ARV bulk drugs and formulations to supply the domestic market. Additionally, the worsening situation in Sub-Saharan Africa and the growing debate surrounding the pricing of ARV drugs by MNCs and the lack of accessibility in Africa created a market opportunity that India firms were well positioned to exploit due to the lack of patent laws in India and the connections the country had to Africa dating back to the times of the British empire. These factors, combined with the enactment of PEPFAR (President's Emergency Plan for Aids Relief) by George W. Bush, led to a surge in demand for ARV drugs and the growth of the ARV cluster in India.

## **9.1 KEY COMPETING CLUSTERS IN OTHER COUNTRIES**

Currently, there are no other significant competing clusters in other countries. India’s cluster has significant built in advantages that

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<sup>15</sup> William Greene, “The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market”, *United States International Trade Commission*, May 2007, <https://www.usitc.gov/publications/332/EC200705A.pdf>, p. 2, accessed March 2017.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

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<sup>18</sup> Primit Mitra, “India at the Crossroads: Battling the HIV/AIDS Pandemic”, *The Washington Quarterly*, volume 27, number 4, Autumn 2004, pp. 95-107, <https://muse.jhu.edu/article/173616/pdf>, p. 100, accessed March 2017.

stem for the historical development of its generics industry, the international positioning of its firms, cultural practices, and the built-in infrastructure and regulatory advantages it already possesses. Furthermore, during the past two decades, Indian firms operating in the ARV sector have built a reputation for excellence and have established deep ties with NGO and government programs (e.g. PEPFAR) for the provision of ARVs destined to treat AIDS in Africa and other developing countries. This has also led to the establishment of several cooperation agreements between Indian ARV firms and MNCs that carve out markets where Indian firms can operate as licensees of MNCs (i.e. not liable to patent infringement) in exchange for not challenging MNCs patent rights to ARVs in their core markets (U.S., Europe, etc).<sup>19</sup> Thus it will take significant time for other clusters to develop and challenge the hold that Indian firms have in the generic ARV sector.

However, it is important to consider that Chinese generic manufacturers are quickly emerging, and with it, the production of ARVs in China is also rising. This is due to the high prevalence of retroviral infections like Hepatitis B in China, which is also treated with ARVs that can be used for the treatment of HIV (Lamivudine 100mg tablets for Hepatitis B vs. Lamivudine 300mg tablets for HIV/AIDS). In spite of this, Chinese firms face several challenges in catching up to Indian firms with the key ones being:

1. The regulatory capabilities of Chinese firms are not superior to those of Indian firms. India has a significantly greater number of FDA and EMA approved pharmaceutical factories and this gap will take considerable time and capital for Chinese firms to breach.
2. China's educated workforce and availability of talent is greater than that of India; however, the number of English speakers in China is significantly lower than in India and this creates barriers to entry for Chinese firms because it reduces their ability to cooperate in countries where Chinese is not spoken.
3. India has a significant advantage in the development and production of Active Pharmaceutical Ingredients (APIs) and in process improvement. This makes their pricing competitive to those of Chinese companies and speeds up the time to market for their ARV formulations.<sup>20</sup>
4. MNCs consider China to be one of their core markets due to stronger IP laws than in India, larger population, higher costs of drugs, higher standard of living, and higher rate of growth. Thus, MNCs are less willing to cooperate with Chinese firms for the development of generic ARVs due to fears of facilitating competition within the Chinese market.

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<sup>19</sup> "Gilead signs generic HIV drug deals with Mylan, Ranbaxy, Strides Arcolab", *firstwordpharma.com*, Aug. 2<sup>nd</sup> 2012, <https://www.firstwordpharma.com/node/1007737?tsid=17>, accessed May 2017

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<sup>20</sup> interview with Praveen Kommana; Associate Director, Business Development – Laurus Labs.

## **10 ARV CLUSTER COMPETITIVENESS ASSESSMENT**

### **10.1 STRENGTHS**

#### **10.1.1 Government Policies**

The stringent rules for the issuance of patents to pharmaceutical products is a major boon to the Indian pharmaceutical industry in general and the ARV sector in specific. This is because the lax patent rules have allowed Indian pharmaceutical companies to innovate in the ARV sector through the development of fix-dose drug combinations that are highly effective in the treatment of HIV/AIDS and represent a massive benefit to patient and clinicians. Treatment for HIV/AIDS is primarily done through Highly Active Anti-Retroviral Therapy (HAART); the key to HAART is combining several different medications into a drug cocktail that the patient must take every day for it to remain effective in containing the virus. Failure to adhere to this strict dosing regimen leads to therapy failure by giving windows for the HIV virus to become resistant to the different drugs the patient is taking, thus increasing viral loads and leading to the emergence of AIDS.

HAART by itself represents a serious challenge to the patient because if the drugs are taken in separate pills then it becomes much more difficult for the patient to adhere to the drug regimen and dosing schedule. This phenomenon is known as the pill burden and it represents a significant challenge in the clinical treatment of HIV/AIDS. What lax patent laws in India have allowed generic companies to do is innovate by developing fixed-dose combination pills that

include different drugs in one single pill that is taken once a day. This “one-pill once a day HAART”<sup>21</sup> leads to significant improvements in therapy adherence and thus improvements in specific patient outcomes. Traditional drug developers cannot compete as easily in this space because the intellectual property rights for the different drugs are usually owned by different companies that are in competition with each other and are thus either unable or unwilling to cooperate to develop such combination drugs. Once the drugs go out of patent then there is little incentive for these innovators to develop the combination drugs because of pricing pressure and competition from better equipped generic manufacturers reduces their ability to derive returns.

#### **10.1.2 English speaking business culture**

The lingua franca of business in India is English and this represents a comparative advantage over other low cost manufacturing countries because it makes doing business with Indian firms much easier than, for example, a Chinese one. Furthermore, the legacy of British colonialism means that there is a shared history with former British colonies in Africa and, in many cases, significant Indian communities in African countries. This shared history creates trade links that gives Indian generic firms easier entry into the ARV markets of Africa which is where most of the HIV/AIDS cases are found.

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<sup>21</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2875721/>

### **10.1.3 Low-cost**

This is a competitive advantage because most HIV/AIDS cases are found in countries that lower-middle income or low income and are not able to afford patented drugs sold by MNCs. Thus, India firms can manufacture at a cost that is competitive within the economic constraints of these territories and this creates barriers to entry that protects Indian firms from competition by innovators. One clear example with this is the ability of Indian firms to employ greater numbers of researchers than their western counterparts, this means that they can invest in R&D focused on process improvement that reduces the manufacturing costs associated with the development of bulk drugs. This also allows the Indian ARV cluster to drive through the R&D development process for combination drugs at a faster pace thus delivering new drug combinations that are able to improve quality of care and further reduce manufacturing costs for ARV.<sup>22</sup> Furthermore, that Indian firms have lower capital costs than their western counterparts and can build up the infrastructure needed to manufacture these drugs at a fraction of what western firms must pay.<sup>23</sup> As a result manufacturers in the Indian ARV cluster can invest in facilities that are world-class and receive relevant regulatory approvals in the form of Good Manufacturing Practices certificates and Marketing Authorizations for ARV products from the US FDA and the European EMA; as a result India

has the second largest number of manufacturing sites approved by the FDA.<sup>24</sup> This is of immense value to the ARV cluster because it is not a capability that competitors like China can easily replicate and, as per the rules of programs like PEPFAR, ARV drugs purchase through these programs must first have obtained tentative marketing approval from the FDA before they can be procured and distributed to target governments and patients in Africa.<sup>25</sup>

## **10.2 WEAKNESSES**

The specific weaknesses of the Indian ARV cluster are the same as those of the Indian generics cluster in general. Among these the following are the most pressing for the cluster:

### **10.2.1 Value Chain**

The industry is concentrated at the lower levels of the value chain; this exposes manufacturers to downwards pricing pressure on ARV drugs and inflationary pricing pressure for wages and production costs in India. The ARV cluster cannot rely on process innovation forever to keep prices down and it needs to move up the value chain into drug discovery and development of new therapies to remain competitive.

### **10.2.2 Expertise Gap**

Indian manufacturers lack specific expertise in drug discovery and do not have the ability to bring new molecular entities through the approval process for regulated markets like the United States. Thus, they must focus in strengthening

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<sup>22</sup> interview with Praveen Kommana; Associate Director, Business Development – Laurus Labs.

<sup>23</sup> <https://www.usitc.gov/publications/332/EC200705A.pdf>

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<sup>24</sup> interview with Praveen Kommana; Associate Director, Business Development – Laurus Labs.

<sup>25</sup> Ibid.

these capabilities if they are to remain competitive with MNCs over the medium and long term.

### **10.2.3 Safety & Quality**

Indian manufacturers have been caught in several safety issues with the most egregious one being the Ranbaxy case in the United States, in which Ranbaxy was found to be exporting substandard drugs to the U.S. and systematically falsifying data.<sup>26</sup> This is a major issue and threat to the cluster because it endangers the very regulatory approvals on which they rely to market ARV drugs to programs like PEPFAR. Thus Indian firms are subject to export bans like the one placed on Ranbaxy and IPCA Laboratories.<sup>27</sup>

### **10.2.4 Pricing Pressure**

India has high logistics costs and these increase pricing pressures on manufacturers within the ARV sector. The central government's efforts to pass a uniform Goods and Services Tax should aid in the easing of some of these logistics costs but the problem of substandard infrastructure remains.<sup>28</sup>

These weaknesses also represent the most glaring competitiveness issues facing the ARV cluster; however, it is salient to point out that there are three trends that bode well for the future of the Indian ARV cluster:

1. The FDA has increased its presence in India and is monitoring manufacturing sites much

more closely as well as working more closely together with Indian regulatory authorities.<sup>29</sup> This should work to reduce the number of regulatory infractions and improve the quality assurance process for Indian ARVs thus maintaining competitiveness.

2. Indian manufacturers are starting to consolidate and create larger economies of scale that allows them to better compete globally against MNCs and late entrants from countries like China. In this regard, the acquisition of Ranbaxy by Sun Pharma is a prime example.<sup>30</sup> By increasing these types of mergers, the ARV cluster will be able to move up the value chain by creating synergies that can be reinvested into improving R&D and drug discovery efforts thus allowing the cluster to move up the value chain.
3. While this move up the value chain is ongoing, the Indian ARV cluster also has the opportunity to seize on the additional revenues generated by the introduction of new ARV drugs by MNCs that are slowly phasing out older therapies that are beginning to lose their efficacy or which simply underperform newer ones. One clear example of this is the current ongoing replacement of Lopinavir/Ritonavir tablets with Darunavir, a

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<sup>26</sup> <http://www.bbc.com/news/world-asia-india-22520953>

<sup>27</sup> <http://www.fiercepharma.com/regulatory/fda-bans-two-more-ipca-plants>

<sup>28</sup> <http://economictimes.indiatimes.com/news/economy/infrastructure/indias-poor-infrastructure-biggest-roadblock-to-make-in-india-sp/articleshow/53508076.cms>

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<sup>29</sup>

<https://blogs.fda.gov/fdavoices/index.php/2016/02/strengthening-our-regulatory-relationships-in-india/>

<sup>30</sup> <http://www.economist.com/news/business/21600695-buying-troubled-rival-will-make-sun-pharma-global-contender-sun-takes-shine-ranbaxy>

drug with a similar mechanism of action but improved performance and safety profiles.<sup>31</sup>

## **11 CHALLENGES AND OPPORTUNITIES IN THE EXPORT OF PRODUCTS TO SUB SAHARAN MARKETS**

There are currently 19 million people living with HIV in Sub-Saharan Africa, with nearly a million new HIV infections each year.<sup>32</sup> Low-cost generic ARV drugs from India have been integral to the rapid scale-up of HIV treatment in Sub-Saharan Africa and other developing countries. More than 4 million people living with HIV were started on treatment between 2002 and 2008.<sup>33</sup> Since 2006, ARVs produced by generic manufacturers in India account for more than 80% of the developing country market and 65% of the total value of ARV purchases.<sup>34</sup>

The large-scale production of affordable ARVs in India is a result of three factors. First, unrestrictive IP and patent laws facilitated the production and availability of new ARV formulations by Indian manufactures, such as fixed-dose combination (FDC), which could be sold for much less than existing drug formulations. Between 2003 and 2006, the number of ARV products increased from 14 to 53. Second, the USFDA and WHO Prequalification Program approved or pre-

qualified 57 FDCs from Indian manufacturers but only 8 produced by non-Indian manufacturers.<sup>35</sup> Finally, high levels of competition among generic manufacturers has led to significant price decreases. A common first-line regimen of treatment decreased from \$414 per person per year to \$74 per person per year for Indian generics.<sup>36</sup>

New global policies threaten India's status as the pharmacy of the developing world. In 2005, India was required to amend its patent law to be in adherence with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The introduction of patent requirements limits competition in Indian generic pharmaceutical markets, stifling new product innovations and driving up prices. In addition, free trade agreement negotiations between the EU and India contain additional provisions that restrict competition and block international trade in cases of patent infringement.<sup>37</sup> These restrictions could severely limit the supply of low-cost ARVs and have a detrimental impact on HIV patients in developing nations in the future.

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<sup>31</sup> interview with Praveen Kommana; Associate Director, Business Development – Laurus Labs.

<sup>32</sup> <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview>

<sup>33</sup> Waning, Brenda, et al. "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. *Journal of the International AIDS society* 2010, 13:35

<sup>34</sup> Ibid.

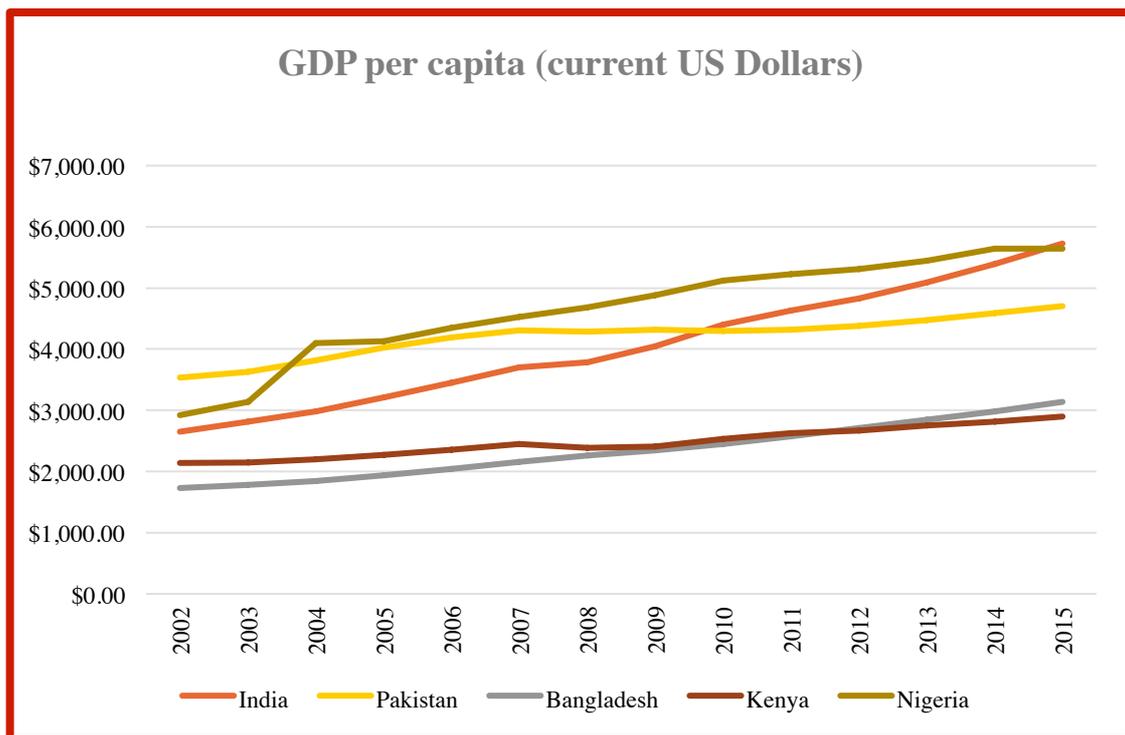
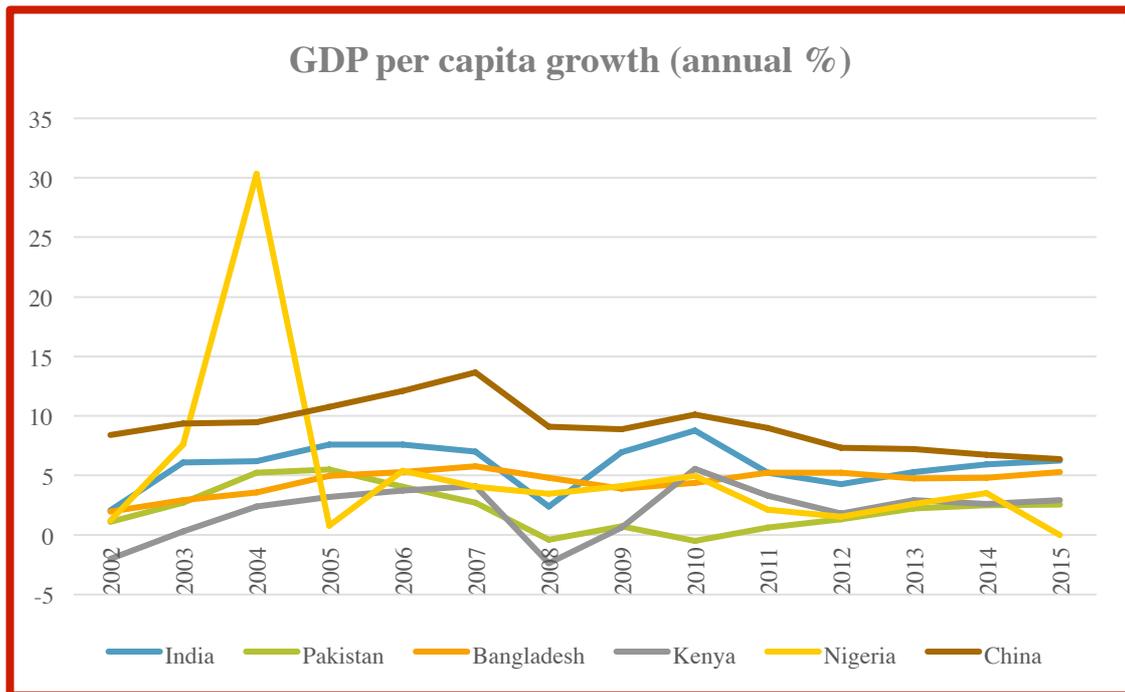
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<sup>35</sup> Ibid.

<sup>36</sup> Ibid.

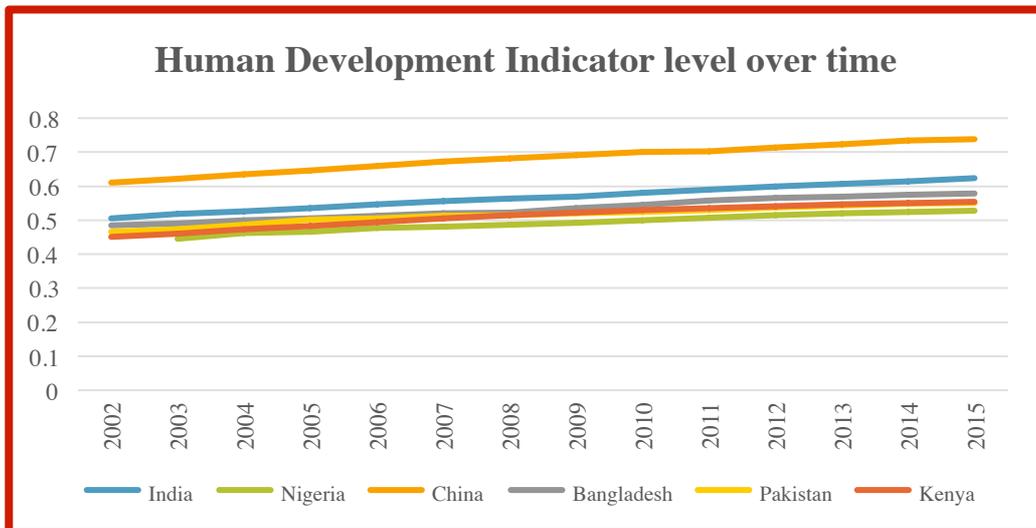
<sup>37</sup> Abbott F: Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: a threat to international trade, development and public welfare. *World Intellectual Property Organization Journal* 2009, 1:43.

## EXHIBIT I: GDP PER CAPITA GROWTH 2002 - 2015



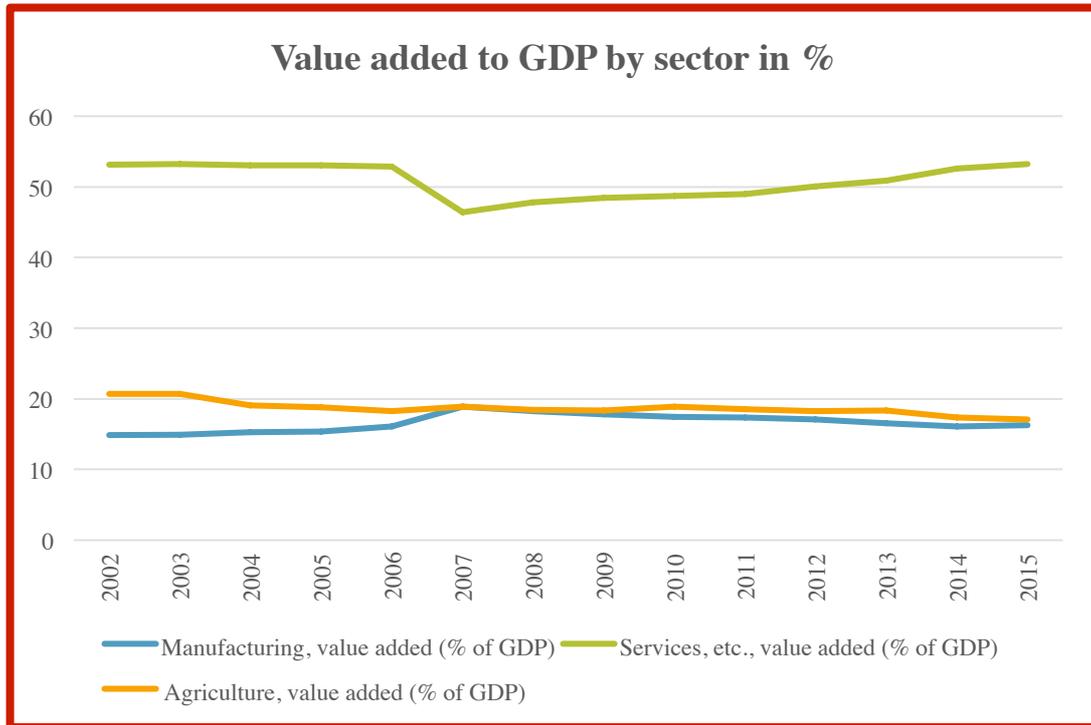
## EXHIBIT 2: HUMAN AND SOCIAL DEVELOPMENT IN INDIA AND COMPARISON COUNTRIES

Country	Human Development Index Rank
China	90
India	131
Bangladesh	139
Kenya	146
Pakistan	147
Nigeria	152



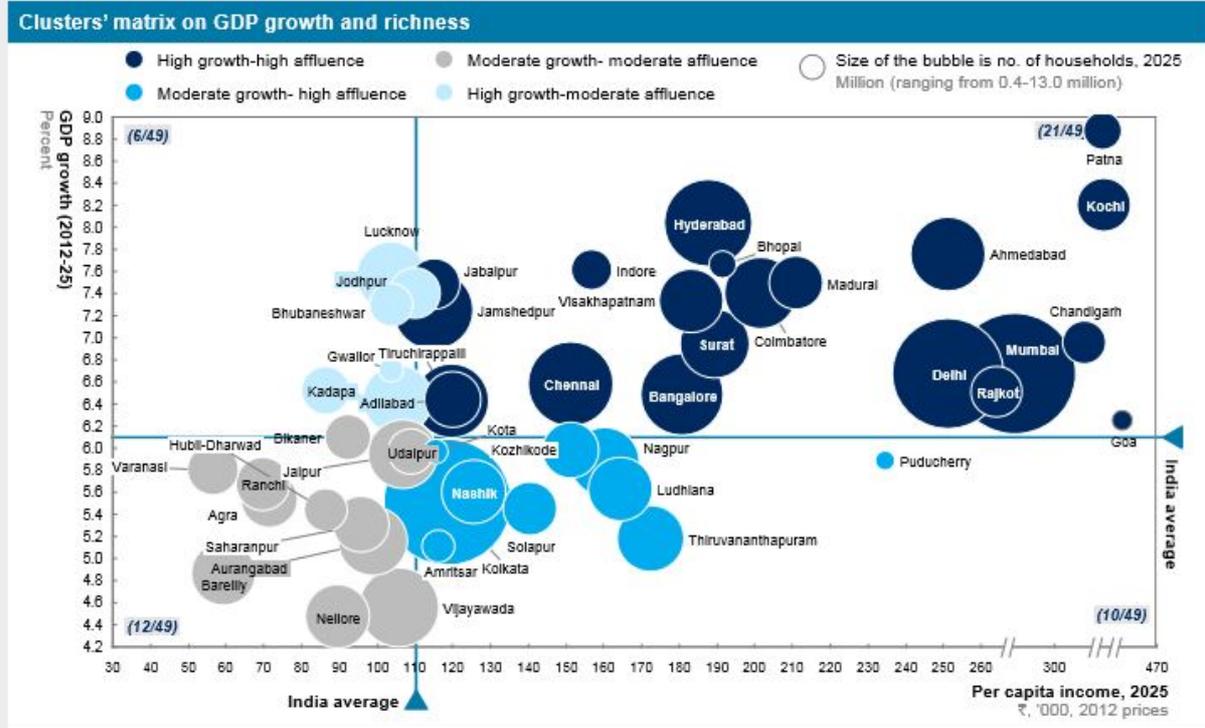


## EXHIBIT 4: INDUSTRY-DECOMPOSITION – VALUE ADDED TO GDP BY SECTOR IN %



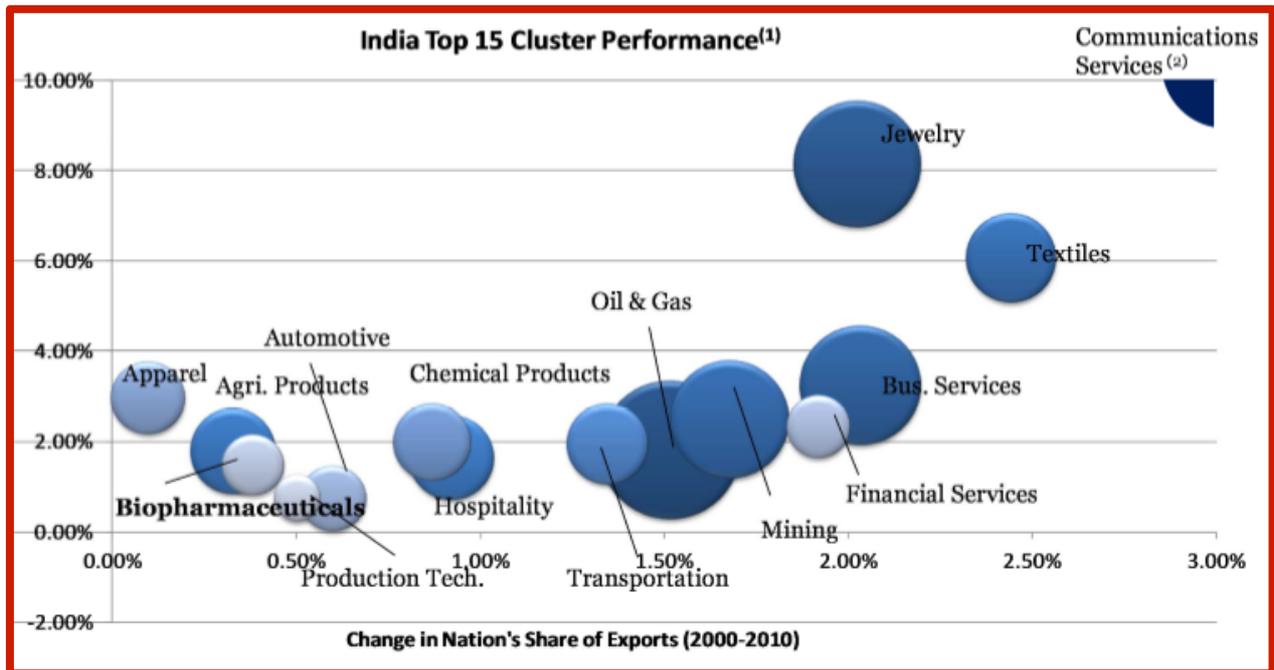
## EXHIBIT 5A: CLUSTERS' MATRIX ON GDP GROWTH AND RICHNESS

Twenty one clusters are likely to be more affluent and grow faster than India



SOURCE: McKinsey Insights India

## EXHIBIT 5B: INDIAN CLUSTER PERFORMANCE<sup>38</sup>



<sup>38</sup> International Cluster Competitiveness Project, Institute for Strategy and Competitiveness, Harvard Business School

## EXHIBIT 6: COMPARISON OF INDIA AND CLUSTER CITIES

Factor	India - total	Bombay	Delhi	Hyderabad
<b>Pr. capita income, PPP adjusted<sup>39</sup></b>	5376 \$ pr. capita	2 <sup>nd</sup> highest: 7005\$ pr. capita	1 <sup>st</sup> Highest: 12.747\$ pr. capita	5 <sup>th</sup> highest: 5051\$ pr. capita
<b>HDI-level (on state level)<sup>40</sup></b>	-	4 out of 17	6 out of 17 (Haryana)	9 out of 17
<b>Technical institutes/ Universities<sup>41</sup></b>	Indian Institute of Technology Madras (ranked 1 <sup>st</sup> )	Indian Institute of Technology Bombay (ranked 2 <sup>nd</sup> )	Indian Institute of Technology Delhi ranked 3 <sup>rd</sup> )	Indian Institute of Technology Hyderabad ranked 7 <sup>th</sup> )
<b>Infrastructure investments</b>	~\$100 bln investment/year Roads, power, bridges, urban infrastructure	Delhi Mumbai Industrial Corridor	Delhi Mumbai Industrial Corridor	Hardware Parks, Software Parks, SEZs, urban infrastructure
<b>Government policies/support</b>	National Health Policy 2015 NPPP-2012 Pharma Vision 2020 R&D Support	State and local support of R&D and production	State and local support of R&D and production	State of Telangana government highly supportive: Initiated Hyderabad Pharma City - a Special Purpose Vehicle - to provide high-quality environment for the pharma industry.
<b>Major companies' HQ</b>	-	Cipla, Lupin		Dr Reddy's, Aurobindo, Mylan

<sup>39</sup> [https://www.brookings.edu/wp-content/uploads/2015/01/bmpp\\_gmm\\_final.pdf](https://www.brookings.edu/wp-content/uploads/2015/01/bmpp_gmm_final.pdf)

<sup>40</sup> <http://www.livemint.com/Politics/3KhGMVXGxXcGYBRMsmDCFO/Why-Kerala-is-like-Maldives-and-Uttar-Pradesh-Pakistan.html>

<sup>41</sup> <http://indianexpress.com/article/education/top-25-engineering-colleges-in-india-nirf-ranking-2016/>

## EXHIBIT 7: DOING BUSINESS RANKINGS FOR INDIA

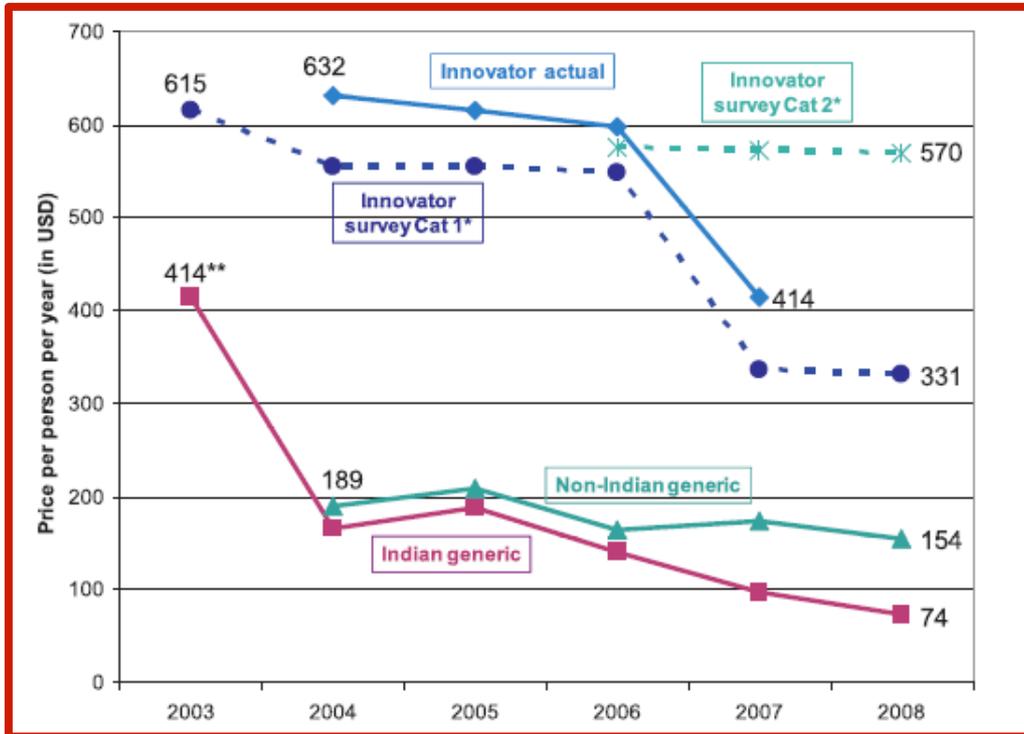
	Ranking (2017)	Ranking (2018)
Ease of Doing Business Rank	130	131
Starting a Business	155	151
Dealing with Construction Permits	185	184
Getting Electricity	26	51
Registering Property	138	140
Getting Credit	44	42
Protecting Minority Investors	13	10
Paying Taxes	172	172
Trading Across Borders	143	144
Enforcing Contracts	172	178
Resolving Insolvency	136	135

## EXHIBIT 8: INDIAN-PRODUCED GENERIC ARVs FOR COUNTRIES WITH HIGHEST PURCHASING

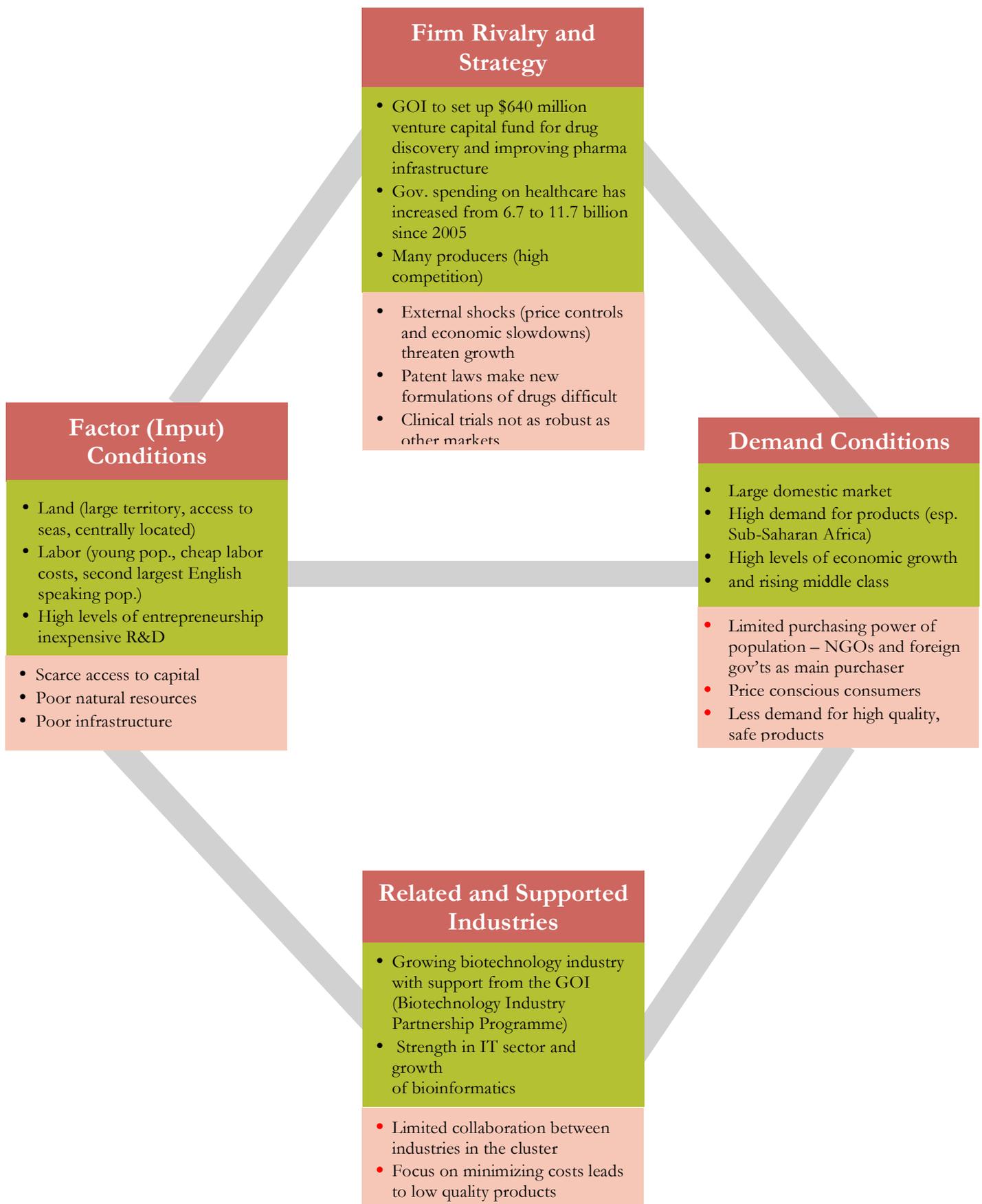
Purchase Volume Rate	Country	% of ARV volume supplied by Indian generic producers	Value of Indian-produced generic ARV purchases (USD million)	# Indian-produced generic ARV dosage forms purchased
1	India	100	25.9	14
2	Tanzania	96	27.3	13
3	Nigeria	84	27.1	28
4	Ethiopia	96	27.6	24
5	Mozambique	99	15.3	16
6	Zambia	94	20.7	19
7	Namibia	99	15.3	23
8	Democratic Republic of the Congo	99	11.4	25
9	Kenya	82	10.2	14
10	Cameroon	93	15.0	30

### VOLUMES

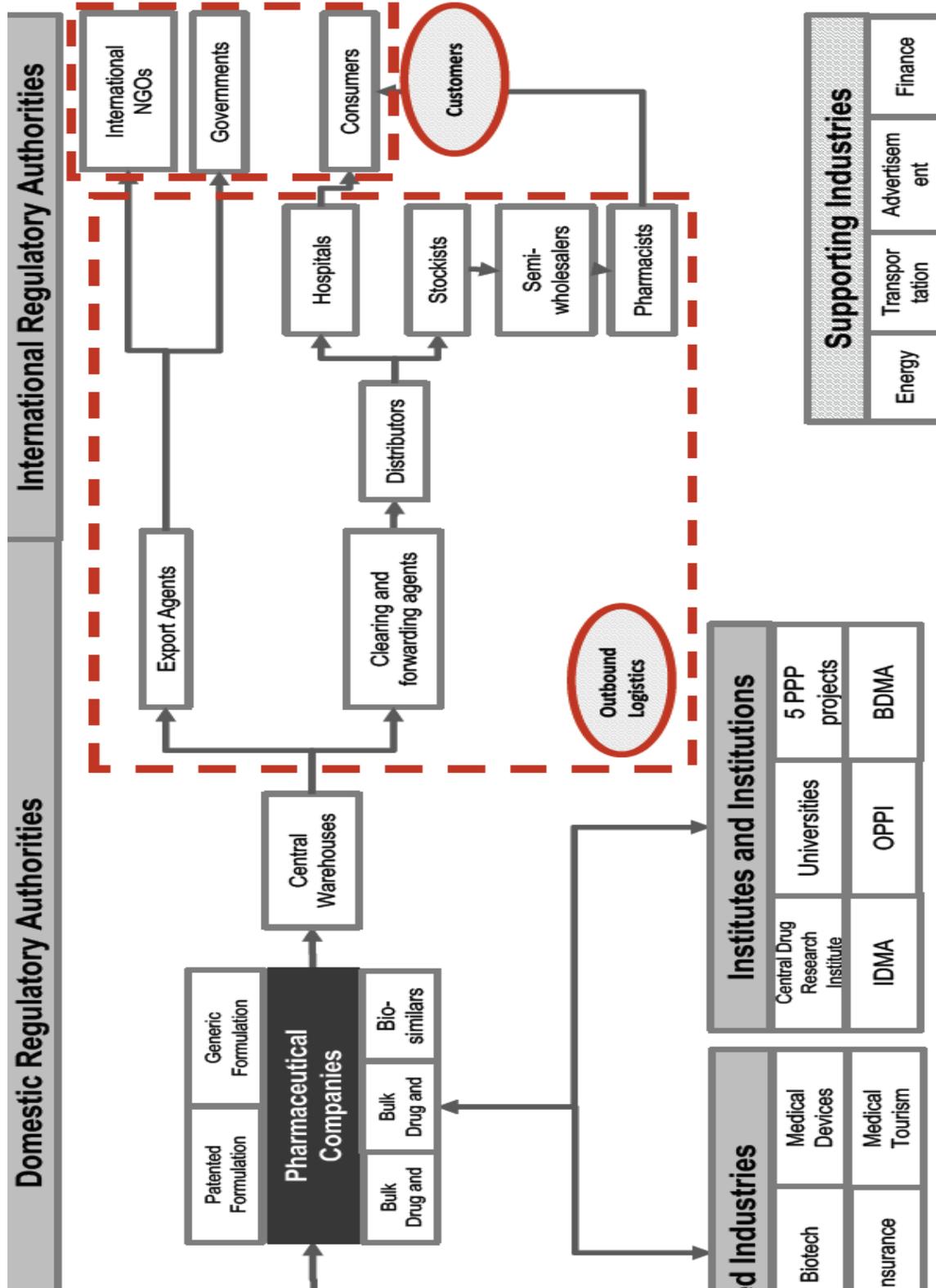
## EXHIBIT 9: PRICE TRENDS FOR GENERIC FIXED-DOSE COMBINATION AND INNOVATOR ARVs, 2003-2008



## EXHIBIT 10: CLUSTER DIAMOND



## EXHIBIT 11: CLUSTER MAP



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