CONTRACT MANUFACTURING & MERCHANT EXPORTERS THE BUILDING BLOCKS OF INDIAN PHARMACEUTICAL EXPORTS.

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ABSTRACT
India has been a major contributor to fulfill the pharmaceutical demand of the world. With world class generics and cutting edge technology for biologics and vaccines Indian manufacturers have been capable enough to meet the rising demands. In the recent era the Indian exports have seen a consistent rise in the contribution by Merchant exporters, who have developed their arena for world class generics by the means of contract manufacturing. It is evident that Indian Pharmaceutical Manufacturers and Merchant exporters have been the corner stone to Pharmaceutical exports from India. The Contract Manufacturing and Loan License manufacturing have also aided this massive growth by providing niche quality pharmaceutical products by complying with GMP requirements for different countries.

KEYWORDS: Exports, Merchant Exporter, CMO, Contract Manufacturing.

Indian Pharmaceutical Industry in the Globe
Medicines have been an integral part of Human beings since the people came in presence. From the most recent century, medicines are formulated and/or blended artificially for the humans & animals. In order to maintain the Efficacy, Safety & rational use of these formulations, regulations have been formed for the control of value, wellbeing and adequacy of the drugs.

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value. Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume.
Consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented. Indian pharmaceutical industry can be broadly divided into two periods, the pre-patent regime (before 2005) and the post-patent regime. While the pre-patent or process patent regime helped the industry develop into a world-class generics industry, the post-patent or product patent regime is aimed at encouraging new drug discoveries over the longterm.

However, the launch of patented products in India has been slow. India gained a foothold in the global arena, with reverse-engineered generic drugs and active pharmaceutical ingredients (API) and now seeks to become a major player in outsourced clinical research and the contract research and manufacturing services (CRAMS) segments. India has the highest number of manufacturing facilities approved by the US FDA. Indian pharmaceutical companies have manufacturing opportunities in two segments - formulations and bulk drugs. India enjoys an important position in the global pharmaceuticals sector. India also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms. Taking into consideration the Global market India has been on a steady rise. This growth is not merely by the Pharma Giants. The semi regulated and Non Regulated markets have been the cornerstone clients for Trade. And Indian Generic Manufacturers have unleashed their potentials to curb the need of these countries.

**Market Share of India in Important Regions 3, 4**

Multinational pharma companies are already taking measures to acquire a larger population by bringing down drug prices and increasing affordability. The Europe is the largest pharmaceutical market of the world. In the year 2013, the Europe imported pharmaceutical products worth US$ 242 billion. During 2013, the Europe accounted for 14.5 per cent share in India’s total exports of drug formulations and biological products. In 2013, among EU countries, UK, with a share of 26 per cent, was the largest market for Indian drug formulations and biological products. Germany is leading for India’s bulk drug exports. USA is the second largest pharmaceutical market in the world. In the year 2013, USA imported pharmaceutical products worth US$ 63 billion. India is the fifth largest supplier of drug formulations and biological products to the USA. The USA made up to a share of 39.1 per cent in India’s total exports of drug formulations and biological products in 2013. USA is
also a significant market for bulk drugs exports from India accounting for 71 per cent of India’s total bulk drug exports to North America. Africa imported pharmaceutical products worth US$ 15.3 billion during 2013. Africa as a region accounted for a share of 21.2 per cent in India’s total exports of pharmaceutical products during 2013. Bulk drug exports from India to Africa amounted to around US$ 371 million in the same year. Asia imported drug formulations and biological products worth US$ 80.1 billion during 2013. During 2013, Asia’s share in India’s total exports of drug formulations and biological products stood at 15.2 per cent. Asia is the second major export destination for India’s bulk drugs exports accounting for 28.9 per cent of total bulk drugs exported from India in 2013-14. Latin America imported pharmaceutical products worth US$ 27.3 billion during 2013. Latin America’s share in India’s total exports of drug formulations and biological stood at 6.8 per cent. Latin America accounts for 8 per cent of total bulk drugs exports from India. Brazil is the second major export destination for bulk drugs exports from India. The country's pharmaceutical exports reported a 9.7 per cent jump in 2015-16, with nearly 33 per cent growth in shipments to the US market, Pharma exports stood at Rs 96,000 crore during 2014-15.

Classification of International Market

Pharmaceuticals are products which are intended for human use and can cause serious conditions if there is compromise in the quality of product. Considering Export of Pharmaceuticals, the international market is classified into 3 segments.
1) Regulated 2) Semi regulated and 3) Non Regulated

REGULATED MARKETS

These are the countries where a strict regulation for manufacture, sale and import of Pharmaceutical drugs and products exists. These countries have a clear mentioned guideline and protocol for drug registrations. And they have guidelines which are exclusive to their region only. Regulated countries include: - North America (US), Europe, South Africa, Australia & Japan.

SEMI REGULATED MARKETS

In these countries also a regulation for manufacture, sale and Import of pharmaceutical products exists. But these regulations are not stringent and exclusive. A Semi regulated market accepts regulations of other countries and other formats over and above their own guidelines.
Semi-Regulated Include
ROW (Rest of the World) consisting Latin America, South America (Brazil), Asean group, CIS countries common wealth of Independent states.

![Figure 1: World Market Segregation](image)

**NON-REGULATED MARKET**
These are the markets where there is no specification or guideline for registration of pharmaceutical products. The term Market authorization or Product registration might exist in these regions but are not mandatory.

Drug regulatory affairs in pharma industries has mandated two types of dossier namely CTD (Common Technical Dossier) and ACTD (Asian Common Technical Dossier). Regulated pharma markets (e.g. USA, Europe, Japan) markets require submission of dossier in CTD format which has to provide clinical trial and bioequivalence studies. As against this, semi-regulated pharma markets (South East Asian and Gulf Countries) require ACTD format which does not require exhaustive details like CTD.

**Introduction to Modes of Pharmaceutical Export**
Exports are of two types.
1. Export by Manufacturer
2. Export by Trader or Merchant Exporter.

**Definition of Manufacturer Exporter 5**
Manufacturer Exporter" means a person who manufactures goods and exports or intends to export such goods. The manufacturer exporter procures and process raw materials at his
factory and exports finished products. Here, the manufacturer exporter procures the export order and exports in their own name. This is the scenario when the manufacturer himself is the exporter. In this case he has the total control of manufacturing quality & Quantity. When Considering Highly Regulated markets such as USA & Europe the exports are done majorly by the big pharma giants such as Zydus, Cadila, Sun Pharma etc. These Exports are done under direct supervision of the company officials and the business starts once the product has attained marketing authorization in the respective country.

Most of the Regulated market has domination by the established and big pharmaceutical companies. The global share of India in Regulated market is around 58 per cent (US$ 289 billion). Europe was the largest importer of pharmaceutical products during the year 2013. Among the pharma emerging markets, India registered a significant growth in exports accounting for 2.4 per cent share in the global pharmaceuticals exports. Over 55 per cent of India's exports are to highly regulated markets.6

Roles & Responsibilities of Manufacturer Exporter
As the Manufacturer himself is the exporter, the burden of work is more. He is the key person responsible for the Quality, efficacy, safety and Shipment of the product consignment.

Roles & Responsibilities of the Manufacturer
- Business development in the international market
- Marketing and Networking with the international buyers
- Identifying the key resource persons in the market
- Development of product as per country specification.
- Preparation of Regulatory Documentation as per the required guidelines (CTD/ACTD)
- Product Permissions and NOC
- Shipment & Logistics Management
- Product registration process and follow ups.
- Agreements & Contracts
- Shipping of samples for Approvals & Testing purpose.
- Financial Negotiations

Definition of Merchant Exporter
Merchant Exporter" means a person engaged in trading activity and exporting or intending to export goods. Merchant exporter procures the material from a manufacturer and exports in his
firm’s name. Here merchant exporter procures the order from international market. Merchant exporter do not have own manufacturing unit or processing factory. Merchant Exporter can export the excisable goods either directly from the premises of the manufacturer, with or without sealing of the export consignments, or through his premises under claim for rebate or under bond.

Roles & Responsibilities of Merchant Exporter
Merchant Exporter has a different set of responsibilities along with some of the manufacturing responsibilities pertaining to the Quality of products. Apart from those following enlisted are the exclusive responsibilities for Merchant Exporter.

- Right-sizing contract manufacturer selection.
- Forecasting with reasonable accuracy.
- Reducing inventory liabilities.
- Eliminating pricing surprises.
- Monitoring quality before and after shipment.
- Managing product changes effectively.
- Defining an exit path with contract manufacturer.
- Assigning the right team.
- Assessing the total cost of offshore manufacturing.

Process Flow for Merchant Exporter

![Process Flow of Trade by Merchant Exporter](image)

Figure 2: Process flow of Trade by merchant Exporter
Pharmaceutical Manufacturing for Export

Manufacturing of the Dosage Form and their Quality is a Key aspect of consideration for Trade across international borders. In order to Export Pharmaceuticals certain prerequisite criteria exists. Such as

- Existing Certification of the Manufacturing Premises
- Licenses Owned by the Manufacturing Premises
- Regulatory Compliances of Countries.

When Exporting Pharmaceuticals a prior confirmation to the buyer party is required regarding the Manufacturing facility, the certifications and Regulatory Agencies approvals which the importing country requires. In certain the officials from Importing country or the importer himself might come for inspection of the site before a particular product is exported.

Manufacturing.7,8

Drug manufacturing is the process of industrial-scale synthesis of pharmaceutical drugs by pharmaceutical companies. The process of drug manufacturing can be broken down into a series of unit operations, such as milling, granulation, coating, tablet pressing, and others.

A manufacturer or a manufacturing company is the body which has the facility to procure, process, analyze, store and Ship the finished formulation to the distribution channel.

Manufacturing can be done by following 3 methods.

1. Self-Manufacturing
2. Loan License Manufacturing
3. Contract Manufacturing

Figure 3: Manufacturing Methods
Self-Manufacturing
The Manufacturing process in which the Manufacturing premise is owned by the Manufacturer or the premises belongs to the company for which the manufacturing is being done. Here the Manufacturer has total independence of which product to manufacture and the amount of Batches to be processed based upon his own requirements.

Loan License Manufacturing
A license issued by a licensing authority to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another license’’ Condition of a loan license under the rules :71 B,74B, 76B.78 B. Loan Licensing is the term used for getting manufactured owns product at other’s premises at loan license contract. Loan Licensing is just like hiring or renting other manufacturing premises for manufacturing owns products. Loan Licensing require two parties: one is marketing company and second one is manufacturing company. In loan licensing marketing company can use its company name at place of manufactured by address but address will be of manufacturer’s company premises. It is similar to third party manufacturing but has few differences. In Loan licensing you can use marketed by address and manufactured by name of your company.

Contract Manufacturing
Contract manufacturing is a strong segment of the domestic market. Indian firms have several advantages over their Western rivals. The expertise gained in manufacturing generics through reverse engineering has helped some companies streamline the process for getting manufacturing up and running. Costs are very competitive; indeed, they are only two-fifths of those involved in setting up and running a new manufacturing facility in the West. They can operate on significantly lower margins, given their low development and labor costs.

Contract manufacturing is one of the easiest and requires very less documentation process. Here a company which is willing to market a particular product will identify a Manufacturer who is manufacturing the product of interest. The marketing company will clarify the product specifications along with the Quality, Quantity and Packaging requirements and the contract manufacturer will provide a Quote for manufacturing of the said Quantity and provide a timeline for shipping the product to the marketing company. When considering International Business all of these manufacturing types are eligible to export with some variation in the trading process in terms of Regulatory documentation and product registrations.
Some Indian pharma companies could probably benefit significantly by moving towards specialty APIs in the future. The Indian contract manufacturing segment was worth around US$605 million in 2008 and is expected to reach around US$916 million in 2010. The US FDA has already approved over 100 manufacturing sites – more than in any country except the US. Among six offices that the US FDA has overseas, two are located in India, in Delhi and Mumbai. All domestic producers have to also obliged with India’s Good Manufacturing Practices, under Schedule M of the Drugs and Cosmetics Act, 1940. Indian manufacturers are currently facing some scrutiny around quality issues. The US FDA undertakes action against companies after conducting a series of inspections and issuing warning letters against these drug makers.

While such sanctions clearly pose significant challenges, some analysts see an opportunity as well. Indian companies are aggressively improving their manufacturing standards in response, and are therefore likely to be better positioned to take advantage of the upsurge in generics production expected as patents expire over the next five years. Some Indian manufacturers are also now incorporating Lean Manufacturing and Six Sigma principles to help them boost operational efficiency and further improve quality, while facilitating compliance.

Benefits of Contract Manufacturing 12

- Cost savings – Companies save on their cost of capital because they do not have to pay for a facility and the equipment needed for production. They can also save on labor costs such as wages, training and benefits. Some companies may look to contract manufacture in low-cost countries, such as India, to benefit from the low cost of labor.

- Mutual benefit to contract site – A contract between the manufacturer and the company it’s producing for may last several years. The manufacturer will know that it will have a steady flow of business until then.

- Advanced skills – Organizations and Traders can exploit abilities that their current office may not have, but rather the agreement producer does. The agreement producer is probably going to have connections framed with crude material providers or strategies for proficiency inside their creation.

- Quality – Contract manufacturers are likely to have their own methods of quality control in place that helps them to detect counterfeit or damaged materials early.
Focus – Companies can focus on their core competencies better if they can hand off base production to an outside company.

Economies of scale – Contract manufacturers have multiple customers that they produce for. Because they are servicing multiple customers, they can offer reduced costs in acquiring raw materials by benefiting from economies of scale.

The more units there are in one shipment, the less expensive the price per unit will be.

Limitations of Contract Manufacturing

- Lack of Control – When a company signs the contract allowing another company to produce their product, they lose a significant amount of control over that product. They can only suggest strategies to the contract manufacturer; they cannot force them to implement them.

- Relationships - It is basic that the organization shapes a decent association with its agreement maker. The organization must remember that the maker has different clients. They can't constrain them to create their item before a competitor's. Most organizations alleviate this hazard by working durably with the producer and granting great execution with extra business.

- Quality concerns – When entering into a contract, companies must make sure that the manufacturer’s standards are congruent with their own. They should evaluate the methods in which they test products to make sure they are of good quality. The company has to rely on the contract manufacturer for having good suppliers that also meet these standards.

- Intellectual property loss – When entering into a contract, a company is divulging their formulas or technologies. This is why it is important that a company not give out any of its core competencies to contract manufacturers. It is very easy for an employee to download such information from a computer and steal it.

- Outsourcing risks – Although outsourcing to low-cost countries has become very popular, it does bring along risks such as language barriers, cultural differences and long lead times. This could make the management of contract manufacturers more difficult, expensive and time-consuming.

- Capacity constraints – If an organization does not make up an extensive bit of the agreement producer's business, they may find that they are de-organized over different
organizations amid high creation periods. In this manner, they may not acquire the item they require when they require it.

- Loss of flexibility and responsiveness – Without direct control over the manufacturing facility, the company will lose some of its ability to respond to disruptions in the supply chain. It may also hurt their ability to respond to demand fluctuations, risking their customer service levels.

**Difference of Manufacturing Exporters & Merchant Exporters.**

- **Table 1 Difference between manufacturing export & merchant Export**

<table>
<thead>
<tr>
<th>Manufacturing Exporter</th>
<th>Merchant Exporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing exporter is the person who export the goods manufacture by him.</td>
<td>Merchant exporter is the person who engaged in the trading activity of export.</td>
</tr>
<tr>
<td>It is possible to manufacturing exporter to deliver the goods as per the given time schedule.</td>
<td>Merchant exporter depends on manufacture for delivery of the goods. It may difficult him to deliver the goods as per time chedule.</td>
</tr>
<tr>
<td>Generally the overseas importers always prefer to buy from manufacture.</td>
<td>Some overseas importers also prefer to buy from merchant exporter if he makes some value addition in the product.</td>
</tr>
<tr>
<td>Manufacturing exporter can prepare the sample as per requirement of the importer.</td>
<td>Merchant exporter is fully depends upon the manufacturer for developing new samples.</td>
</tr>
<tr>
<td>Any modification in the product can be done easily by the manufacturing exporter.</td>
<td>Modification in the product is the big challenge for merchant exporter due to his dependency.</td>
</tr>
<tr>
<td>Manufacturer has relatively less scope for value addition in the product. He has more attention on the manufacturing activities.</td>
<td>There is large scope of value addition in the products. The merchant exporter can attract the importer with value addition services like packing, repacking, labeling, relabeling, kit making, set making, etc.</td>
</tr>
<tr>
<td>Manufacturer exporter generally exports its own goods.</td>
<td>The merchant exporter can offer wide varieties of the products of different manufacturers.</td>
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**Government Policy for Promotion of Pharmaceutical Export.**

The Government has always been a key player when it comes to export of pharmaceuticals. The existence and growth of small and medium enterprises (SMEs) is an important feature of industrial structure in India. Within the SME sector, Indian pharmaceutical industry has emerged as a strong player, although it is now facing increasing national and international
competition. Since the first Industrial Policy of 1948, the pharmaceutical SMEs have been facilitated by various favorable policies like the exemption from the Drug Price Control Order (DPCO), reservation of drugs for exclusive production in small scale sector, process patent regime permitting them to develop their own process of making a drug at a lower cost, preference in procurement for government health services, etc. Pharmaceutical SMEs also benefited from various other provisions for SMEs in general like provision of finance, training, technical, marketing and other support measures, access to raw materials, etc. These strategic interventions have been instrumental in ensuring the rapid growth of SMEs in the pharmaceutical industry and these small firms in turn played their important role in supplying a diversified portfolio of essential lifesaving drugs at affordable prices.

Small and medium pharmaceutical firms have consistently expanded their export activities since 1975–76. The volume of exports have grown from about Rs. 6 crore in 1975–76, to Rs. 82 crore in 1986–87 and to Rs. 234 crore in 2001–02. But the share of SMEs to total pharmaceutical exports has constantly declined from 35 per cent in 1974–75, a lowest ever value of just 2.4 per cent in 2001–02. During 1990s SMEs export expansion has significantly lagged behind as compared to their large counterparts. The lower shares of SMEs in total exports reflect that SMEs failed to realize their export potential unlike large firms and continued to rely on domestic market for growth. The export intensity, measured as the proportion of export to total production, of small scale sector has fallen from 7.3 per cent in 1976–77 to 4.13 per cent in 2001–02. This is a dismal indication for the SME sector because trans nationalization of market is crucial to meet the global competition. The low export performance of Indian Pharmaceutical SMEs is because of a large proportion of them either completely focused on domestic market or just carries out irregular export order received from abroad. An analysis of Prowess database indicates that non-exporting SMEs constituted about 35 per cent of total SMEs and another 29 per cent are irregular exporters. About 22 per cent of the SMEs are regular exporters and another 14 per cent have recently transformed into regular exporter status. Between small and medium firms, small firms seem to be less inclined for exporting with 40 per cent of them are not exporting and another 36 per cent are irregular exporters. The levels of export intensity also suggest that although export intensity of small firms has consistently increased since 2000, it has remained below the 10 per cent mark. Medium firms have performed slightly better than small firms in terms of export intensity and the large firms have witnessed a dramatic growth in their export intensity. Their export intensity jumped three and half times between 1990–91 and 2004–05. The low levels
of export intensity of the sample Indian pharmaceutical SMEs confirmed that their pace of trans nationalization through export activities is very slow as compared to their large counterparts.

Looking at the historical scenarios and the possibility of a global reach of the small and medium enterprises in terms of world class manufacturing potential and a perspective view to International trade, a large number of Schemes have been initiated by the Government of India to promote and encourage the SME’s. Some of the schemes are enlisted below.10

- Challenge Fund for the Indian Missions Abroad-Guidelines
- Export Promotion of Consultancy and Management Services from India
- India's Schedule of Concessions
- Focus Africa-Ongoing Schemes and Activities
- Focus Africa-Marketing Development Assistance (MDA)
- Focus Africa-Market Access Initiative (MAI) Scheme
- Focus CIS-Market Development Assistance (MDA) Scheme
- Focus CIS-Market Access Initiative (MAI) Scheme
- Duty Free Tariff Preference Scheme for Least Developed Countries
- Focus LAC-Market Access Initiative (MAI) Scheme

CONCLUSION

Thus it is pretty much evident that India has already gained a foothold in the global arena of export due to its high proficiency in manufacturing fantastic quality of drug products. Moreover due to the high number of Contract manufacturers available in India there is a wide spread growth of Indian pharmaceutical industry making them a Building block of Indian Pharmaceutical industry.

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