

Pharmaceutical Export Growth Pre and Post WTO: A Detailed Study

Abstract

Pharmaceuticals are directly linked with the economic and social development in India. For the foregoing facts, Pharmaceuticals being in WTO has become of much concern to all developing countries even to the upper-middle income countries like China and South Korea where contribution of Pharmaceuticals to their GDP is less than 10 per cent. For the upper middle countries, healthcare, environmental issues and rural development are looked at as matters of urgent concern to their security, sovereignty and welfare of their citizens.

Keywords: WTO, Pharmaceutical Export, Compound Annual Growth Rate.

Introduction

Pharmaceuticals has been brought into the line of WTO because it has long been considered as one of the most important, and it is argued that pharmaceutical production and trade are highly distorted by large-scale patents related issue. Also, it is argued that protectionist measures like patents, quality adherence according to GMP standards, have depressed and destabilized world prices for pharmaceuticals especially by China. The distorted world prices, in turn, prevented producers around the world from realizing the benefits of their true competitiveness. The limitation and possibly the elimination of those distortions were perceived to be through the inclusion of pharmaceuticals into the framework of TRIPS in 1995. Thus the principles and rules of WTO are expected to market distortions and allow producers to compete tough in the world market. But the very short we will experience pharmaceuticals under TRIPS and WTO the following.

1. The overwhelming majority of Pharmaceuticals producers are small-scale producers who are supposed to compete with large-scale producers and multinational companies of the developed world, which control the supply of technology and finance necessary for pharmaceutical production and development.
2. The pharmaceutical productivity in most developing countries is low and attributed to two major limitations. The relatively low level of manufacturing technology and the limited technical know-how among small producers represent the most significant technical limitation. Similarly, the persistent decline production capacity, the increasing pressure to adhere on GMP standards and environmental changes has been the most significant institutional limitations.
3. Small producers in India would not be able to compete with the heavily subsidized surplus pharmaceutical production from China their survival is threatened. In addition, their access to highly regulated market like USA, EUROPE, AUSTRALIA, SOUTH AFRICA, JAPAN, and Etc. markets of high purchasing power is restricted by stringent quality and drug registration measures.
4. The undertaking of economic reforms has been the prerequisite for entering the world market. As result, the role of government with regard to their support to the small producers in terms of subsidies and price support is diminishing. Certain issues and developments arising out of WTO regime, pose a major challenge to our manufacturers. Due to TRIPs with GMP compliances schedule M compliance was made mandatory. As GMP is considered as the bench mark of product quality, it is important not only for maintaining market share in domestic market but also for accessing extremely competitive export markets. As financial constraints hindering the small firms for adopting GMP criteria as a result 9% of SSIs were unable to comply with it and 8% were closed. (1 year, 2008). It adversely affects the production of bulk drugs and level of employment.



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The foregoing WTO shortcomings and the other not mentioned could have their implications in the pursuance of pharmaceutical development in most developing countries to realize the overriding objective such as quality and economical healthcare, production surplus to enhance healthcare development, increased income and employment to alleviate poverty and the conservation of the environment for sustainable production and social welfare.

Despite these shortcomings, there is strong argument that globalization or WTO will create, through export-led expansion, the potential for repaid overall output growth thereby increasing national wealth and contribution to improved living standards. The experience of last 10 years Indian Pharmaceutical exports cited as an example as it has managed to grow at 19% CAGR per cent and more because they have adopted export-led growth strategies.

In addition, it is argued that globalizations and access to wide variety of consumption goods, new technology and knowledge and finance. It is also an access to new ideas and international best practices in different fields and realms.

This proposition or argument could be the key to the core to this study investigate the likely implications of WTO on pharmaceutical development in India. The study will limit itself to the likely implications on pharmaceutical productivity and exports, as effective stimuli for Pharmaceutical development.

Trade in wider sense refers to exchanges between one country and other countries of commodities, services, commercial ideas, knowledge of the technical sphere, ordinary labour, skilled & technical labour, stocks and shares, lairs over real estates, financial and real capital assets and claims over them, etc. It encompasses a major chunk of international contracts and relations. It reflects for a single country, opportunities for learning from other countries, especially in areas in which that country has a deficiency, actual or potential.

There is dismay among many even today as to how India can export pharmaceutical production, particularly food items, when a vast majority of the population is struggling to meet their basic consumption needs. A kind of a wild reaction after a lot of debate and argument, those people would come round and say yes, you can export, provided there are surpluses and the domestic consumption needs are fully meet. With the growth in economy, especially the growth of more import intensive sectors such as 'industry, the need for foreign exchange earnings from pharmaceutical exports becomes increasingly more important form the national point of view. From pharmaceutical producer's point of view, expanding exports opportunities mean bigger markets and higher value for their output.

The pharmaceutical exports have mainly been improved under the new economic policy introduced in India in the year 1991 and the WTO has opened up new opportunities and challenges for the Indian economy in this regard.

Need of Study

India is the 4th largest producer of pharmaceutical in the world. It is consider now the world medicine capital. It has tremendous growth in last 2 decades in healthcare and pharmaceutical growth in world. There is no country in the world where Indian medicine is not available. As of now while writing there will be one Indian medicine is under consumed by out of 6 medicines.

Indian Pharmaceutical Contribution to GDP is 2% and 12 % contribution in Indian manufacturing sector. This is facts that are exporters of pharmaceutical products as major source of foreign currency income. Moreover, more than 80 percent of population in third world countries reside in rural areas and relatively poor and hoping for economical and quality products for supporting and curing them. . Pharmaceutical production therefore is directly linked with the economic and health development in rural areas. For the foregoing cited facts medicines being in WTO are of much concern to most of the developing countries become of its impact in most aspects such as health, besides economic and social development in general. Pharmaceutical industry has long being regarded a one of the most important areas blocking the many to the strengthening of a liberal trade system.

Domestic and export subsidies, coupled with protective measures such as regulations, variable tariff levels and minimum export prices depressed and destabilized world prices. Therefore, the object of pharmaceutical in the multilateral trading system is to limit those distortions and hopefully to completely eliminate them.

Objective of the Study

To examine the Pharmaceutical growth of export after implementation of WTO policies

Review of Literature

Innovations in Indian Drug and Pharmaceuticals Industry: Have they impacted exports? Journal of intellectual property rights, Vol. 19, July 2017, pp 243-252 - by Shilpi Tyagi, Varun Mahajan and D K Nauriyal; The study has found that the growth rate of India's pharmaceutical exports has outweighed the corresponding growth rate of all other merchandise products, while import requirement has registered a decline over the period of time. The analysis suggests that despite being one of the major producers of generic drugs, except for one, none of the Indian pharmaceutical firms feature in the top ten generic producers in the world. Further, the paper highlights that the rise in R&D expenditure, resulting in the patent filings, has helped the Indian firms to expand by introducing incremental research. The Indian firms were also found to be recording a relatively steady growth in patent filings except for Ranbaxy which has experienced a sharp decline in patent output after 2006 because of increasing cases of litigation for the infringement of patent rights of other pharma majors. The impact of R&D and patents on exports was also examined and it was found that lagged R&D expenditure and lagged total patents granted significantly and positively impacted the exports across drug classes and treatment categories.

Since increased R&D was found to have a positive impact on the export performance and global expansion of the firms, it should logically encourage pharma companies to increase the flow of resources towards R&D as a part of their strategy for survival and growth in a dynamic world market. However, given the dense concentration of top firms in R&D, it appears that this route to further expansion is not a very preferred one, in sharp contrast to clear priorities for commercial harnessing of the generic segment where R&D investment is minimal. The most plausible explanation for it lies in the requirement of huge and consistent R&D expenditure on Drug discovery, with high risks and uncertainty, along with regulatory, technical and economical issues involved, which goes beyond the intents and means of almost all the Indian pharma companies including the top companies. One of the conceivable ways to do it to encourage public-private partnership directed to basic research which could identify the basic molecule, to be commercially harnessed by the interested private sector partner(s).

Indian Pharmaceutical Industry: An Overview-Gulshan Akhtar Volume 13, Issue 3 (Jul.Aug. 2013), PP 51-66 e-ISSN: 2279-0837, p-ISSN: 2279- 0845; Indian Pharmaceutical industry is one of the world's largest and most developed, ranking fourth in terms of volume and thirteenth in terms of value. The country accounts for an estimated 10% of global production and 2% of world markets in pharmaceuticals. It has over the years made significant progress in infrastructure development, technical capability and hence produced a wide range of pharmaceutical products. Journal of Intellectual Property Rights Vol 17, January 2012, pp 82-86 Progress of the Indian pharmaceutical industry: A shifting perspective Kamble Pravin, Ghorpade Swapnil, Kshirsagar Rajesh and Kuchekar Bhanudas, Journal of Intellectual Property Law & Practice, 7 (1) (2012) 48-51; The Indian pharmaceutical industry is one of the fastest growing industries in the world competing with the global pharmaceutical industries. It is in the front rank of India's science-based industries with a wide range of capabilities in the complex field of drug manufacture and technology. In the post independence era (i.e. post 1947) the Indian pharmaceutical industry was completely dominated by multinational companies (MNCs) and drug price in India was among the highest in the world. In 1970, the Indian parliament passed the Indian Patents Act 1970 with provisions to allow only process patents for pharmaceutical molecules and new chemical entities (NCEs). The Indian Patents Act 1970 was the main reason for the fast and continuous growth of the Indian pharmaceutical industry. The Indian pharmaceutical industry until 2005, engaged in generic product development hence there was no significant activity in patenting in India. In 2005, the Indian Patents Act was amended to include a 'product patent' regime to make Indian patent law compliant with TRIPS. This shifted the Indian pharmaceutical industry's focus from generic products to research based 'NCEs' and 'novel drug delivery products'. The post TRIPS era saw vigorous activity in patenting in India. The present

review aims to study the growth and various transition phases in the Indian pharmaceutical industry in light of pharmaceutical patenting by members of the Indian pharmaceutical industry in India

Performance of the Indian Pharmaceutical Industry in Post TRIPS Period: A Firm Level Analysis International Review of Business Research Papers Vol. 5 No. 6 November 2009, Pp.148-160 ,Ravi Kiran and Sunita Mishra; The Indian Pharmaceutical Industry has shown the strongest performance in post- TRIPS period. Not only did the industry improve its production performance seen in the previous decades, the industry turned into a net foreign exchange earner during the decade in question. Under this backdrop, the present paper examines the impact of new Patent Act on Pharmaceutical Industry of India especially on R&D. This paper seeks to evaluate the performance of a few leading Pharmaceutical Firms especially in terms of their ANDA filings and approvals as well as DMF filings with USFDA in post-TRIPS period.

The study by Dhar & Gopakumar (2006) provides analysis to indicate the performance of the firms in the Indian pharmaceutical industry following the changes in the patent regime necessitated by the Agreement on TRIPS. The study shows that the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's has shown increase in Post-TRIPS period. As a result, R&D intensities of the firms have improved significantly. Sunil (2006) in his working paper undertakes a detailed mapping out of the sectoral system of innovation of India's pharmaceutical industry. The study shows that the TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both research budget and patenting. In his working paper, Chaudhuri (2007) explores that R&D expenditure has dramatically increased for a segment of the Indian pharmaceutical industry after TRIPS came into effect. It is not only that the amount of R&D expenditure has increased, but there has been a drastic shift in the structure of R&D activities of the Indian companies. Earlier they were primarily engaged with the development of new processes for manufacturing drugs, now they are also involved in R&D for new chemical entities (NCE).

Research and Development, Exports and Patenting in the Indian Pharmaceutical Industry: a Post TRIPS Analysis- Eurasian Journal of Business and Economics 2011, 4 (7), 53-67. Ravi Kiran and Sunita Mishra; A few empirical studies showing performance of pharmaceutical industry in post TRIPS period are mentioned here. In the past three and a half decades most of the large private Indian pharmaceutical firms focused on reverse engineering R&D, and activity was limited to applying known knowledge, or to making small adjustments in the contents (Wendt, 2000). This resulted in introducing new drugs early in the markets. (Lanjouw, 1996) opines that production technologies were well mastered and the lag period between the launch of a new product in its first market and India was thus reduced, in some cases as low as two years. The

earlier literature points out that the firms in developing countries compete on the basis of production capabilities, largely acquired from elsewhere and reinforced by basic to intermediate technological capabilities related to a simple knowledge base (Lall, 1987; Bell and Pavitt, 1995). With the signing of WTO, specifically TRIPS in 1994, the Indian industry and market structure is poised to change. Methodology plays an important role in research technique. It is the nucleolus of any investigations, which cover collection of data, analytical tools applied and finally presentation and interpretation of data. In order to analyses the impact of World Trade Organization on Pharmaceutical Development in India. Here we have taken the data of pharmaceutical production and exports from India.

Methodology

Data Sources

Keeping in view the objective of the present study, the secondary data have been taken from the reputed sources. Notable among these are:-

1. Handbook on Indian Economy, Reserve bank of India 2015
2. Pharmexil - Pharma Export Promotion Council
3. Director General of Foreign Trade.
4. Ac Nelson - Org Marg Surveys

5. IMS data
6. Data from EXIMCO
7. National Sample Survey
8. Monthly review of Indian Foreign trade
9. Pharma Biz Weekly & Monthly Journal- Saffron Media
10. The data published in reputed Journals , book and English news papers have also been used

Statistical Techniques

Here we calculate the compound annual growth rate of export by the following formula to draw a conclusion whether this growth rate is significant or not.

$$Y = AB^t$$

Where,

Y = Growth rate of the given variable. I.e. production and exports

t = Time period

A & B = Coefficient

Then, compound annual growth rate is given below:

$$CAGR = (b-1) \times 100$$

Where,

A= Intercept

b= Antilog of log 'B'

Data Analysis

Indian Pharmaceutical Exports-From 1974 till 2011

A Comparative analysis pre and post WTO era

Total Pharmaceutical Export from India			
Year	Total Exports	Year	Total Exports
	\$ Million		\$ Million
1973-74	47.9	1995-96	698.7
1974-75	54.3	1996-97	1152.1
1975-76	48.7	1997-98	1458.1
1976-77	60.3	1998-99	1462.3
1977-78	70.8	1999-00	1668.5
1978-79	83.9	2000-01	1910.9
1979-80	87.9	2001-02	2196.6
1980-81	96.3	2002-03	2464.1
1981-82	106.4	2003-04	3177.3
1982-83	114.9	2004-05	3312
1983-84	156.5	2005-06	4863.6
1984-85	182.9	2006-07	5751.2
1985-86	158.9	2007-08	7411.5
1986-87	174.5	2008-09	8801.2
1987-88	223.4	2009-10	8953.6
1988-89	322.9	2010-11	10435.8
1989-90	514.6	CAGR_before1995	17.51
1990-91	536.6	CAGR_After1995	18.67
1991-92	613.7	CAGR_Total	16.36
1992-93	486.2		
1993-94	567.9		
1994-95	694		

Source - Compiled from DGCIS - & Pharmexil Data and CAGR calculated

Conclusion

Indian Pharmaceutical has been facing serious challenges and huge opportunities after implementation of the WTO policies. From the present result we can say that the overall export of the pharmaceutical products is showing positive compound annual growth rate and it is significant.

Here we can say that compound annual growth rate of pharmaceutical exports is positive and

highly noteworthy. Therefore, we can say that the WTO policies are positively affecting the pharmaceutical sector. Production related data shows that we are diversifying from traditional small scale pharmaceutical production. From the data related to export shows positive compound annual growth rate post WTO and it is also significant. From the table we also conclude that we are still exporting at minimal level, which have huge demand of Indian medicines in

Remarking An Analisation

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the international basket. Alternatively by exporting other allied like herbals, photochemical and devices products that give higher return should be promoted. Encouragement to new high end product should be made; new export markets should be explored for surplus pharmaceutical production.

India had benefited from joining the World Trade Organization (WTO), India's exports have almost 150 Times more in less than a decade with exports going up from US \$ 694 Million in 1994-95, when India joined the WTO, to US \$ 10,435.8 in 2010-11.

Exports of pharmaceutical products got a big boost with economic reforms in the initial years. During the pre WTO period pharmaceutical export did not show much increase. The WTO has opened up new path of growth. India has a competitive advantage in manufacturing of pharmaceutical exports because of near self-sufficiency of inputs, relatively low costs and availability of technical expertise.. These factors have enabled export of Indian medicines over the years.

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