Pharmaceuticals – Industry Structure

The Indian Pharmaceuticals Industry has undergone a massive makeover from a regime of "process patents" in the seventies to a more modern and WTO compatible regime under the TRIPs agreement in 2005. It is among the top science based industries in India with wide ranging capabilities in field of drug manufacture and technology ensuring quality and diversification.

The Indian pharmaceutical industry is fragmented with more than 10,000 manufacturers in the organised and unorganised segments. Pharmaceutical manufacturing units are largely concentrated in states of Maharashtra, Gujarat and Andhra Pradesh. These states account for about 45% of the total number of pharmaceutical manufacturing units in India[6].According to the Confederation of Indian Industries (CII), there are around 8,000 small and medium enterprises (SME) units, accounting for about 70% of the total number of the pharmaceutical units in India. Indian SMEs are also opening up for emerging opportunities in the pharmaceutical industry in the field of CRAMS, clinical research etc. These would drive them to play a definitive role in the transitional global pharmaceutical environment, where a sizeable number of drugs are expected to go off patent in the coming years. The Indian government has been making every attempt to support SMEs through several incentives. One such effort is the development of SME clusters in various parts of the country.

The products manufactured by the Indian pharmaceutical industry can be broadly classified into bulk drugs (active pharmaceutical ingredients - API) and formulations. Of the total number of pharmaceutical manufacturers, about 77% produce formulations, while the remaining 23% manufacture bulk drugs[6]. Bulk drug is an active constituent with medicinal properties, which acts as basic raw material for formulations. Formulations are specific dosage forms of a bulk drug or a combination of bulk drugs. Drugs are sold as syrups, injections, tablets and capsules. Formulations can be categorised under various therapeutic groups:

- Chronic Therapy Segment
    - Cardiovascular
    - Neurological
    - Anti-diabetes
    - Oncology
- Acute Therapy Segment
    - Anti-infective
    - Gastro-intestinal
    - Respiratory
    - Analgesics/Pain management
    - Vitamins/Neutraceuticals

Based on the pharmaceutical customer base, the Indian API manufacturing segment can be divided into two sectors – innovative or branded and generic or unbranded. In 2009, the global generic drug market was estimated to be US$ 84 billion, of which the US accounted for 42%[6].

[6] D&B Analysis

Market Segment

Branded Generics

- Any non patented molecule with a brand name other than the innovator's name is termed as a branded generic

Generic Generics

- Market share is very low- Lack of proper regulations and guidelines and doctor's comfort
- Government of India generic generics drug programme 'Jan Aushadi'

Over-The-Counter Products

- Drugs legally allowed to be sold 'Over The Counter' by pharmacists, i.e. without the prescription of a Registered Medical Practitioner
- All the drugs not included in the list of 'prescription-only drugs' are considered to be OTC drugs

Patented Products

- Market share is very small
- MNcs unwilling to introduce patented products (IPR not providing adequate protection in the past and presence of inexpensive generic produce)

The global API market can broadly be divided into regulated and semi regulated markets. The semi regulated markets like India offer low entry barriers in terms of regulatory requirements and intellectual property rights. The highly regulated markets, like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices. The regulatory process by which API manufacturers generally register their products for commercial sale in the U.S. and other similarly regulated countries is via the filing of a Drug Master File (DMF). DMFs are confidential documents containing information on the manufacturing facility and processes used in the manufacture, characterization, quality control, packaging and storage of an API. The DMF is reviewed for completeness by the FDA, or other similar regulatory agencies in other countries, in conjunction with applications filed by finished dosage formulation manufacturers, requesting approval to use the given API in the production of their drug products. For European markets, companies need to submit a European Drug Master File (EDMF) and, where applicable, obtain a certificate of suitability (CoS) from the European Directorate for the Quality of Medicines.

The growth in the Indian industry is mainly driven by Contract Manufacturing, and latest estimates show that India has submitted the most Drug Master Files (DMF). The merchant API industry in India has traditionally catered to the domestic as well as export markets with their supply largely restricted to manufacturers of generic drugs. This is because sourcing of APIs for patented drugs is maintained in-house by majority of the innovator companies in order to maintain greater flexibility and quality control. As the patented drugs near the end of their exclusivity, innovator companies gradually begin outsourcing of APIs in order to achieve greater cost efficiencies in light of the consequent entry of generics.

In recent years, many of the large domestic pharmaceutical companies such as Lupin Limited (Lupin) and Dr. Reddy's Laboratories (DRL) have increased backward integration into bulk drugs especially for some of their key product segments in order to maintain control over quality and costs. Furthermore, with

many of the domestic pharmaceutical companies present in the highly competitive US generic formulation market, the requirement for in-house API supply is gaining prominence.