

Outsourcing in the context of the pharmaceutical industry



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What is Outsourcing in context to pharmaceutical industry?

The Food and Drug Administration (FDA) indicates in its guidance for Industry, Quality Systems Approach to Pharmaceutical Regulations that “ Outsourcing involves a second party under a contract to perform the operational processes that are a part of a manufacturer’s inherent responsibilities.”

Why do companies outsource?

Increase Core Competency – Core competency means a product from a company which provides benefits to the customers, it is not easy to imitate by the competitors and is a point of difference for the company with respect to its competitors.

Outsourcing helps to increase the product range of the company.

Sometimes cost of production is high in a country, hence to bring the cost of production down, it is advisable to outsource. Take China for example; where labor cost is low, hence companies outsource the production to China.

Outsourcing also reduces the time taken by a product to be launched in the market.

As the pharmaceutical industry is being globalised, it is better to produce the drug near the market and hence outsource. For example; if a drug has to be circulated in India, then the drug manufacturing for India is outsourced to India.

Companies need not setup facility and have dedicated resources for something whose requirement is variable. They can outsource the manufacturing work and pay as per their needs.

They can avail the service of highly skilled and educated labor at a lower cost.

Companies can have faster access to latest technologies and processes followed by outsourcing to the Clinical Resource Organization (CROs) in the low cost countries like India and china and hence minimize the investments in capital-intensive facilities.

Global Scenario

The pharmaceutical companies world over are now making Outsourcing a part of their strategy to meet the new challenges posed by increased competition and globalization. To remain competitive, companies are focusing on their core competences and outsourcing other activities. These activities include Contract Research, Drug Recovery and Development, Manufacturing, Managing clinical data, back office functions. There are other organization functions which are considered to be outsourced like Payroll, logistics, procurement and distribution. The costs of manufacturing and for Research and Development in developed countries have increased. Whereas countries like India and China provide highly skilled labor and state of the arts facilities at much lower cost compare to that in developed countries.

Outsourcing survey done by CONTRACT PHARMA organization reveals that this year 44% respondents to the survey indicated that their spending on

outsourcing increased compare to that of previous year. Whereas 34%
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respondents indicated that their spending on outsourcing is going to be less than previous year.

The survey also revealed the trend that 54% of top 20 pharmaceutical companies in the world are going to spend more on Outsourcing this year compare to previous year, whereas the number is 40% for medium and small size companies. This indicates that large companies are spending more on outsourcing to be able to focus on their core competencies and being more competitive.

The chart below reveals that 45% of the companies outsource their work to be able to focus on their core competencies.

List of 10 Best Outsourcing Companies in the world compiled by International Association of Outsourcing Professionals (IAOP):

Corbus

CPA Global

Intelligroup

Johnson Controls

Jones Lang LaSalle

Nair & Co.

PAREXEL International

Synggy

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TEKsystems Global Services

Wicresoft

Indian Scenario

Indian pharmaceutical companies are highly active in Contract Research and Manufacturing Services (CRAMS) and Custom Manufacturing Services (CMO) segments.

Pharma companies like Cipla pharmaceutical, Piramal healthcare, Sun pharma, Ranbaxy pharma, Zydus Cadila, Torrent Pharma, Divi's Laboratories, Indoco Remedies, Dr Reddy's laboratories, Alkem, Lupin, Alembic and almost all players in the industry have been very active in CRAM activities. This is because of the ability to create a differentiating cost proposition driven by its cheaper manufacturing costs, strong technical know-how and skilled workforce and also the existence of more than 80 United States food and drug administration (FDA) approved manufacturing facilities, this makes India the only country outside the US to have the highest FDA certified manufacturing facilities.

India is the fastest growing CMO destination with a growth rate of 43 percent which is three times the global market rate and the industry top analysts predict that CMO business may rise to \$7-8 billion in the next four to five years as it is growing at 35 to 40 percent over the next two years.

Advantages

Most of the Pharmaceutical companies across the world are looking towards India and outsourcing the drug making process. Now, let's look at some facts

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and figures as to why are they outsourcing? Indian pharmaceutical industry is 4th largest in terms of volume and 13th largest in terms of value. In over 60 therapeutic categories with over 60000 brands, the market share comes close to USD 5bn. India is the country with cheap labor due to its population and also has world class facilities and expertise in manufacturing of drugs and thus without hampering the quality of the drug, mass production can be brought into picture. This reduces the cost of production to a great extent. Study says that at least 35% of the drugs used in the US are manufactured in India.

All this happened after the Indian Patent Act of 1970. This act removed the product patents in the agro-chemical, pharmaceutical and food processing sectors, hence preparing of patent drugs in India became legal. Due to this, the entrepreneurs of India legally reversed the engineering plant, change the manufacturing process and by pass the patents and thus having no research and development cost to recover, could sell the same drug at a much lower cost than the price of the original drug. India began to follow the World Trade Organization's Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS) agreement and acknowledged product rights after the revision of the Indian Patent Act in January 2005.

From the year 2007 to 2008, the Indian pharmaceutical market has grown over 4% and thus reaching a new high of USD 7, 734m. It has been estimated that the market will keep on rising at a rate of 13. 2% from 2009 till 2014 and can reach a new high of USD 15, 490m by 2014.

Another reason for the involvement of the global pharmaceutical companies is due to the immense growth perspective furnished by the elderly population, developing patent system and other socio-economic reasons.

Challenges for India

- The pharmaceutical industry in India is overregulated. This may hamper new players coming into market and existing player's growth.

-Ethicality of trials is also an issue.

- Inadequate funds and lack of infrastructural facilities required to become a global leader in healthcare.

Top Pharmaceutical companies in India

Rank

Companies

Turnover (as in 2007)

1

Ranbaxy Laboratories

Rs 4, 198. 96 crore

2

Dr. Reddy's Laboratories

Rs 4, 162. 25 crore

3

Cipla

Rs 3, 763. 72 crore

4

Sun Pharmaceuticals

Rs 2, 463. 59 crore

5

Lupin Labs

Rs 2, 215. 52 crore

6

Aurobindo Pharma

Rs 2, 080. 19 crore

7

GlaxoSmithKline

Rs 1, 773. 41 crore

8

Cadila Healthcare

Rs 1, 613. 00 crore

9

Aventis Pharma

Rs 983. 80 crore

10

Ipca Laboratories

Rs 980. 44 crore

Ranbaxy Laboratories - This is the India's biggest pharmaceutical manufacturing company, holding 8th position among the global generic pharmaceutical companies. Ranbaxy has world-wide presence in 48 countries and this includes world class manufacturing facilities in 10 countries. This company's India operations are a strong force in a number of participating therapeutic segments, for example Anti-infectives, Statins, Dermatology and Pain Management. This is a public listed company and Ranbaxy India is also a member of Indian Pharmaceutical Alliance (IPA) & Organization of Pharmaceutical Producers of India(OPPI).

Dr. Reddy's Labs - The company has a large number of active pharmaceutical ingredients around 60 to manufacture diagnostic kits drugs, critical care products and biotechnology products. The company has 6 FDA plants that produces active- pharma ingredients and it has 16 world-class manufacturing facilities of which 9 have a long history of regular USFDA inspections. With an annual capacity of nine billion tablets/ capsules a year, dedicated to servicing the more regulated markets, one of the finished

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dosages facilities is among the largest in Asia. The company facilities are designed in such a way that the plant can react to a wide range of technologies oral solids, injectibles, topicals, inhalers, cytotoxic, hormonals and other dosage forms.. Such manufacturing capabilities and the technical expertise to navigate intellectual property road blocks make it a preferred partner for some of the world's leading pharmaceutical companies.

Cipla - This is an Indian pharmaceutical company reputed for the manufacture of low cost anti -AIDS drugs. The company's product range consists of anthelmintics, oncology, anti-bacterials, cardiovascular drugs, antibiotics, nutritional supplements, anti-ulcerants, anti-asthmatics and corticosteroids. The company also offers different services like quality control, engineering, project appraisal, plant supply, consulting, commissioning and know-how transfer, support.

Glaxo Smithkline -This is a UK based pharma company and it is the world's 2nd biggest pharmaceutical company. The company's pharma products portfolio includes oncology, vaccines, anti-infectives, central nervous system, respiratory and gastro-intestinal/metabolic products among others. FDA had announced in the month of nov, 09 that the H1N1 vaccine manufactured by GSK would join the list of the four vaccines approved.

The following table indicates the size of the market, market share of major pharmaceutical companies and the growth rate year-on-year basis for the year ended 2009.

Company

Size (\$ Billion)

Market Share (%)

Growth Rate (%)

Others

5.4

Cipla

0.36

5.3

13.4

Ranbaxy

0.34

5

11.5

Glaxo Smithkline

0.29

4.3

-1.2

Piramal Healthcare

0. 27

3. 9

11. 7

Zydus Cadila

0. 24

3. 6

6. 8

The following are the leading Indian CRO's(Contract Research Organisations) :

GVK Biosciences,

Syngene

Sai Advantium and

Accutest.

The following are the top Indian companies, which offers contract services as well as conducts their own internal drug discovery

Dr. Reddy's Laboratories

Nicholas Piramal

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Advinus Therapeutics

Jubilant Biosys

Suven Life Sciences and

In-House Offshore Initiatives to India

Company

Work Done and Future Plans

GSK

- Emphasis on collaborative research work with UK.
- R&D has already started for development of indigenous technologies for new drugs and process improvements of old drugs.
- Started building its in house capacity for clinical research in 2004 and plans to further it in the subsequent years.
- Identifying institutes in India for long term collaborations.

Pfizer

- Plans to make India the prime R&D Hub
- Has invested more than 13 million \$ in India in various segments of psychiatry, cancer, infectious disease, etc.
- Has conducted over 20 clinical studies so far

Aventis

- Plans to make India an research hub and shift major part of its global R&D operations to India
- Plans to make India a base for clinical development in cardiovascular, diabetes and oncology segments

AstraZeneca

- Has captive centre at Bengaluru, set up in 2001 to discover new drugs for the treatment of TB
- Plans to scale up the operations in India
- Plans to make India the base for clinical development for asthma related drugs, cardio-vascular and oncology.

SWOT Analysis

Strengths

Weakness

Low cost of production.

Efficient cost effective technologies for large number of Generics

Clinical research and trials in world-class process development labs and having non-infringing processes of Active Pharmaceutical Ingredients (APIs)

Government- Increasing liberalization of government policies.

Large pool of skilled, low cost technical manpower

High-quality formulations , drugs and standards of purity

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Large pool of installed capacities

Strong and well-developed manufacturing base

Low Indian share in world pharmaceutical market (about 2%)

Low R&D investments

Absence of association between institutes and industry

Low healthcare expenditure

Production of duplicate drugs

Fragmentation of installed capacities

Low technology level of Capital Goods of this section.

Non-availability of major intermediaries for bulk drugs.

Lack of experience to exploit efficiently the new patent regime.

Very low level of Biotechnology in India and also for New Drug Discovery Systems.

Lack of experience in International Trade.

Low level of strategic planning for future and also for technology forecasting.

Opportunities

Threats

Incredible export potential, Easier international trading.

Increasing health consciousness

New innovative therapeutic products

Globalization, New markets are opening

Contract manufacturing

Clinical trials & research

Drug molecules

Aging of the world population.

Growing incomes.

New diagnoses and new social diseases.

Spreading prophylactic approaches.

Saturation point of market is far away.

New drug delivery system management.

Spreading attitude for soft medication (OTC drugs).

Spreading use of Generic Drugs.

Containment of rising health-care cost.

High Cost of discovering new products and fewer discoveries.

Stricter registration procedures.

High entry cost in newer markets.

Outdated and high cost of sales and marketing.

Competition, particularly from generic products.

More potential new drugs and more efficient therapies.

Small number of discoveries

Competition from MNCs

Transformation of process patent to product patent (TRIPS)

Non-tariff barriers imposed by developed countries

Strategies employed by various outsourced firms

Reorganizing R&D units to create Centers of Excellence: Drug Discovery, drug development, Manufacturing, Sales, Marketing and distribution. A drug discovery team has a full range of disciplines required for early phase drug discovery. A Drug development Unit is the coming together of personnel resources and services necessary to design, execute, analyze, and report a clinical research protocol. The CMO companies have evolved as specialized units and have consolidated their position in different centers of excellence to emerge as major players at a Global stage. Ranbaxy has a capable DDU the ownership of which has been recently shifted to Daiichi Sankyo. Dr. Reddy's Laboratory has set up a foundation exclusively for new drug development, namely. Dr. Reddy's Research Foundation (DRF) which caters to the Drug development needs of the outsourcing companies.

Developing and implementing change management processes throughout the organization: The CMO companies have identified a need to have a change management framework so that the changes to the new and existing systems, environments can be tracked. Central documentation of the completed changes increases responsibility and authority and as a result the processes before the production phase can be better controlled during the validation and developmental environment. This also helps them to have a stable and secure environment for all the applications.

Diversification: From early stage drug development to commercial manufacturing and distribution for every form of dosage, the CRO companies have also diversified into clinical operations and data management to become full service CROs. They are also moving into providing more services such as central labs, imaging, contract staffing, data management. Hence they hold a great potential for growth in the niche fields like toxicology studies.

Adaptability to new Business models of growth: The traditional CRO business model which was free-for-service model has now evolved to a partnership model and gradually to a risk-share model where the projects are funded by both the parties. The partnership level has risen to include the equity collaboration along with the technical partnership. At the global level Accenture- Wyeth, Covance -Lilly, Suven-Lilly, Syngene- BMS are some of these new types of evolving models.

Compliance to US FDA regulations: The CRO companies have also expressed their continuous faith in complying with the norms of US Food and Drugs

Administration (USFDA). They have tried to shatter the outsourcing firms' belief that the plants overseas are less strict adhering to laws and subjected to less FDA inspections and the trust over the quality of the manufactured products can now be more. They are emphasizing on US FDA setting up offices in India which will certainly go a long way in upgrading their facilities and Goods manufacturing practices.

Robust risk management practices: The competent CMO companies have realized that the business risk which is involved in failing to meet timelines and the resultant financial impact it can cause on the outsourcing firm is very high. Many of them as a result insist on a complete planned activity of technology transfer from the pharmaceutical customer, specifying clearly the specifications at the time of contract and rely on complete process validation. They also make sure that the risk of drug development ie the possibility of a drug not moving through the development process to commercial manufacture is assumed by the outsourcing company.

Growth of pharmaceutical outsourcing in India

The Indian Pharmaceutical Industry, as per the current growth rate, is estimated to be US\$ 20 billion industry by 2015.

The Indian Pharma sector is anticipated to be amid the top 10 Pharmaceutical based markets in the globe in the next 10 years.

The sales of the Indian Pharmaceutical Industry are estimated to be of US\$ 43 billion in the next 10 years.

The Pharmaceutical market in India will experience rise in the sales of patent drugs.

With the concentration of Multi-National pharma companies in India at a large scale, it becomes far easier to pull in foreign direct investments. The Indian Pharmaceutical industry is one of the chief FDI (Foreign Direct Investments) encouraging sectors.

Resettlement into a product patent based regime is expected to renovate industry fortunes in the long term. The patent product regime will bring along new innovative drugs. This shall increase the profitability of MNC pharmaceutical companies and force domestic pharmaceutical companies to focus more on Research & Development. Another advantage of this migration could be in consolidation. Very small industries may not be able to deal with the difficult and challenging environment and may give way to giants.

Many drugs went off-patent in the US and in Europe in the year span 2005-2009. This offers a big prospect for the Indian companies to confine this market. By nature, generic drugs are commodities and so Indian pharma producers have the competitive benefit. This is because they are the lowest cost producers of drugs in the globe.

In a long term perspective, opening up of health insurance sector and the estimated growth in per capita income are main growth drivers. This leads to the growth and development of healthcare industry and pharmaceutical industry is an integral part of it.

Indian companies, being the lowest cost producer, can become a worldwide outsourcing center for pharmaceutical products.

Future Perspectives of Indian Pharmaceutical Industry

The future aspect of Indian pharma industry appears to be in positive tone. Consumer spending on healthcare products and services has improved in India due to the rising affordability, shifting disease patterns and modest healthcare transformation. Budget for Healthcare of a normal Indian household is expected to rise from 7% in 2005 to 13% in 2025. The future trends of pharmaceutical industry in India can be listed as under.

Fig - Indian Pharma Industry Trends

By 2015, India is expected to open a US\$ 8 billion market in multi national pharmaceutical companies selling expensive drugs, as predicted by the FICCI.

The Indian pharma market is expected to reach US\$ 20 billion by 2015.

As per the approximates given by of the Ministry of Commerce, Government of India, an amount of US\$ 6. 31 billion will be invested in the pharmaceutical industry of India.

Because of the low cost of Research & Development, Indian pharmaceutical off-shoring industry is foreseen to be a US\$ 2. 5 billion prospect by 2012.

Patented drugs are expected to confine up to a 10% share of the Indian pharmaceutical industry by 2015 having a market size of US \$2 billion.

The branded generics market is expected to continue to lead over the pharmaceutical industry in India. Between 2011 and 2013, 61 drugs worth US \$80 billion will go off-patent at the US Patent and Trademark Office. However, the authority of physicians shall remain high and it will ensure reasonable competition on the basis of scientific detailing and quality of product.

By 2015, 45% of the pharmaceutical market will be explained by the specialty and super-specialty therapies. The rising lifestyle disorders, mostly metabolic disorders like obesity and diabetes. Also, coronary heart disease and hypertension, cardiovascular, neuropsychiatry and oncology drugs are expected to gain considerable impact.

Mass therapies shall remain important in the Indian pharmaceutical industry, even though there will be an inclination towards specialty therapies. The growing income levels shall also increase expenditure on basic healthcare.

The pharmaceuticals industry of India has grown rationally during the past 10 years and has the potential to make over itself over the next decade too. The domestic pharmaceutical market of India will play a vital role in combating the growing diseases. The full potential of pharmaceuticals in India can only be achieved through continuous, progressive and joint efforts by the government and pharmaceutical industry as a whole.

Conclusion

An ageing population and increase in healthcare costs continue to put pressure on all major pharma markets like the United States, Europe and

Japan, thereby encouraging higher penetration of generics through a mix of <https://assignbuster.com/outsourcing-in-the-context-of-the-pharmaceutical-industry/>

legislation and incentives to doctors and pharmacies. For formulations companies, the domestic branded generics business has traditionally been the cash cow, providing steady cash flows that serve as a buffer against the uncertainties of international ventures. The growth prospects continue to remain strong on back of increasing healthcare awareness, rising penetration in semi-urban and rural markets and changing disease profile. Most MNC pharma majors have also stepped up their focus on Indian market exploring opportunities of expanding their product portfolio.