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An Analysis of Indian Pharma Trade and Future Challenges

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Abstract

It was argued in the context economic reforms in pharmaceuticals sector, particularly in the context of changing patent regime, that growth in exports would be restricted, imports would get a flip and balance of trade would be adversely affected. The work looks into the recent experience in exports and imports of drugs and pharmaceutical products. It is found that there is a tremendous growth in the exports. The focus of exports has shifted from intermediates and bulk drugs to formulations. The expiry of patents on drugs worth billions of dollars in the near future would provide a big opportunity for Indian generic producers. The removal of ratio parameter linking the production of intermediates and bulk drugs to the production of formulations has eliminated compulsions on the indigenous production of intermediates and bulk drugs.

Introduction

Over the past 50 years, Indian pharmaceutical industry has undergone a massive makeover – from a modest beginning of "process patents regime" in the seventies to a modern and WTO-compatible regime under the TRIPs Agreement in 2005. In last two decades, India has witnessed significant trade and industrial policy liberalization, which have led to structural changes in the domestic industries. This was accompanied by rapid growth in the pharmaceutical sector in India which was led by the migration of economic and research activities from Europe to India in particular and some other fast-growing markets [1-5].

According to the Organization of Pharmaceutical Producers of India (OPPI), the Indian pharmaceutical industry is highly fragmented and is estimated to have over 10,000 manufacturing units. The organized units account for just 5 percent with around 300 players, while 95 percent of the units are in unorganized sector. A large number of players of the latter are small and medium enterprises and this segment contributed 35 percent of the industry's turnover.

Objectives

This paper would attempt it under the following specific objectives:

1. To identify HS (Harmonized system) tariff codes which constitute the pharmaceutical sector in India and bifurcation of the sector into sub-sectors- bulk drugs and intermediaries and formulations- Based on Indian Tariff Classification(8 digit HS)
2. to analysis trends in pharmaceutical sector exports and imports of India

Methodology

The first task in the analysis is to identify the pharmaceutical products. The currently available data sources seem not to follow a uniform view of what are pharmaceutical products [6].

Scope of the study

Defining the term drugs or pharmaceuticals which would include formulations (medicines ready for the internal or external use), active pharmaceutical ingredients (APIs/Bulk Drugs), intermediates and excipients which go into the production of formulations; medicated bandages and dressings; medical devices such as syringes; blood products; glands, organs and extracts of them. APIs can be of two types: APIs consisting of single chemical substances which fall under the category of fine chemicals and APIs consisting of two or more chemical substances and Analysis of trends in exports and imports of Indian pharma sector.

Literature Review

In order to identify the gap in the research we have undertaken an extensive literature survey of the pharmaceutical sector in general. Therefore, this section interplays between with trade and investment. The issues are in the nature of competitiveness; research and development (R&D) intensity; TRIPs issues; productivity and competitiveness; import intensity; and lastly the structural changes of these two economies. It is observed that the pharmaceutical industry has been witnessing an accelerated pace of change this is especially true for the last decade.

There have been a number studies on liberalization of the economy, TRIPs compatibility, R&D intensity and performance in terms of competitiveness. The external sector liberalization which was initiated in 1991 is a major issue across many of the studies reviewed under this section. The issue of product patent regime introduced in 2005 and its implication for the R&D and innovation across this is another issue reviewed. The structure of the Indian pharmaceutical has undergone significant changes over time. Pharmaceutical products consist of two main components - (i) the active pharmaceutical ingredient (API) or bulk drug; and (ii) the formulation segment (i.e., a suitable final dosage form). Up to the year 2001, the bulk drug production increased by nearly 20 per cent annually, whereas the value of formulations increased at an average rate of 15 percent per year (Joshi, 2003) [7].

(Table 1). In exports, the top five countries account for 43 per cent share. USA is the largest destination accounting for one-fourth of total formulation exports, worth $305.16 million in 2012-13. Growth in exports to USA has been tremendous as it was only $2.9

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Value in USD million						
India's exports Region Wise						
Region	**2010-11**	**2011-12**	**2012-13**	**YOY%**	**CAGR%**	**%contbn**
Africa	1823.96	2258.38	2562.85	13.48	19%	17.46
Asian	695.16	848.89	942.84	11.07	16%	6.42
Asia (Excluding Middle East)	462.38	558.1	557.34	-0.14	10%	3.80
CIS	717.28	692.1	891.4	28.80	11%	6.07
EU	2002.45	2603.56	2655.05	1.98	15%	18.09
LAC	698.03	832.33	922.23	10.80	15%	6.28
Middle East	826.1	931.18	1072.76	15.20	14%	7.31
North America	2650.09	3526.13	4014.21	13.84	23%	27.34
Oceania	155.76	222.71	240.54	8.01	24%	1.64
Other America	143.18	98.99	86.36	-12.76	-22%	0.59
Other European Countries	128.85	159.11	155.26	-2.42	10%	1.06
Others	8.96	44.43	50.28	13.17	137%	0.34
South Asia	409.23	487.52	525.25	7.74	13%	3.58
Total Exports	10725.18	13267.85	14680.55	10.65	17%	100.00
Source: CMIE/DGCIS						

Table 1: Up to the year 2001, the bulk drug production increased by nearly 20 per cent annually, whereas the value of formulations increased at an average rate of 15 percent per year (Joshi, 2003).

million (1.8 per cent of total formulation exports) in 1990-91. The other four destinations are Russia, UK, Germany, South Africa, Nigeria and Ukraine. Antibiotics are the mostly exported category to these countries, except UK where export is mostly accounted by non-steroidal anti-inflammatory drugs (NSAIDS). The share of export to UK has also increased slightly during this period; from 4 per cent to 5 per cent. Share of Nigeria declined from 6 per cent in 1990-91 to 4 per cent in 20012-13.

The 'low volume high value' market of USA remains the main attraction for Indian companies. India has approximately 320 FDA approved plants; the largest number outside the USA and approximately twice the amount that China presently has. Recent market estimates indicate that there would be further acceleration of Indian exports to USA. It is estimated that about 250 Indian generic products have been launched in the US market in 2008, as opposed to 93 in 2003. It is estimated that in USA, $40 billion worth of drugs are expected to go off patent in the coming years. Up until the end of the 1980s, Indian firms focused extensively on the other world markets, especially USSR where there was little patent protection coupled with lax registration requirements [8].

Conclusion

Indian pharmaceutical industry has undergone major structural changes in its trade orientation during the post 1991 period. The focus now is more on the value added segments - formulations, as the share of this category has increased from about one-third in early 1990s to two-third in 2012-13. The largest of Indian generic firms have entered into highly regulated and at the same time highly profitable markets of Western Europe and Northern America while keeping their 'high volume low value' markets safe, the smaller firms have increasingly entered into the less regulated and 'high volume low value' markets of Asia and Africa. As a result, the share of export earnings of the largest firms have grown from about one-fifth in early nineties to about two-third by 2012-13 and that of the industry as a whole has increased from less than 10 per cent in 1990-91 to 45 per cent 2012-13. The fact that the APIs used for ANDA filings by Indian firms in the US constitutes only about half of their DMF filings, speaks for the enormous export potential existing in US and other regulated markets.

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