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Import and Export of Drugs-Processor Aspects

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Abstract:

Liberalization "measures in the pharmaceutical sector have brought about major changes in the industrial licensing policy; Exports of formulations have grown faster while their imports have not registered any jump, keeping the balance of trade positive. But there has been a decline in domestic production of bulk drugs and a growth in imports because the industry is moving away from intermediates and is focusing on bulk drugs at the high end of the value chain."
Key Words: *"Formulations, Imports, Liberalization, Value chain"*

I. Introduction

The "liberalization measures in the Industrial Licensing Policy Statement of July 1991 were implemented in the pharmaceutical sector in 1994 through the Modification in Drug Policy 1986. Key elements of the liberalization measures were as follows: (a) Abolition of industrial licensing for all bulk drugs and their intermediaries and for all formulations except specifi c cell/ tissue-targeted ones; (b) Elimination of the ratio parameter linking the production of formulations to that of indigenous Production of bulk drugs from the basic stages; (c) Abolition of restrictions on import of drugs and pharmaceuticals and placing Them in the OGL category; (d) Reduction in tariffs for the import of pharmaceuticals; (e) Automatic approval of foreign Direct investment (FDI) up to 100%; and (f) Relaxation of the drug price control mechanism. These measures essentially came about as a result of the endogenous policymaking process, but the most significant policy change in the post-1994 period – the change in the patent regime – came about as an outcome of India's obligations under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement."

II. Description of the study

Pharmaceutical "products are classified into formulations (dosage forms) and bulk drugs (active pharmaceutical ingredients, or APIs). The European Medicines Agency (EMA) defines a formulation as "the physical manifestation that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the dose form can be the state of matter, delivery method, release characteristics and the administration site or route for which the product is formulated. A pharmaceutical dose form is the form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor".4 The US Food and Drug Administration (FDA) defines a bulk drug as "any substance or mixture of substances intended to be used in the Manufacture of a drug (medicinal) and that when used in its production becomes an active ingredient of the drug product. Such substances

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are intended to furnish pharma cological activity or other direct" effect in the diagnosis, cure, "mitigation, Treatment or prevention of disease or to affect the structure and function of the body."5 In India, these terms are defi ned in the Drugs Price Control Order (DPCO). The DPCO defi nes a formulation as "a medicine processed out of, or containing the use of any one or more bulk drug or drugs with or without pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease"6 and a bulk drug as "any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo- isomers and derivatives, conforming to pharmacopoeial or other standards specifi ed in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation."

III. Export and Import Policies:

The pharmaceutical "industry is comprised of companies engaged in researching, developing, manufacturing and distributing drugs for human or veterinary use. New drugs have an enormous positive influence on global health, prosperity and economic productivity by saving lives, increasing life spans, reducing suffering, preventing surgeries and shortening hospital stays. Advances in medicine have eliminated deadly diseases and have brought other life-threatening conditions under control. Drug therapy is now an integral part of nearly every facet of healthcare, and new breakthroughs promise to revolutionize the treatment of non- communicable diseases. The pharmaceutical industry is one of the most heavily regulated sectors in the world. Drugs are evaluated for safety, efficacy, manufacturing quality, misleading product claims and illicit inducements to choose a particular drug. Prices are regulated in many countries through their respective healthcare and insurance systems. While product success in the U.S. market is largely determined by open competition based on quality, safety and price, internationally, companies face a patchwork of uneven regulations, protectionist policies and price controls. These obstacles are increasingly being instituted in both developing and developed countries. Regulatory complexity and efforts to contain accelerating health costs are key challenges in" India.

Understanding Pharmaceutical Industry Products:

For "the sake of simplicity and unless otherwise noted, 'pharmaceuticals' (or 'drugs', 'medicines') in this report refers to innovative and generic products, chemically-derived and biologically-derived products, and prescription-based and over-the-counter products. See below for a breakdown of pharmaceutical product sectors: *Pharmaceuticals (biopharmaceuticals, drugs, medicines)* are defined as any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or any substance (other than food) intended to affect the structure or function of the body.2 Drugs are produced in forms such as pills, tablets, capsules, vials, ointments, powders, solutions and" suspensions.

Innovative (originator) chemically-derived "drugs are developed through extensive R&D and clinical trials in both humans and animals. The innovator relies on patents, regulatory data protection and other forms of intellectual property rights (IPR) to justify the investment required to bring a product to market. The U.S. patent term is 20 years, and drugs are eligible for at least five years of market exclusivity depending on the time between patent validity and U.S. Food and Drug Administration (FDA) approval. The pharmaceutical industry is heavily dependent on the development of new molecules to replace the revenue stream of older drugs that are approaching the expiration of their

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patent terms. Pricing of new drugs is designed to cover past and" future R&D expenditures.

IV. Important to the Economics Development.

The Indian "Pharmaceutical Industry, sized at USD 34 billion (including exports) in 2013-14, has remained on a strong growth trajectory, over the past few years. The industry size is expected to increase to USD 48 billion by 2017-18 at a CAGR of 14%. Indian Pharma industry is ranked 3 globally in terms of volume and 10 in terms of value, supplying 10 % of global production. Of the USD 34 billion market, the domestic formulations market is about USD 10.9 billion (or INR 660.7 billion) and constituted around 1.1% of the global pharmaceutical market in value terms. This is because of lower drug prices and lesser penetration of healthcare, vis-a-vis developed markets, such as US and Europe. India spends only 3.5 - 4% of its total gross domestic product (GDP) on healthcare and hence, ranks amongst the lowest in this respect, globally. In contrast, developed countries spend about 10- 13% of their GDP on healthcare. The Indian Pharmaceutical Industry is highly fragmented with about 15,000 players, mostly in the unorganized sector. Out of these, about 300 - 400 areclassified as belonging to medium & large organized sector. However, organized players dominate the formulations market, in terms of sales. In 2013-14, the top 10 formulations companies accounted for 42.3% of total formulation sales. MNC pharmaceutical companies have steadily gained a foothold in the Indian formulations market. As of March 2014, they enjoyed a market share of 20- 24%. The key drivers are majorly knowledge, skills, low production costs, and quality. Due to this there is demand from both domestic as well as international markets."

The Key Segments in the Indian Pharmaceutical Industry are as follows:

A. API Manufacturers / Traders (Bulk Drugs)
B. Formulation Manufacturers
C. Contract Research and Manufacturing Services Companies
D. Biotechnology Companies

V. Formulation (Exports)

Formulation "exports grew at 17% CAGR to an estimated USD 11.1 billion in 2013-14 from USD 5.2 billion in 2009-10. Growth was enabled by a 22% growth (CAGR) in exports to regulated markets. Exports to semi regulated markets, which have grown at 13% over the same period, also supported growth in overall exports. India's overall exports grew by nearly 11% during 2013-14 to about USD 11.1 billion. The slowdown in exports was mainly on Account of lower growth in the regulated markets compared to semi-regulated markets. Growth in exports to the semi-regulated markets sustained at nearly 12% during the year, while the exports to the regulated markets grew at a modest 10% compared to 18% growth seen last year. The slowdown was mainly on account of import alerts on Indian companies, slowdown of growth in Europe and increased competition during the year. In the overall regulated markets, exports to the US grew at about 11% to USD 3.4 billion, lower than the close to 22% growth seen last year. On the other hand, exports to the European Union grew by just about 6% during the year to ~ USD 1.5 billion in exports. This was

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another consecutive year of slow growth, with 10% growth seen in 2012-13. Region-wise, the European Union market recorded" an almost-flat "growth in the leading markets of the UK, Germany, the Netherlands, Belgium and Spain during the year. Exports to semi-regulated markets grew steadily by an estimated 12% y-o-y in 2013-14 led by exports to the African and Asian continent during the year. Exports to Asia and Africa grew by almost 17% to reach close to USD 4.5 billion in 2013-14 (about 78% of the total semi-regulated market exports), mainly led by growth in exports to the top 30 destinations out of the roughly 124 export destinations in these two continents put together. Exports to these 30 countries grew by nearly 20% and accounted for up to 79% (~ USD 3.5 billion) of the total Indian exports to these two continents in 2013-14."

VI. Conclusions:

India's formulation "exports are expected to grow at a CAGR of 14-16% between 2013-14 and 2018-19. Steady growth is expected in exports to both regulated and semi-regulated markets over the next 5 years. During the period between 2012 and 2017, drugs generating annual sales of about USD 130 billion are likely to lose patent protection and will be exposed to generic competition. We therefore expect sales of generics to grow at a CAGR of 7-9% over the next 5 years, outperforming the overall global pharmaceutical market, whose growth is Expected to be limited to 3-5%. Indian players are currently well placed to widen their presence in the generics market. This is reflected in the rising number of Indian players seeking Abbreviated New Drug Application (ANDA) approvals and tentative approvals from the US FDA (Food and Drug Administration). Additionally, midsized and small-sized Indian formulation manufacturers, who traditionally resorted to contract manufacturing, are also looking to tap the generic opportunity in regulated markets."

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