# A thorough analysis of TRIPS and its effects on exports and imports in the global pharmaceutical industry and in India.

**Ms. Shuchi Kukreja[1], Ms. Priyanka Gupta[2] ***

[1]Student, Department of Regulatory Affairs, Chandigarh College of Pharmacy, Landran Mohali,Punjab,India.
[2]Assistant Professor, Department of Regulatory Affairs, Chandigarh College of Pharmacy, Landran Mohali, ,Punjab, India.

**Abstract: The Pharmaceutical Industry witnessed a change after the formation of World Trade Organization (WTO) when India, being a signatory member of WTO, adopted Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.  Indian pharmaceutical industry, being a highly fragmented one and dominated mostly by many smaller enterprises, was also apprehensive when TRIPS was included in WTO. This article examines the Impact of TRIPS on: Research and Development, Exports and Patenting activity of The Pharmaceutical Industry of India, an increase in R & D Expenses, and R& D Intensity of leading pharmaceutical companies in the post-TRIPs period. This also examines the issue of patents and its impacts on the pharmaceutical industry in different countries.**

*Keywords: WTO, TRIPS, Pharmaceutical Industry*

## I. Introduction:

The modern form of pharmaceutical industry in India was laid down in 1901 when Prof.  P.  C.  Ray has established 'Bengal Chemicals and pharmaceutical Works' in Calcutta to produce allopathic form of medicine.  Yet the growth of this industry was very slow till the year 1970.   Prior to 1970, over 90 per cent of the market of Indian Drugs & Pharmaceutical Industry was dominated by Multinational Companies (MNCs).  This made the country increasingly dependent on import of bulk drugs and formulations.

With a view to develop a self-reliance indigenous industry, the Government of India took some important steps in 1970 to break the multinational dominance. The most Important step was the introduction of Indian Patent Act 1970 (IPA 1970). The provision of this patent was totally opposite to the international norms. This Act recognized the 'process'  to  manufacture  a  product not  the  end  product.  Indian pharmaceutical companies took advantage of the patent act and did well in producing molecules, which were under patent protection elsewhere, at a cost that was lower than the original research cost. By taking this cost advantage, Indian companies fixed their drugs prices lower than the drug prices fixed by the MNCs.

Additionally, The Drug Price Control Order was publicized on 16th May 1970 by the govt of India. The main objectives were to facilitate the growth, rationalize the price and to provide sufficient incentive to the industry. As a result, the Indian companies fractionalize their cost in the research and development as compared to the   MNC'S. Hence the reduction in the launch of new products facilitated further scope for Indian manufacturers. MNC's imported bulk drugs from their parent companies and used to manufacture only formulations in India. The Govt of India increased the tariff for importing bulk drugs which resulted in the decrease of market share of MNC and increase of the share od Indian companies.   As Per the below chart of year 1990 to 2000 an increase in number of manufacturing units and production volume, exports from the industry, particularly in 1990s, has increased manifold. The exports of this industry grew by 35 per cent annually over the past decade to reach Rs.  20.10 billion
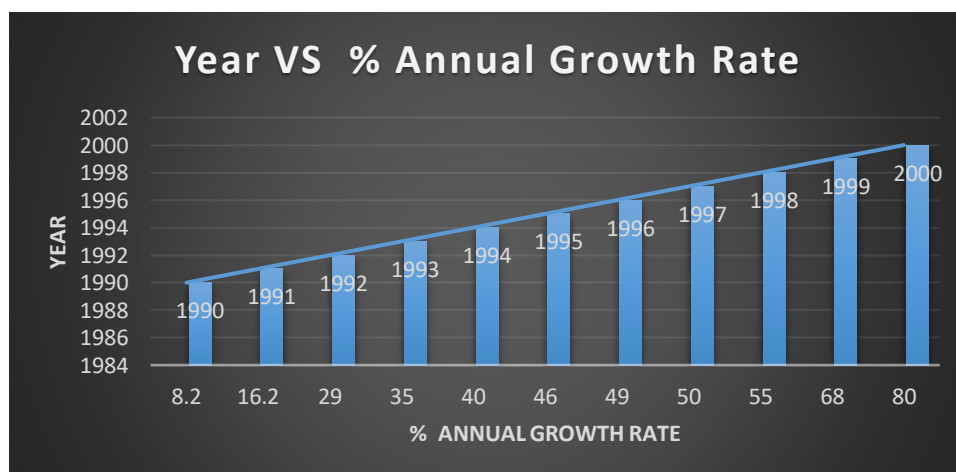


Fig 1 : Year/Annual Growth Rate

Implementation of TRIPS and its importance:

TRIPS: The agreement on trade related aspects of intellectual property rights is an international agreement administered by WTO. It was negotiated at the end of Uruguay round of General agreement on Tariff and Trade 1994 (GATT). It specifies enforcement procedures, remedies, and dispute resolution procedures. It also introduced IP laws into international trading system.

Trips laid down rules and norms for seven types of IPR and related rights.

- Patent
- Trademark
- Copyright
- Industrial Designs
- Geographical Indications
- Layout Design
- Contractual licenses

Intellectual property rights are statutory rights which allow the creator to exclude others from exploiting the same for a given period. It allows the creator to have benefits from their work when these are exploited.

Patent is a grant of exclusive rights to the owner to exclude others from making, using, offering for sale, or importing. It is granted by: Indian patent office or Ministry of commerce or Govt of India.

There are some Patenting Criteria which are as below:

-Novelty: It means invention which is not published anywhere before.

-Inventive Step: For technical advancement and economic significance.

-Industrial Application: Capable of being used

-Non-Patentable: Any artistic creation, Mathematic method, business scheme or anything against law The Traditional form of Indian pharmaceutical industry was comprised of only Ayurvedic, Shidha and Unani system.

Steps and patent Procedure to file a Patent:

-Filing Application: First provisional then complete

-Publication Of Application: In official gazette in digital format within 18 months

-Request For Examination: Whether the patent meets the criteria of patentability.

-Examination -Issue Offer: Examiner makes report and list objections if any.

-Grant Of Patent: If no objection patent is approved by the controller within one month.

Copyright means exclusive rights to do or authorize others to do certain acts in relation to literary, dramatic, music and artistic works. Also, Cinema, Television, and sound recordings. Information provided by the drug companies may be protected by copyright law.

Trademark: Any design that can distinguish the goods of one trade from another. It includes words, logos, pictures, or combination of these. It is used as a marketing tool for product positioning. Consumers rely on labels and certain expectation is related to that. Its term is 10 years. To register trademark, it must be distinctive and not identical to earlier mark. Tradenames can be registered in pharma as trademark.

**Objective of the Study is to see:**

1. The export performance of pharmaceutical industry in the post trips period.
2. Effect on the compositions and formulations in the post trips period.
3. Countries which became the lead exporters in the post trips period.
4. Effect on the performance of pharmaceutical companies at product level and firm level.
5. Effect on the domestic firms in the post trips period.
6. Effect on the multinational companies, their growth and expansion.
7. Whether, under TRIPs agreement, foreign ownership has any effect on the export performance of Indian drugs and pharmaceutical industry

**Analysis of study:**

To analyze the firm level export performance of Indian pharmaceutical industry, data on various fields such as exports, sales, imports, ownership groups, date of incorporation etc. were obtained covering the period 1995-2010. Initially data were obtained for a sample of 133 pharmaceutical firms. However, out of these 133 firms, there were some firms for which continuous data on sales-exports were not available for the entire period. There were only 44 firms for which the continuous data were available for the period under study. Therefore, the present study is based on a sample of these 44 pharmaceutical firms.

TABLE No.1: Growth of Production Units of Indian Pharmaceutical Industry

| Year | No. of Unit | Year | No. of Unit |
|------|-------------|------|-------------|
| 1953 | 1752 | 1984 | 9000 |

| 1970 | 2257 | 1985 | 9234 |
|------|------|------|------|
| 1978 | 5201 | 1986 | 9540 |
| 1980 | 5126 | 1990 | 16000 |
| 1981 | 6417 | 2001 | 20053 |
| 1983 | 6631 |      |      |

Apart from the growth in production and production unit, the industry exhibits phenomenal growth in many other aspects during the post – TRIPs period. These are discussed below.

Aggregate Level Analysis

Aggregate level analysis was carried out by, firstly, examining the export performance of Indian pharmaceutical in totality i.e. in first step, industry level export performance was analyzed. This step was adopted to examine the overall export performance of the industry. Thereafter, with a view to examine the effect on the composition of export of the industry, the product level export performance was examined taking bulk drugs and formulations separately.

To examine the effect on the direction of export, the industry as well as product level export performance were also analyzed by examining the India's export of pharmaceutical industry to the different countries (regions) of the World. The entire analysis was carried out on the basis of univariate technique and for these three indices were computed. These indices were– 'absolute export', 'normalized trade balance' and 'share of export in total export'. The computation process of these indices is as below.

Absolute Export (AEXP)

This index was obtained by simply observing the export at different point of time (or period) of covered period.

$AEXP_t = EXP_t$

$AEXP_T = \sum EXP_t$

where $AEXP_t$ indicate the absolute export of the industry at time t, $AEXP_T$ indicate the absolute export of the industry for period T. $EXP_t$ indicate export at specific point of time t e.g. t = 1995, 1996, 1997……,

2011. It has computed to discuss the trend during the entire period of the study. Accordingly-

$AEXP_{1995} = EXP_{1995}$, $AEXP_{1996} = EXP_{1996}$, ----------- $AEXP_{2011} = EXP_{2011}$

$AEXP_{1995-1999} = \sum EXP_t$ , t = 1995, 1996, 1997, 1998 and 1999.

$AEXP_{2000-2004} = \sum EXP_t$ , t = 2000, 2001, 2002, 2003 and 2004.

$AEXP_{2005-2011} = \sum EXP_t$ , t = 2005, 2006, 2007, 2008, 2009, 2010, 2011.

Normalized Trade Balance (NTB)

Normalized Trade Balance (NTB-index) measures the export performance in relation with import. The formula for computing NTB index is: -

$NTB_t = \{(X_t - M_t)/(X_t + M_t)\} * 100$

where $NTB_t$ = Normalized Trade Balance at time t, $X_t$ = value of export at time t

and $M_t$ = value of import at time t; t = 1995, 1996,1997,……,2011.

It was also computed to discuss the trend during the entire period of the study.

Value of this index lies between '100' and '– 100'. If a country exports only then its value will be 100 and if a country imports only then its value will be '-100' and if value of export and import of a country is equal, then value of this index will be '0'. Obviously, the positive value of this index reflects that export can balance the import while negative value of this index reflects that import offsetstheexport.

Value of NTB was also computed for different point of time and different sub-periods of the covered period of study. These values were computed by following formulas:

$NTB_t = \{(EXP_t - IMP_t)/(EXP_t + IMP_t)\} * 100$

$$NTB_T = \{\sum (EXP_t - IMP_t)/\sum (EXP_t + IMP_t)\} * 100$$

where $NTB_t$ indicate the absolute value of normalized trade balance at time t, $NTB_T$ indicate the absolute value of normalized trade balance for period T. $EXP_t$ and $IMP_t$ indicate values of export and import at specific point of time t and t = 1995, 1996, 1997,……, 2011.

Share of Export in Total Export (SHEXP)

Likewise, the previous indices, share of export in total export was computed for different point of time as well as for the different sub- periods of the covered period of study. These values were computed by following formulas: -

$SHEXP_t = EXP_t / TEXP_t$

Where $EXP_t$ is export of Indian pharmaceutical industry at time t and $TEXP_t$ is total export of India at time t; t = 1995, 1996, 1997…., 2010, 2011.

$SHEXP_T = \sum EXP_t / \sum TEXP_t$

$SHEXP_{1995-1999} = \sum EXP_t / \sum TEXP_t$, t = 1995, 1996…………….1999. $SHEXP_{2000-2004} = \sum EXP_t / \sum TEXP_t$, t = 2000, 2001…………..2004.

SHEXP2005-2011 = $\sum$EXPt / $\sum$TEXPt, t = 2005, 2006…………… 2011.

The computed values of above indices for the different point of time were used to observe trend in export performance over the entire period of the covered period of study i.e. 1995-2011. This trend was used to examine that weather export performance of Indian pharmaceutical industry exhibits any significant difference during the entire period of the study. The computed values of indices for different period were used to compare the export performance of Indian pharmaceutical industry for different periods i.e. pre-TRIPs period (1995-1999), Transition period (2000-2004) and post- TRIPs period (2005-2011).

Apart from the above computation, the aggregate level export performance was examined by using 'Polynomial Trend Line' and 'Change Point Analysis' tools. In a polynomial trend line, the marginal increment of any variable varies linearly with the time which means the variable increase first (or decrease) and then decrease (or increase) thus it will show the turning point on the time-variable graph.
    A polynomial of order two is:
$Yt = a + b*x + c* x^2$

Where Yt is the trend value of a variable at time t; t = 1995, 1996, 1997……, 2011.
We need to find out the "best" values for a, b, and c, so that we plug it in above formula and determine an approximation for Y.
The 'change point analysis was used to detect the significant change during the entire period of study starting from the year 1995 till the year.

Market Structure: -
Market structure of Indian Pharmaceuticals is determined by the degree of market concentration and the market size. Market concentration is measured by Hirschman–Herfindahl Index, widely known as H-Index whereas market sized is expressed in terms of total sales of the industry over the year.

Exploring Global Market: -
The policy of globalization and liberalization has opened new opportunities to strengthening internationalization activity of the pharmaceutical industry. It is measured in terms of computing 'Trade Balance'. It is the value of export over import, which may be positive, negative or zero. Positive value shows export can balance the import while negative value shows import offsets the export. If the value of export and import of a country in any year is equal, then the trade balance will be zero. It reflects Industry's position into the foreign market. Moreover, export intensity and import intensity has also computed for relative measurement of internationalization activity of the industry.
The Indian pharmaceutical industry exhibits increasing internationalization activity during the post TRIPs period which suggest that during this period pharmaceutical units can explore the global market. The evidence of increased internationalization of Indian pharmaceutical companies is shown in the table–IV.4 and figure–IV.2. Positive trade balance values, shown in the third row of Table–IV.4, throughout the entire period. Value of trade balance has touched the figure of Rs. 36537.6 crores in 2011 against the figure of Rs.1575.1 crores in 1995, reported 23 times increment in foreign income of the industry. It explains that Indian firms have successfully utilized the opportunities driven by the globalization. These observations reflect that the export in pharmaceutical can balance the import in pharmaceutical.
Region-wise absolute value of export of bulk drugs has also been computed for the entire of study to discuss the region-wise trend in export of bulk drugs. Export of bulk drugs to America has drastically increasing but not constantly. Analysis of Firm Level Export Performance: -
Previous four chapters presented the results and findings of industry level and product level export performance of Indian drugs and pharmaceutical industry during the period (1995-2010). This chapter presents the result and analysis of export performance of selected firms, operating in this industry. Export performance of firms was evaluated in terms of absolute measurement as well as relative measurement. Absolute measurement of export performance was computed by average export of pharmaceutical firms whereas the relative measurement of export performance was computed by widely used indicator 'Export Intensity'.Firm level export performance was also evaluated by making comparison between foreign and domestic firms. Besides, the export behavior of the firms was also examined. Results obtained on firm level export performance are discussed as follows.

**Result on Absolute Export Performance:** -
Year-wise average export of the firms selected in the sample was computed for the entire period of the study (1995-2010). Increasing throughout the entire period of study (1995-2010). It has increased by average export value of Rs. 18.26 crores in 1995 to the average export value of Rs. 46.97 crores in 1999, Rs. 164.29 crores in 2004 and Rs.389.41 crores in 2010. These results indicate exceptional growth in the export of drugs and pharmaceuticals by the firms operating in Indian drugs and pharmaceutical industry.With 100% confidence level, the CPA detected only one significant change in the average export of firms during the entire period of the study, which estimated to have occurred to have occurred in 2006.

**Summary of Findings, and Conclusions:** -
The new policy framework, created by TRIPs agreement, has created a challenging environment for overall performance of Indian pharmaceutical industry in general and for export performance. In this context, the present study was an attempt to examine the effects of TRIPs agreement on the export performance of Indian pharmaceutical industry. In fact, the study tried to answer the question that whether there is any adverse effect on export performance of Indian drugs and pharmaceutical Industry during the period of TRIPs regime or not.

Few studies found that export of bulk drugs has increased during the post-TRIPs period. In the early years of post-independence period, industry was dominated by foreign multinationals and country had to rely upon import. With a view to develop indigenous industry, government of India announced various policies during 1970s. Among these policies there were two specific policies-- Drugs Policy of 1978, and Patent Act of 1970. These policy instruments provided immense protection to indigenous industry from international competition. But the scenario has change completely after the initiation of New Economic Policy in 1991 in general and establishment of World Trade Organization (WTO) in 1995.

The growth momentum that the industry received during the 1980s continued in 1990s and even in the post-TRIPs period. Apart from the growth in production and production unit, the industry exhibits phenomenal growth in many other aspects such as market size, export, trade balance and R&D activity during the post–TRIPs period. Interestingly, even in the post-TRIPs period, domestic firms are doing better than the foreign companies.

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