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India's Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges

Reji K Joseph*

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 fillip and balance of trade would be adversely affected. The paper 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. However, the expansion of formulation exports is increasingly facing challenges from various corners-increasing application of non tariff barriers by importing countries, authorised Indian generics being targeted by global anti-counterfeit drive and competition from China. Import of formulations did not increase as has been anticipated. Paper also finds that there is a negative and growing trade balance, owing to the import of intermediates and bulk drugs. The industry is now increasingly adopting the strategy of importing intermediates and bulk drugs and processing them into formulations. 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.

1. INTRODUCTION

The impact of policy reforms in the post 1991 period on trade in drugs and pharmaceuticals has been an issue discussed widely. This discussion became lively in the context of the changes in the patent regime that were expected to adversely affect the generic producers dominating the Indian pharmaceutical industry. It was argued that growth in exports would be restricted due to the restrictions in the generic producers' scope of operations, particularly in their ability to export to preferred destinations and imports

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would get a fillip because of the restricted scope of operation of the domestic producers for the patented medicines and thus leaving the balance of trade in bad shapes. Further more the removal of regulations insisting upon local production and abolition of restrictions on foreign firms were expected to encourage import of pharmaceutical products into India. This paper makes an attempt to analyse the trends in exports and imports of drugs and pharmaceuticals and to capture the emerging opportunities and challenges facing Indian exporters.

2. The Background

There have been a major changes in the government's approach towards industrial licensing, foreign equity and technology collaborations and import policy in the beginning of 1990s. Major reforms were introduced in the pharma sector in September 1994 with the 'modification in the Drug Policy 1986'. The major liberalization measures in the post 1994 period were:

1. Industrial licensing for all kinds of drugs was abolished.[1] However, the need for obtaining manufacturing license under Drugs and Cosmetics Act, 1940 continues to apply for all firms.
2. Abolished the restriction imposed on the use of imported drugs. Import of drugs and pharmaceuticals are regulated through EXIM policy in force and currently all items except those requiring clearance under the Narcotics and Psychotropic Substances Act 1985 are allowed under OGL.
3. Permitted 100 per cent foreign equity holdings and automatic approval of foreign technology agreements in the case of all bulk drugs, their intermediates and formulations except those involving the use of recombinant DNA technology or tissue/cell targeted formulations.[2]
4. The ratio parameters linking bulk drugs and formulations production was removed. The mandatory requirement of supply of a percentage of bulk drug production to non-associated formulators was also abolished.

In 1994 Government of India ratified the Final Act of 1986-1994 Uruguay Round of trade negotiations establishing the WTO and India became a Member of WTO and a party to the TRIPS Agreement. India complied with its obligations under the TRIPS Agreement in three steps. The first step was the Patents (Amendment) Act of 1999, which provided for receiving

of patent applications (mail-box applications) and for exclusive marketing rights.[3] If the products figuring in the mail-box applications were granted a patent in any of the WTO member countries and the products had obtained marketing approval in any of the WTO Member countries, then, according to Article 70.9, five years exclusive marketing rights (EMRs) had to be granted by India before the patent on the product was either granted or rejected in India. The Patents (Amendment) Act 2002 introduced comprehensive amendments to bring together various provisions of the Patents Act 1970 into conformity with the TRIPS Agreement.[4]

These reform measures are expected to have their impacts on exports and imports. Abolition of industrial licensing would encourage firms to restructure their production portfolios in tune with the opportunities thrown open in the world market. Liberalization of imports was not expected to have any major adverse impact as India had already become the producer of drugs at prices lowest in the world. But with India signing the TRIPS Agreement, changes in the patent law became inevitable in order to provide for product patent rights. Available evidence suggested that the balance of trade in drugs and pharmaceuticals would be adversely affected with the implementation of product patent rights. The study of Maskus and Penubarti (1995) based on OECD countries' exports in 28 manufacturing sectors to 25 developing countries in 1984, found that exporting firms discriminate in their sales decisions, taking account of local patent laws. Hence exports were larger to countries with stronger patent laws. A later study by Smith (1999) based on more disaggregated industry wise data[5] confirmed the view that export decisions of firms are influenced by the strength of patent rights in the importing countries. The study was based on US exports (of all manufacturing industries at two digit level) to 92 countries in 1992. It found that US exports has been significantly influenced by patent rights in the importing countries, but the direction of the relationship i.e. market expansion and market power effect[6], depended on the threat of imitation. Strengthening of patent rights in those countries posing a strong threat of imitation would enhance the expansion of exports whereas strong patent rights would enhance market power in countries where the threat of imitation is week. India had been classified under the category of countries with weak patent rights and strong imitative abilities where market expansion effect would take place.

Following this reasoning, it is expected that imports to India, a country with credible threat of imitation, would expand with the implementation of the product patent rights.

The studies in the Indian context also suggested that imports of formulations would increase; but they did not see any threat to balance of trade as firms would engage more in the export of intermediates and bulk drugs. The study of Lanjouw (1999) on the one hand argued that import of formulations will increase, but on the other held that BoT would not be adversely affected because of the export potential in the bulk drugs category. Her interviews with foreign MNCs revealed that they would be interested in importing into India rather than producing in India for two reasons. One, the transfer pricing loophole would give the patent owning MNC an incentive to produce drugs elsewhere and then import them into India. Second, unlike generic drugs, manufacturing costs are a small component of the price of patented drugs and, therefore, India's advantages as low cost manufacturer would not be particularly useful in attracting investments in local production facilities. However, she did not see an imminent threat to BoT as the bulk drugs, which were exported mostly to the West, would continue to be exported. Grace (2004) was also of the view that there would not be any immediate threat of reduced exports and increased imports, leading to a decline in BoT. She pointed out that the Indian companies which used to focus on domestic generic market will have to look beyond for sustaining their sales. There exists a latent trade opportunity in pharmaceutical products for India; better compliance to good manufacturing practices (GMP) and low-cost production[7] and the expertise derived from more than three decades of reverse engineering of on-patent medicines would make Indian firms explore export opportunities in 'low volume-high priced' regulated markets while retaining its traditional 'low priced-high volume' markets of Asia, Africa and Latin America. She also argued that the fast growing bio pharma sector in India would further boost its exports.

In this context it becomes important to see how the industry has been responding to the changes in the policy regime. This paper looks into the destinations of trade, actors involved and products traded over a period of 18 years from 1990-91 to 2007-08.

3. 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. Table 1 below shows the variation in the estimates of different agencies for the latest years for which data are available.[8]

Table 1: Export and Import of Drugs and Pharmaceuticals

(Rupees in crore)

	2003-04		2004-05		2005-06	
	Export	**Import**	**Export**	**Import**	**Export**	**Import**
Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers (Annual Report 2006-07)	7445.0	1150.0	9263.0	1303.0	10821.0	1945.0
Department of Chemicals and Petrochemicals (http://chemicals.nic.in/pharma1.htm)	15213.0	–	17857.0	–	22116.0	
Report of Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan, Planning Commission of India	15213.2	2956.6	17857.8	3169.4	21579.0	4515.2
IDMA (45th Annual Publication, 2007)	15213.2	2956.6	17857.8	3169.4	21579.0	4515.2
OPPI (Indian Pharmaceutical Industry: Fact Sheet – 2005)	–	–	–	–	19800.0	4800.0
BDMA (www.bdmai.org)	14324.2	5085.0	16681.0	5630.0	–	–
Difference between lowest and highest figures (per cent)	104.3	342.2	92.8	332.1	104.4	146.8

There are huge differences in the figures provided by the different sources referred to in Table 1. For example, in 2004-05, the lowest estimates for both exports and imports were provided by the Department of Chemicals and Petrochemicals. While the Indian Drug Manufacturer's Association (IDMA) and the Working Group on Drugs and Pharmaceuticals for the Eleventh Plan provided the highest estimate for exports, the Bulk Drug Manufacturer's Association (BDMA) provided the highest estimates for imports. The magnitude of difference between the highest and the lowest estimates shows the extent of variation in the estimates available currently.

In case of exports, the magnitude of exports of pharmaceutical products reported by the Department of Chemicals and Petrochemicals was only one half of that reported by the IDMA and the Working Group on Drugs and Pharmaceuticals for the Eleventh Plan. The difference between the lowest and highest estimates in case of imports was considerably larger. BDMA reported a figure that was more than three times larger than that provided by the Department of Chemicals and Petrochemicals. The fact that the trade figures given in the Annual Report of the Department of Chemicals and Petrochemicals are substantially different from the trade figures given in the website of the Department of Chemicals and Petrochemicals and in the Report of the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan shows the magnitude of the lack of understanding of the issue even at the official level.

Figures provided by different industry sources are also at variance, particularly in respect of imports. There is a striking difference between the figures of BDMA on the one hand and IDMA or OPPI on the other. The difference was 42 per cent in 2003-04 and it increased to 44 per cent in 2005-06. A plausible explanation of the difference in the figures provided by the BDMA and OPPI-IDMA is the following. In India there is a highly competitive bulk drug industry spreading across large, medium and small scale sectors. These producers largely depend on imported intermediates to process them into bulk drugs[9]. And BDMA, being an association of the producers of bulk drugs in the large, medium and small scale sectors, covers a larger number of production units as compared to IDMA or OPPI whose membership do not include the smaller producers. This may explain why the import figures of BDMA are larger than the figures of all other sources.

What explains these large variations in the estimates in both exports and imports of pharmaceutical products that are shown in Table 1? The answer to this question, which we shall elucidate below, is to be found in the definition of the term ‘pharmaceuticals’ that have been adopted by these agencies indicated in the Table.

The Department of Chemicals and Petrochemicals considers pharmaceuticals as bulk drugs of two or more than two chemical substances;

formulations; medicated bandages and dressings; medical devices such as syringes; blood products; and glands, organs and their extracts. In fact, the figures for export and import of pharmaceuticals that are reported by the Department in the Annual Report of the Ministry of Chemicals and Fertilizers largely correspond to those that are provided by the Directorate General of Commercial Intelligence and Statistics (DGCIS) for Chapter 30-pharmaceutical products, of Indian Trade Classification (ITC).[10] Chapter 30 of ITC has six components: glands, organs and their secretions; blood and blood products; bulk drugs consisting of two or more chemical constituents; formulations; medicated bandages and dressings; and medical devices, dental cements and fillings, etc. This Chapter excludes intermediates and bulk drugs of single chemical substances which constitutes a significant share in India's pharmaceuticals trade. It is to be noted that intermediates and bulk drugs of single chemical substances largely fall under chapters 28 and 29 of ITC.

The data provided by industry sources, on the other hand, include intermediates, bulk drugs (bulk drugs of single chemical substances as well as bulk drugs of two or more chemical substances) and formulations. However, products such as blood and blood products; glands, organs and their secretions; medicated bandages and dressings; medical devices, dental cements and fillings, etc. are excluded.

Trade data given in the Report of the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan, which is sourced from DGCIS, is substantially different (99.4 per cent difference in exports and 132.1 per cent difference in imports) from the data given in the Annual Report of the Department of Chemicals and Petrochemicals, which has also seemingly sourced the data from DGCIS. This may be due to the different methodologies adopted by these two agencies. Surprisingly, the data of the Working Group is the same as that given by one industry association - IDMA. To understand the methodology, it is important to know the products considered while compiling the data. IDMA is the only source which gives a list of products that are exported and imported. The 42nd Annual Publication (2004) of IDMA gives a detailed list of exports and imports of intermediates, bulk drugs and formulations (from ITC chapters 28, 29 and 30) at 8-digit level for 2002-03;

581 products for exports and 738 products for imports. Trade quantities and values of these products are the same as given by the DGCIS. Exports add up to Rs. 9714.41 crore and imports to Rs. 8846.1 crore. However, these values do not match with the values for total exports and total imports given in a separate pate of the same report - Rs. 11925 crore exports and Rs. 1102.5 crore imports. Thus, it comes out that there are serious problems with the aggregate trade data given by industry associations as well. In this confusing scenario, it may be wise for one to collect data at the level of individual items to arrive at the aggregate trade figures.

Significantly, all recent studies on India's trade in drugs and pharmaceuticals have glossed over the above-mentioned data problems by relying on data either from the Annual Reports of the Department of Chemicals and Petrochemicals or from the Annual Reports of IDMA or OPPI. For instance, Dhar and Rao (2002) use the data of the Department of Chemicals and Petrochemicals and OPPI to argue that the Indian pharmaceutical industry has turned into a foreign exchange net earner on its trade account in 1988-89, and this surplus has been increasing. Chaudhuri (2005) and Lanjouw (1999) have used the IDMA trade figures to arrive at the same conclusions. This paper would attempt to provide estimates of pharmaceutical trade that India is involved, based on what is considered is a more accurate definition of drugs and pharmaceuticals.

3.1. What are pharmaceutical products?

In order to identify the pharmaceutical products, the definition for drugs given in the Drugs and Cosmetics Act, 1940 is used.[11] Section 3(b) of the Drugs and Cosmetics Act, which covers all aspects of drug regulation in India, defines a drug to include all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes; such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins or insects which cause disease in human beings or animals, as may be specified from time to

time by the Central Government by notification in the Official Gazette; all substances intended for use as components of a drug including empty gelatin capsules; and such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.[12]

Under this definition the term drugs or pharmaceuticals 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[13] and APIs consisting of two or more chemical substances. Thus the term 'drugs' or 'pharmaceuticals' is used to mean medicines and other goods used for the treatment of humans and/or animals. The term distinguishes itself from drugs used for other purposes, such as narcotic drugs.

Data for pharmaceuticals is collected from chapters 28, 29 and 30 of Indian Trade Classification (ITC) and given by the Directorate General of Commercial Intelligence and Statistics (DGCIS). Table 2 gives a description of how products from these three chapters are classified into different categories.

Table 2: Categories of Pharmaceutical Products and their HS Codes

Categories	ITC Chapter 30	ITC Chapter 28&29
Formulations	3004, 300220, 300230	
Intermediates and bulk drugs	3003	365 products at 8 digit level for exports 651 products at 8 digit level for Imports
Other Pharmaceutical Products	All other items under chapter 30	

Data for intermediates and bulk drugs of single chemical substance is collected from chapters 28 and 29 using the list of products at 8 digit level in IDMA's 42nd Annual Publication; 365 products for exports and 651 products for imports. Items in ITC chapter 3004, 300220 (Vaccines for human medicine) and 300230 (Vaccines for veterinary medicine) are considered as formulations and items in chapter 3003 are bulk drugs of two or more chemical substances. The remaining items in the chapter 30 are other drugs and pharmaceutical products. The DGCIS data in this study has been accessed through India Trades data base of CMIE. India Trades does not include data for USSR for three years from 1990-91 to 1992-93 and provides the data for CIS countries from 1993-94. Data for USSR for the three years has been taken from the March issues of Monthly Statistics of Foreign Trade, published by DGCIS, of these years[14].

4. Trends in the Pharmaceuticals Trade

The Tables 3 and 4 shows trends in the export and import of pharmaceutical products since 1990-91.

Table 3: Export and Import of Pharmaceuticals

(In US$ Million)

	Export	Import	Balance of Trade
1990-91	482.5	641.7	-159.2
1991-92	563.6	470.8	92.8
1992-93	453.3	497.3	-44.0
1993-94	589.7	682.1	-92.4
1994-95	736.1	1149.4	-413.3
1995-96	911.6	1489.2	-577.6
1996-97	1055.9	1493.2	-437.3
1997-98	1207.3	1500.1	-292.8
1998-99	1133.1	1166.1	-33.0
1999-00	1343.4	1398.7	-55.3
2000-01	1614.0	1338.2	275.8
2001-02	1733.3	1544.2	189.1
2002-03	2226.3	1906.3	320.0
2003-04	2324.8	2171.1	153.7
2004-05	2767.5	3034.6	-267.1
2005-06	3250.8	3746.5	-495.7
2006-07	4076.3	4516.1	-439.8
2007-08	5381.6	5803.8	-422.2

***Source*:** DGCIS.

Table 4: Export, Import and Balance of Trade of Different Categories of Pharmaceutical Products

(In US$ Million)

	Formulations			Intermediates & Bulk Drugs			Other Drugs and Pharma Products		
	Exp	**Imp**	**BoT**	**Exp**	**Imp**	**BoT**	**Exp**	**Imp**	**BoT**
1990-91	165.9	51.3	114.6	300.2	579.7	-279.5	16.3	10.6	5.6
1991-92	306.5	52.6	253.9	246.5	409.6	-163.1	10.6	8.5	2.1
1992-93	235.2	46.8	188.4	207.0	439.7	-232.7	11.1	10.8	0.3
1993-94	306.4	36.0	270.4	268.4	635.7	-367.3	15	10.5	4.5
1994-95	373.9	31.1	342.8	347.1	1102.5	-755.3	15.1	15.8	-0.7
1995-96	494.6	46.4	448.2	402.0	1407.4	-1005.4	15	35.3	-20.4
1996-97	528.6	38.4	490.2	507.3	1439.4	-932.1	20	15.5	4.5
1997-98	608.3	70.8	537.5	559.8	1396.0	-836.2	39.1	33.3	5.8
1998-99	577.7	87.4	490.3	536.9	1049.6	-512.6	18.4	29.2	-10.8
1999-00	661.2	83.6	577.6	660.6	1284.8	-624.2	21.6	30.4	-8.7
2000-01	754.7	92.9	661.8	817.9	1215.3	-397.4	41.4	30.1	11.3
2001-02	836.3	94.3	742.0	863.2	1405.6	-542.5	33.9	44.3	-10.4
2002-03	1090.6	161.4	929.2	1099.4	1692.8	-593.3	36.3	52.1	-15.8
2003-04	1356.7	178.2	1178.5	922.4	1941.4	-1018.9	45.6	51.6	-6.0
2004-05	1648.7	210.2	1438.5	1058.9	2768.5	-1709.6	60.0	55.9	4.1
2005-06	2185.5	329.3	1856.2	1014.4	3333.3	-2319	50.8	83.8	-33
2006-07	2800.1	492.7	2307.4	1205.2	3901.9	-2696.6	70.9	121.6	-50.7
2007-08	3419.3	524.7	2894.6	1827.7	5154.0	-3359.2	134.6	139.1	-4.5

Source: DGCIS.

It is seen from Table 3 that the pharma sector has been having BoT deficit for most of the years under analysis and it has increased from $-159.2 million in 1990-91 to $-422.2 million in 2007-08. This is quite contrary to what the literature suggests that BoT in the pharma sector will not be adversely affected. The breakup of the pharmaceutical products (given in Table 3) indicates that there exist major differences in the trends in exports and imports across various categories. While formulations exhibit a steadily growing trade surplus, intermediates and bulk drugs show a consistent trade deficit. The third category 'other drugs and pharmaceutical products' shows a mixed trend; however it accounts for only 2 per cent of pharmaceuticals trade and may not have a significant impact on the sector as a whole. As the third category accounts for only a minuscule portion of pharma trade, the analysis in this paper will be based on the other two categories.

The trade surplus in formulations has been accounted for by growth in exports rather than any decline in imports. Formulation exports have grown by 20 times between 1990-91 and 2007-08 and the average annual rate of growth has increased from 19.7 per cent in the last decade to 23 per cent in the current decade. The share of formulations in total pharma exports has also increased from one-third (34.3 per cent) in 1990-91 to about two-third (63.5 per cent) in 2007-08. These observations about formulation exports confirm the view that there would be an increase in the export of generics from India. Import of formulations while showing only a marginal increase in terms of share in total pharma imports[15], has shown remarkable acceleration in rate of growth. The average annual rate of growth of imports of formulations has increased from 10 per cent in the 1990s to 28 per cent in the current decade. Prima facie this observation may seem to confirm the view that import of formulations would increase, but this is not a major cause of concern as of now. However, it needs to be acknowledged that the rate of growth of imports as well as the share in the import basket of formulations would have been larger except for two provisions in the Patents Act – Section 3(d) and Section 11.A.7.

Section 3(d) states that inventions are not patentable if,

> *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*
>
> *Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".*

This section has been brought into the Patents Act to prevent the 'evergreening' of patents or 'patenting of known substance', a practice

followed by major Pharma firms to extend patent monopoly even after the expiry of the original patent. Generally patenting of known substance are claimed in the form of compositions, formulations, salt, esters, ether, polymorph, pure form, particle size, combination, derivatives, crystalline, new use, method of treatment, etc. Now there is a burden on the part of the patent applicant to prove that the inventions of salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance differ significantly in properties with regard to efficacy. Since section 3(d) explicitly mentioned that such forms of a substance cannot be patented, it has been a powerful instrument in preventing frivolous patents, often inviting the ire of pharma MNCs. Novartis' case in India would be the best pointer in exposing how effective is this section in preventing frivolous patents. Novartis had applied for patents though the 'mailbox' for crystalline form of *imatinib mesylate*, for the treatment of chronic myeloid leukaemia. This molecule in original form has been patented in 1992 in Switzerland and subsequently in other countries. The original molecule is not patentable in India as there is prior publication of the invention in pre-1995 period and hence the company has sought for patent on the crystalline form. In 2003 Novartis secured an Exclusive Marketing Right for its drug Glivec (*imitinib mesylate*) and obtained injunctions against Natco, the only producer of generic version Glivec and against six other potential manufacturers of the generic version of Glivec. However, amendment of Section 3(d) in 2005 using TRIPS flexibilities prevented patenting of 'salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives' of already known substance unless they significantly enhance the efficacy of the already existing substance. After the 2005 amendment, generic companies and patient groups challenged the patent over *imitinib mesylate* on various grounds and the Patents Office rejected Novartis' patent application on beta crystaline salt of *imatinib mesylate* in January 2006. Pharma majors with their advanced technical capabilities are able to incorporate incremental modifications to the original invention and thus able to prolong the life of patent even after the expiry of original patent. A comparison of the number of new chemical entities patented and the number of patent applications would show the

extent of attempts to the patenting of known substance. Under the TRIPS Agreement, India provided for mail-box and accepted patent applications during the period between 1995 and 2005. India received approximately 9500 patent applications in the mail-box of which around 9000 were relating to pharmaceuticals. However, during this 10 year period only 297 new chemical molecules were approved by the USFDA[16]. This would show that majority of the 9000 applications fall within the category of patenting of known substance or incrementally modified innovations category.

Section 11.A.7 provided for the continued manufacture of drugs with application in the mailbox. Mailbox was an arrangement mandated by the TRIPS agreement for those countries availed the transitional period of 10 years. The applications in the mail box would be examined only after 1st January 2005. India incorporated this provision into its Patents Act through the amendment in 1999. Many Indian companies started producing medicines for which applications were filed in the mailbox as it was legally permissible to do so. It was apprehended that after the final amendment of the Patents Act to allow for product patents from 2005, drugs which are produced by Indian companies and for which applications are pending in mail box would go off the market once patents are granted. But the final amendment provided that 'patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprise'. Even if an application in the mail box is granted patent rights, those generic firms producing that drug will not be prevented from doing so. If there are Indian producers, the incentive of foreign firms to import that drug into India will be less due to the cost advantage that Indian firms are having.

Trends in the intermediates and bulk drugs category are quite interesting. As expected there has been expansion in exports, but the expansion in imports was not anticipated. During the period between 1990-91 and 2007-08, exports grew by six times while imports grew by nine

times. While India's exports to the Western regulated markets continued, it has explored new markets in Asia and Africa and in other parts of the Western world. Indian companies have set up subsidiaries in many foreign countries and a portion of the exports could be accounted for by export of Indian firms to its subsidiaries. The increase in imports is surprising because despite the fact that India was exporting bulk of its intermediates and bulk drug exports to regulated markets of the West indicating the competitiveness of the Indian industry, the country has become increasingly dependent on imports. This is against the hypothesis that BoT will not be adversely affected due to the increase in the exports of bulk drugs.

The following sections will further explore the characteristics of exports and imports of formulations and intermediates and bulk drugs.

4.1. Formulations

Formulations constitute the fastest growing export category of pharmaceutical products with a high average annual rate of growth in exports of 21.3 per cent, amounting to more than the 16.9 per cent growth of India's merchandise exports during 1990-91 to 2007-08. The share of formulations in India's merchandise exports has grown from 1.3 per cent in 1990-91 to 2.1 per cent in 2007-08. The pharma sector had always been given various kinds of incentives for engaging in exports. The 1986 Drug Price Control Order (DPCO) provided complete flexibility in producing any product with their existing facilities for the export purposes without having to seek an industrial license. Further, pharmaceuticals produced for export purposes had been completely exempted from application of DPCO provisions. Apart from these sector specific incentives, pharmaceutical exporters have immensely benefited from the Foreign Exchange Regulation Act (FERA) exemptions. FERA had required all the MNCs and their subsidiaries to bring down their equity share up to 40 per cent, provided certain exemptions based on export performance. Those firms which exported minimum of 60 per cent of their production were allowed to keep equity level up to 74 per cent and 100 per cent equity was allowed in the case of totally export-oriented companies. More recently firms operating in export processing zones are entitled to customs benefits, tax benefits for export (which could extend up to 15 years) and also capital expenditure benefits.[17]

In imports, however, formulations account for only a minor share. One of the major achievements of the Indian pharmaceutical industry has been its reduced dependence on imports. At the time of independence in 1947, India's pharmaceutical market was dominated by foreign firms that controlled 90 per cent of the market primarily through importation[18]. There was no basic pharma industry existing in India at that time. Indian pharmaceutical industry has evolved from import dependence to self reliance in the entire range of formulations and 70 per cent of bulk drug requirement[19]. The policy interventions in the pharma sector especially in the 1970s through the industrial licensing policy and import policy purposefully restricted the import of drugs not only by the MNCs but also by domestic firms and insisted on local production. In order to enhance the production capabilities of Indian firms, MNCs had been discriminated against. The report of Hathi Committee (1975) had observed that most of the MNCs established themselves as mere trading concerns (importing finished drugs from abroad and selling them in India) without establishing manufacturing units in India and recommended imposition of restrictions on their activities. The Bhatia Committee (1975) further recommended that no new foreign concerns should be allowed to set up factories unless they manufacture products, which are not manufactured by others, starting from basic chemicals or intermediaries. These Committees also recommended reforms in the patent system by eliminating product Patent rights. The Ayyangar Committee (1957) which was appointed to recommend reforms to India's patent law, had found that 80 to 90 per cent of the patents in India were held by multinational companies, and that more than 90 per cent of these patents were not even being exploited in India. The Committee stated that the existing patent regime system was being exploited to achieve monopolistic control over the market in vital industries such as food, chemicals, and pharmaceuticals, resulting in medicines being unaffordable. Based on the recommendations of these Committees, the patent law in India was revamped in 1970 though the Patents Act 1970. It eliminated product patent rights in food, chemicals and drugs and provided for only process patent rights in these sectors. The term of patent was reduced from 14 years to 7 years.[20] All these measures resulted in making the Indian pharma industry competent in terms of not only in production at low costs but in process technology as well. Indian firms were

able to develop alternate process for patented medicines and produced them within India at very low cost forcing the originators to stay away from the market. We now turn to the direction of trade.

Table 5: Share of Exports and Imports of Formulations - Regionwise

	Exports					Imports		
	Africa	**America**	**Asia**	**Europe**	**Oceania**	**Europe**	**America**	**Asia**
1990-91	5	2	13	80	0	79	7	12
1991-92	9	4	22	64	1	77	6	16
1992-93	17	5	23	53	1	78	13	9
1993-94	17	6	26	50	1	78	13	7
1994-95	17	7	32	44	1	84	7	7
1995-96	17	9	32	41	1	77	9	12
1996-97	16	9	33	40	1	67	7	25
1997-98	18	10	32	39	1	75	6	19
1998-99	22	13	37	27	1	79	6	14
1999-00	20	11	37	30	1	85	4	11
2000-01	23	15	32	30	1	80	6	13
2001-02	24	20	28	27	1	72	9	18
2002-03	23	24	25	26	1	77	7	15
2003-04	22	22	27	28	1	81	6	10
2004-05	21	21	25	31	1	82	10	8
2005-06	23	21	23	32	1	80	13	6
2006-07	23	27	20	29	1	82	9	7
2007-08	22	32	17	27	1	78	13	8

Source: DGCIS

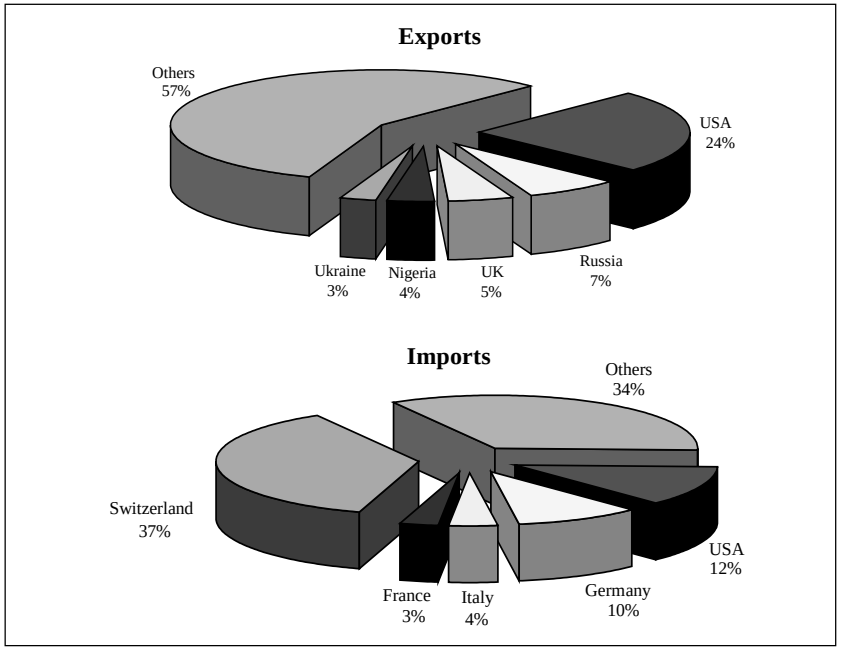
In 1990-91, 80 per cent of exports were destined for Europe. By 2007-08, the share of this region has declined to 27 per cent. This decline, however, was because of the decline in the value of exports but rather the expansion of exports to other regions. In fact, exports to Europe has increased from $132.6 million in 1990-91 to $928.8 million in 2007-08. Decline in the share of Europe was commensurately adjusted by the expansion in exports to other regions especially to America and Africa. Now, America is the region accounting for the single largest share in exports (32 per cent). Export to America has grown from a mere $3.7 million in 1990-91 to $1097.5 million in 2007-08. USA accounts for three-fourth (76 per cent in 2007-08) of exports destined to America. The share of Africa has increased from 5 per cent in 1990-91 to 22 per cent in 2007-08. In the case of Asia, there was an increase

in the share in the 1990s and it declined in the current decade. Share of Asia has increased from 13 per cent in 1990-91 to 37 per cent in 1999-00 and declined to 17 per cent in 2007-08.

In imports, Europe is the major source of supply accounting for almost four-fifth of total imports. Imports from Europe increased from $40.4 million in 1990-91 to $409.3 million in 2007-08. Switzerland is the most important source of supply accounting for $193 million in 2007-08. The remaining imports are from America and Asia. More than half of the import from Asia is accounted for by China (23 per cent), Singapore (17.5 per cent) and Saudi Arabia (13 per cent) in 2006-07. More than four-fifth of the import from America was accounted for by the USA in 2006-07.

India's top five export destinations and sources of imports are shown in Figure 1.

Figure 1: Top Destinations of Exports and Sources of Supply Formulations in 2007-08



Source : DCCIS

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 $834 million in 2007-08. Growth in exports to USA has been tremendous as it was only $2.9 million (1.8 per cent of total formulation exports) in 1990-91. The other four destinations are Russia, UK, Nigeria and Ukraine. Antibiotics is 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 2007-08. Russia and Ukraine were part of Soviet Union in 1990-91 and no separate estimate is available for these two countries in that year.

The 'low volume high value' market of USA remains the main attraction for Indian companies. India has approximately 119 FDA approved plants[21]; 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.[22] It is estimated that in USA, $40 billion worth of drugs are expected to go off patent in the coming years.[23] 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. The accumulation of enhanced technologies and production capabilities coupled with the change in the global patent regime led to a gradual shift of focus to the highly lucrative US generics market while retaining the old markets.

In order to market a generic drug in USA, a company needs to file ANDA (Abbreviated New Drug Application). When filing an ANDA, the company is required to certify that its product is not infringing any patent rights or the patent is invalid (para IV certification). If the company successfully proves that the patent is invalid or if it is the first one to get approval for the generic version, it gets market exclusivity for 180 days during which no other generic company is permitted to enter the market. This exclusivity is available under the Drug Price Competition and Patent Restoration Act of 1984 or better known as the Hatch-Waxman Act. A

successful first to file para IV ANDA can bring immense profits to the company. Dr. Reddy's, the first Indian company to get the 180 exclusivity for marketing fluoxetine 40 mg in August 2001, saw its sale of generics increasing from Rs304 million in 2000-01 to Rs. 4066 million in 2001-02. Sale of fluoxetine 40 mg contributed 81 per cent of total generic sales and about half of Dr. Reddy's operating profit in 2001-02 (Chowdhuri 2007). Patent litigation under para IV is highly risky also as a failure means a loss of several years of hard work and huge legal expenses. Companies also engage in developing non-infringing process for ANDA filing. Matrix Laboratories was the first Indian company to develop a non-infringing process for manufacturing citalopram. The company was able to reap huge benefits with its sales of the product were Rs5600 million till 2005-06. Another commercially successful example is the cefotaxime process developed by Lupin (Chowdhuri, 2007). Since 2002, both Ranbaxy and Dr. Reddy's have taken steps towards registering themselves as the first movers in the generics' for a number of drugs. Data obtained from the FDA shows that while Ranbaxy has been able to obtain approvals for 22 drugs as the 'first-time generics' between 2002 and 2005, Dr. Reddy's has been able to obtain similar approvals for 8 drugs (Dhar and Gopakumar, 2008). More recently Glenmark got first to file status for three drugs having combined revenue of over $2 billion. The three drugs are Zetia (Ezetimibe) with annual sales of $1.5 billion in the US in 2008, Tarka (Trandolapril+Verapamil) with annual sales of $72 million and Cultivate (Fluticasone lotion) with annual sales of $37 million.[24]

Only few companies, particularly Ranbaxy and Dr. Reddy's had ANDAs in their name till recently. Companies like Cipla had ANDAs in the names of their marketing partners in the USA. This situation has changed dramatically in recent times and more companies are engaged in securing ANDAs. From 161 ANDAs filed by four companies – Ranbaxy, Dr. Reddy's, Wockhardt and Lupin in the last quarter of 2003, the number has gone up to 701 ANDAs filed by 17 companies by the second quarter of 2007 (Chaudhuri 2007). ANDA approvals held by Indian firms as percentage of total approvals have gone up sharply from 7 per cent in 2001 to 21 per cent in 2006 to 30 per cent in 2008 and to 35 per cent in 2009 till 23rd February.[25]

There are two sets of indicators showing the extent to which generic

firms have been seeking opportunities to market their products in the US. The first set of data pertains to the market approvals (ANDAs) that the leading generic firms have received for their products in the USA. The second set of data relates to the Drug Master Files (DMFs). A DMF is a package of proprietary information that is voluntarily filed by a firm with the FDA and therefore can be seen as an expression of interest that firms that have filed them have in obtaining marketing approval in the USA. There are five types of DMFs: Type I relating to Manufacturing Site, Facilities, Operating Procedures, and Personnel (no longer applicable), Type II relating to Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product, Type III relating to Packaging Material, Type IV relating to Excipient, Colorant, Flavour, Essence, or Material Used in Their Preparation and Type V on FDA Accepted Reference Information. Information on type II DMF applications would indicate the approximate number of drugs (active ingredients) in which the firms are interested in the US market. Following table shows the number of ANDA and DMF filings made by India's top 10 exporting firms. Data on market approvals in the US provided by the FDA shows that these 10 Indian firms as on 31st March 2009 have obtained 1072 approvals (Table 6).

Table 6: Market Approvals Obtained by the Leading Indian Firms in the US

	ANDAs												DMFs	
	Till 1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*	Total	APIs	DMFs#
Ranbaxy	39	18	7	26	37	34	26	13	34	8	9	251	72	95
Dr. Reddy's	4	3	14	6	5	11	8	29	28	41	28	177	49	99
Aurobindo						7	14	25	64	49	14	173	49	126
Wockhardt	8	4	2	1	4	0	7	9	30	39	12	116	38	45
Sun	4	0	0	0	0	0	0	13	26	50	16	109	34	76
Lupin					9	2	14	13	20	16	7	81	22	81
Glenmark	4	0	0	0	0	0	0	11	22	11	15	63	23	40
Orchid	0	0	0	0	0	0	17	15	9	11	7	59	17	24
Cipla									4	11	8	23	9	130
Matrix	0	0	0	0	0	3	0	0	0	11	6	20	6	115
Total	59	25	23	33	55	57	86	128	237	247	122	1072	319	831

* As on 31st March 2009

Type II DMFs

An overwhelming proportion of the approvals obtained by the Indian firms were in the post-2000 period. For instance, Ranbaxy, which has the largest number of approvals among the Indian firms, had only 39 approvals prior to 2000. But in the following 10 years, the firm had obtained approvals for another 212 drugs. The 10 firms together have got 1072 approvals on 319 APIs. This means that on average these firms have obtained 3.4 approvals per APIs. The difference in the number of active ingredients in which the 10 firms have expressed interest in the USA (DMFs) and the number of active ingredients used in ANDAs shows the potential exist in the US for the Indian firms; these firms so far have not used even half of the DMF filings.

A significant recent development for the Indian firms is their entry in the market for anti-retroviral (ARV) drugs in the USA. Two firms, viz. Ranbaxy and Aurobindo Pharma, have been able to obtain tentative or full approval from the US Department of Health and Human Services (HHS) and the FDA for five ARV drugs during 2004-05. These drugs were approved as a part of the Emergency Plan for AIDS Relief[26] that President George Bush had announced in 2003 for bringing low-cost, high-quality anti-retroviral therapy (ART) to the patients. The Indian firms had also marked their significant presence in the implementation of the Global Fund to Fight AIDS, Tuberculosis and Malaria that was established in 2002 (Dhar and Gopakumar 2008).

Major Indian firms like Ranbaxy, Dr Reddy's, Sun Pharma and Cipla are certified suppliers of generic medicines in the EU, in particular the UK. Dhar and Gopakumar (2008) points out that the two leading firms, Ranbaxy and Dr Reddy's, have led the way and they have been joined by three other firms, viz. Aurobindo Pharma, Nicholas Primal and Orchid Healthcare. Ranbaxy obtained the largest number of approvals (204), followed by Dr. Reddy's Laboratories (57). Though Indian interest is expanding in EU, it generally viewed as problematic as compared to USA due to the various kinds of barriers faced like different regulatory approval requirements within the community, linguistic difficulties and complex pricing dynamics (Sampath 2008).

Table 7: Top Ten Exporters of Pharmaceuticals

Company	2007-08			1990-91		
	Exp. ($Mi)	Exp. per cent Sale	Share in Exp*	Exp. ($Mi)	Exp per cent Sale	Share in Exp*
Dr. Reddy's Laboratories Ltd.	561.6	63	11	4.6	15	2
Ranbaxy Laboratories Ltd.	555.9	69	11	32.2	22	12
Cipla Ltd.	522.3	49	10	5.3	8	2
Lupin Ltd.	336.9	51	7	20.7	16	8
Aurobindo Pharma Ltd.	332.9	56	6	0	0	0
Orchid Chemicals & Pharmaceuticals Ltd.	250.6	81	5	0	0	0
Divi's Laboratories Ltd.	239.3	92	5	0	0	0
Sun Pharmaceuticals Ltd.	200.4	33	4	0	0	0
Glenmark	168.3	48	3	0	0	0
Pharmaceuticals Ltd.	152.2	63	3	0	0	0
Matrix Laboratories Ltd.	3320.4	-	65.0	62.8	-	24.0

***Source**:* PROWESS.

* Share in the total exports by pharma industry

Table 7 shows the top 10 exporters of pharmaceuticals in India. PROWESS data provides information on export of goods and does not distinguish between finished goods and raw materials. Though it is difficult to argue that export of these firms have been accounted only by formulations, they constitute a major share in the product portfolio of these firms. The share of formulations in principal products of some of the firms are: Lupin (100 per cent), Aurobindo (100 per cent), Cipla (93 per cent), Sun (82 per cent), Wockhardt (81 per cent), Ranbaxy (78 per cent) and Dr. Reddy's (60 per cent).[27] Moreover, these firms are known for their business in formulations and not in intermediates & bulk drugs and hence it is reasonable to consider that formulations constitute a major chunk of the export basket of these firms.

Most of the firms listed in the table are highly export oriented as more than half of their sales are accounted by exports: it accounts for as high as 92 per cent of sales (Divi's lab.). Whereas in 1990-91 only four of these 10 firms engaged in exports and the maximum share of exports in sales was 22

per cent, for Ranbaxy. The export performance of companies in recent years indicates gains from scale economies and diversification in key markets. Ranbaxy and Dr. Reddy's which had set the trend of focusing on regulated markets initially showed that winning a 180 days exclusivity to sell their generics first in the US market was a very lucrative option. Even when firms do not gain 180 days exclusivity a simple entry into US market brings in large benefits due to the price competitiveness of Indian generics.

In imports, Switzerland is the largest source of supply, accounting for 37 per cent of formulation imports in 2007-08. It is followed by USA, Germany, Italy and France. Hormones are the major imported category from these countries except US from where it is antibiotics. Of the top five countries, four have seen their share increasing between 1990-91 to 2007-08; Switzerland (from 17 per cent to 37 per cent), USA (7 per cent to 12 per cent), Italy (5 per cent to 9 per cent) and France (2 per cent to 3 per cent) and the share of Germany declined (13 per cent to 10 per cent).

Table 8: Top Ten Importers of Formulations

	2007-08			1990-91		
Company	**Imp. ($Mi)**	**Imp% Sale**	**Share in Imp***	**Imp. ($Mi)**	**Imp% Sale**	**Share in Imp***
Novartis India Ltd. (Foreign)	13.8	10	15	0	0	0
Aventis Pharma Ltd. (Foreign)	13.1	6	14	4.4	3	26
Glaxosmithkline Pharmaceuticals Ltd. (Foreign)	10.8	3	12	4.0	2	24
Piramal Healthcare Ltd. (Indian)	8.7	2	10	0	0	0
Fulford (India) Ltd. (Foreign)	8.6	22	9	0	0	0
Organon (India) Ltd. (Foreign)	6.6	14	7	1.3	5	8
Wyeth Ltd. (Foreign)	5.4	6	6	0	0	0
Merck Ltd. (Foreign)	4.1	5	5	0	0	0
Cadila Healthcare Ltd. (Indian)	4.0	1	4	0	0	0
Abbott India Ltd. (Foreign)	3.1	2	3	0	0	0
Total of 10 Firms	78.2		85.0	9.8		58.0

Source: PROWESS.

* Share in the import of formulations by the pharmaceutical industry

PROWESS data gives information on forex earnings on goods and forex spending on finished goods and raw materials. Forex earnings on

goods of pharmaceutical companies would mean export of formulations and intermediates & bulk drugs. Forex spending on finished goods would mean import of formulations. It is seen from Table 8 that in 2007-08 the top 10 players imported formulations worth $78.2 million. This amounts to 85 per cent of the total formulation imports. Eight out of these 10 firms are foreign firms accounting for 71 per cent of the total formulation imports. Though all of these were operating in India in 1990-91, only three had imported formulations with all the three being foreign firms.

It is increasingly becoming clear that foreign firms tend to resort to imports rather than local production despite the cost advantages the country has. The liberalization of import licenses seems to have encouraged imports especially by foreign firms. Imports of formulations now constitute as high as 22 per cent of total sales of firms (Fulford India). However, import of formulations constitute only a minor share in pharma trade, and so this has not turned into an alarming situation.

Table 9 shows the therapeutic wise share in exports and imports of formulations. This categorization is based on ITC chapters 300220, 300230 and the 6-digit classification given by DGCIS for ITC chapter 3004. For products falling under 'others' category in chapter 300490, the relevant sub-classifications were used. Details of classification of ITC chapters is given in annexure 4.1.

Table 9: Therapeuticwise Share in Exports and Imports

	Exports (%)		Imports (%)	
	1990-91	**2007-08**	**1990-91**	**2007-08**
Antibiotics	17.4	24	10.2	3.3
Vitamins	19.4	5.8	0.3	1.0
NSAIDS	1.9	5.7	0.0	0.1
Antihistaminics, antacids, antiulcer, antiemitics and other gastrointestinal drugs	0.0	4.8	0.0	0.3
Antihypertensives	0.1	4.7	0.0	0.5
Anthelmintics, antiamoebic and antifungal drugs	0.1	3.6	0.1	0.6
Vaccines	1.7	3.3	13.5	10.2

Table 9 continued

Table 9 continued

Hormones	0.0	2.2	2.0	15.0
Anticancer	0.0	1.8	0.0	1.2
Ayurveda, homeo, unani	3.7	1.5	3.7	0.9
Drugs containing Alkaloids	0.3	1.1	0.1	0.1
Anti TB, antileprotic & anti malarial	0.2	0.6	0.5	0.4
Other pharmaceuticals	55.2	41.0	69.6	66.2
Total	100.0	100.0	100.0	100.0

Source: DGCIS.

In exports, antibiotics account for about one-fourth share followed by vitamins and NSAIDS in 2007-08. Antibiotics had a share of 17.4 per cent in 1990-91. The share of vitamins which was the leading category in 1990-91 has reduced significantly by 2007-08. India did not have any export of anticancer drugs in 1990-91 and in 2007-08 it accounted for 1.8 per cent of the formulation exports valued at $ 62.3 million. The other major observation in the export front is the decline in the share of alternate therapies such as ayurveda, homeo and unani. There have been import restrictions in the EU and US on the products of Indian medicaments system due to safety concerns.

In imports, hormones are the leading category with 15 per cent share in 2007-08 followed by vaccines with 10.2 per cent share. It should be noted that hormones had only 2 per cent share in 1990-91. The share of antibiotics has declined from 10.2 per cent in 1990-91 to 3.3 per cent in 2007-08. Vaccines is one of the emerging sectors in India, which was once considered to be a low margin business. The vaccine market in India is expected to grow by over 10 per cent and the boosting factors are increasing public and private health spending, the birth of 25 million babies every year and more infectious and chronic diseases. There is a dominant presence of MNCs in the Indian vaccine market with a host companies like Wyeth, GSK, Sanofi-Aventis and Eli Lilli launching a vast array of innovative products. Vaccines are available now for cervical cancer, pneumonia, rotavirus, hepatitis A, heparins and chicken pox. In 2008, GSK launched three paediatric vaccines- infanrix, boostrix and rotarix.[28]

4.1.1. Future of Formulation exports

We have already seen that TRIPS regime did not have adverse impacts on

the export of formulations and Indian firms are increasingly engaging in exports to regulated markets of US and EU as well as other markets in Africa and Asia. Will this scenario sustain for long? The emerging evidences on confiscation of shipments containing generic medicines from India in the pretext of 'anti-counterfeit drive', enforcement of TRIPS Plus IPR standards through bilateral and multilateral agreements, increasing application of non tariff barriers (NTBs) and the mounting competition from China especially in Asia and Africa region cast shadow on the prospects of formulations' exports. This section is an analysis of the threats to exports of Indian pharma products.

Anti-Counterfeiting initiatives

Recent incidents of confiscation of Indian shipments of generic medicines destined to countries in Latin America in European ports *en route* has to be viewed in the context of global developments. EC held that the confiscations are based on EU Council Regulation 1383/2003 which provides for customs to detain goods suspected of infringing IPRs including patents, even when goods are in transit.[29] These drugs were authorised generics as they did not have valid patents either in India or in the importing countries. Article 51 of TRIPS provides for adopting procedures to enable a right holder, who has valid grounds for suspecting that the importation of goods involving infringement of IPRs to lodge an application in writing with competent authorities for suspension by customs authorities of the release into free circulation of such goods. Article 52 of TRIPS clarifies that any right holder initiating procedures under Article 51 will have to provide adequate evidence to prove that there is prima facie an infringement under the laws of the country of importation. Article 41.1 of TRIPS requires that enforcement procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. The export of approved generic drugs that are not covered by patents in either the country of export or the country of import will qualify as legitimate trade.

The current initiatives extend the scope of coverage of the counterfeit and pirated goods beyond what is considered by TRIPS as counterfeit and piracy (trademarks and copyrighted products) to include patents, plant variety

protection laws and geographical indications. Such developments in IP front are definitely harmful for the interests of Indian generic pharma industry as legitimate trade of authorised generic drugs can be affected. INTERPOL, one of the core organizers of 'Global Congress on Combating Counterfeiting' which was instrumental in the G8 taking up the issue of counterfeiting and IPR enforcement resulting in World Customs Organization coming up with 'Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE)' and the negotiations on a plurilateral Anti Counterfeiting Trade Agreement (ACTA), explains that "trademark counterfeiting and copyright piracy are serious Intellectual Property (IP) crimes that defraud consumers, threaten the health of patients, cost society billions of dollars in lost government revenues, foreign investments or business profits and violate the rights of trademark, patent, and copyright owners".[30] The Kenyan anti-counterfeit act should be seen in this context. The Kenya Anti-Counterfeit Act 2008 states that copies or generic versions of all products having patent protection in Kenya or elsewhere can be considered 'counterfeit' in case of an intellectual property dispute with the patent holder. This may subject a genuine drug exported from India to Kenya as counterfeit drug if the company which is holding a patent of that particular drug in some other country raises a dispute over it. The Secretary General of Indian Pharmaceutical Alliance, DG Shaw is reported to have commented that the Kenyan Act would sound the death knell of India's pharmaceutical exports to Africa as other may follow the suit.[31] Following the Kenyan Act, a few African countries – Nigeria, Uganda and Libya – banned import of drugs from India. During the meeting with the Ambassadors/High Commissioners from Africa on 24th April 2009,[32] many of the Ambassadors pointed out that they are not aware of the global developments on the anti-counterfeiting and they were under the impression that the so called counterfeit drugs are sub-standard drugs. They were completely ignorant about the fact that it was the genuine generic medicines that have been branded as counterfeits.

FTAs with TRIPS Plus provisions

The increasing tendency of the developed countries to enforce TRIPS Plus provisions through bilateral FTA in areas like Data Exclusivity has the potential of hampering Indian pharma exports. For example, para 22 of the

US-Jordan FTA states "it is understood that, in situations where there is reliance on evidence of approval in another country, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use". The U.S-Jordan FTA includes TRIPS-plus language on registration data that requires Jordan to provide exclusivity for the same period as granted by the country where the data was filed, if it was filed outside of Jordan. Thus, Jordan may be made to honour United States' terms of protection - or even the longer term of protection afforded in the European Union, which is not a signatory to the U.S-Jordan FTA, and requires a longer exclusivity period than the United States - without specified exceptions. Jordan is also required to provide data exclusivity for a period provided in those countries from the date of marketing approval. In other words, if Jordan relies on test data filed in European Union in 2000 for approving a drug in 2007, it has to grant data exclusivity until 2017 for the data referring to that drug whereas in European Union the exclusivity would have got over by 2010. Such provisions would delay the entry of generics and Indian exports would be affected.

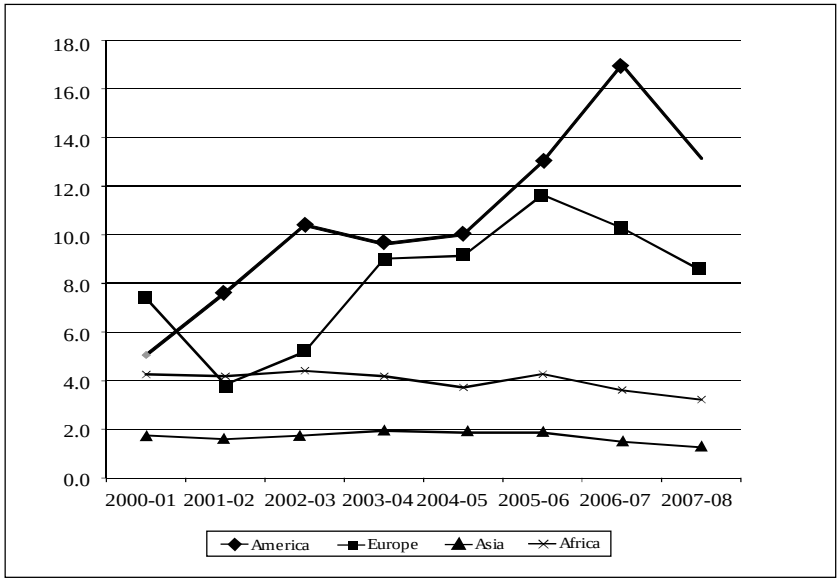
Non – tariff barriers

There are a range of non-tariff barriers (NTBs) that restrict the export of Indian Pharma products to foreign markets. For example, Indian pharma firms do not export to Japan due to language barriers and other requirements such as pharmaceutical export companies have to keep an inventory of product for five years and these firms are required to partner with Japanese enterprise/trading houses for local marketing. The generic penetration is very low in Japan the Government of Japan has decided to increase the generic use from current level of 17 per cent to 30 per cent by 2012. It will be difficult for most Indian firms to utilize this opportunity due the NTBs facing them in the Japanese market. The expansion in the generic market was a major factor in Japan's Daiichi Sankyo taking over India's flagship firm Ranbaxy. Daiichi will have its nose in front in the expanding generic market because the company is getting Ranbaxy's cheap, high-quality manufacturing facilities.[33] There are similar kinds of NTBs in countries like Argentina preventing Indian firms from exploiting market opportunities.[34]

Competition from other countries – China

The threat perception from China is quite real in the case of formulation exports. China is following a strategy of focusing on the 'high volume low value' non-regulated markets of Asia and Africa to which Indian firms especially the small and medium ones are also focusing their attention. China exports more than three-fourth of its formulation exports to these two regions. Share of exports to these two regions has increased from 75 per cent in 1994-95 to 82 per cent in 2006-07. In America and Europe, India has a clear cut advantage as the ratio of India's exports of formulations to China's exports of formulations is increasing. Higher the value of the ratio, larger is the advantage. In the case of Asia and Africa, the ratio is not only very small but is coming down. This can be seen from Figure 2.

Figure 2: Ratio of India's Exports of Formulations to China's Exports of Formulations



Source : DGCIS and China Customs.

The threat of competition from China in Asia and Africa, which is clear from the declining ratio of imports of India to China, is further

confirmed by the higher rate of growth of export of formulations from China to these regions.

Table 10: Average Annual Growth of Exports of Formulations from India and China from 2003-04 to 2007-08

America	India	34.6
	China	30.2
Europe	India	26.7
	China	17.1
Asia	India	16.6
	China	24.4
Africa	India	25.1
	China	33.2

***Source**:* DGCIS and China Customs

***Note**:* Data for China is available in the calendar year.

It is clearly seen from Table 10 that Chinese exports to Asia and Africa are growing at rates way ahead of India. During the last 5 years Chinese exports to Asia and Africa has grown at 24.2 per cent and 32.7 per cent respectively whereas the growth of Indian exports was 16.6 per cent and 25.1 per cent respectively. In America and Europe Indian export is growing at a higher rate.

4.2. Intermediates and Bulk Drugs

Data on the export and import of intermediates and bulk drugs is taken from ITC chapter 28, 29 and 3003. The Drug Price Control Order of India defines 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 specified 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" and intermediates are the substances used for the production of bulk drugs. Bulk drugs are also known as active pharmaceutical ingredients (APIs). Bulk drugs can be of two kinds – bulk drugs constituting of single constituent and bulk drugs constituting of two or more constituents. Goods under chapter 3003 which is described as

'medicaments constituting of two or more constituents which have been mixed together for therapeutic or prophylactic uses not put up in measured forms or in forms or in packings for retail sale' represents the latter category.

The bulk of the trading activity[35] in pharmaceutical products is accounted for by intermediates and bulk drugs - 62.3 per cent in 2007-08. It contributes 33.9 per cent of exports and 88.5 per cent of imports in 2007-08. While its share in exports has declined from 62.2 per cent in 1990-91 to 33.9 per cent in 2007-08, its share in imports has remained more or less the same.

Table 11: Share of Exports and Imports of Intermediates and Bulk Drugs - Regionwise

	Exports				Imports		
	Africa	**America**	**Asia**	**Europe**	**America**	**Asia**	**Europe**
1990-91	3	14	23	60	22	25	53
1991-92	4	16	30	49	18	36	46
1992-93	7	15	35	42	19	38	42
1993-94	7	17	34	41	15	41	41
1994-95	5	15	38	42	15	53	31
1995-96	6	17	41	36	16	50	31
1996-97	5	18	43	32	19	54	25
1997-98	6	20	41	32	20	58	20
1998-99	8	22	44	26	17	55	26
1999-00	8	20	43	28	17	54	28
2000-01	7	23	42	27	12	60	27
2001-02	6	26	40	26	12	59	28
2002-03	7	29	37	26	13	59	26
2003-04	7	27	35	30	12	62	23
2004-05	7	28	35	29	12	65	21
2005-06	9	20	41	30	11	66	21
2006-07	11	23	36	29	12	70	16
2007-08	12	22	37	28	11	68	18

Source: DGCIS.

It is very clearly seen from Table 11 that there is a shift in the focus of exports from Europe to other regions. The exports to Europe have declined from 60 per cent in 1990-91 to 28 per cent in 2007-08. Asia has become the leading export destination now accounting for more than one-third of total

intermediates and bulk drugs exports. The combined share of Africa and America has increased from 17 per cent in 1990-91 to 34 per cent in 2007-08. Though the share of exports to Europe has declined, the exports in terms of value has not declined; it has grown from $179.7 million in 1990-91 to $510.7 million in 2007-08.

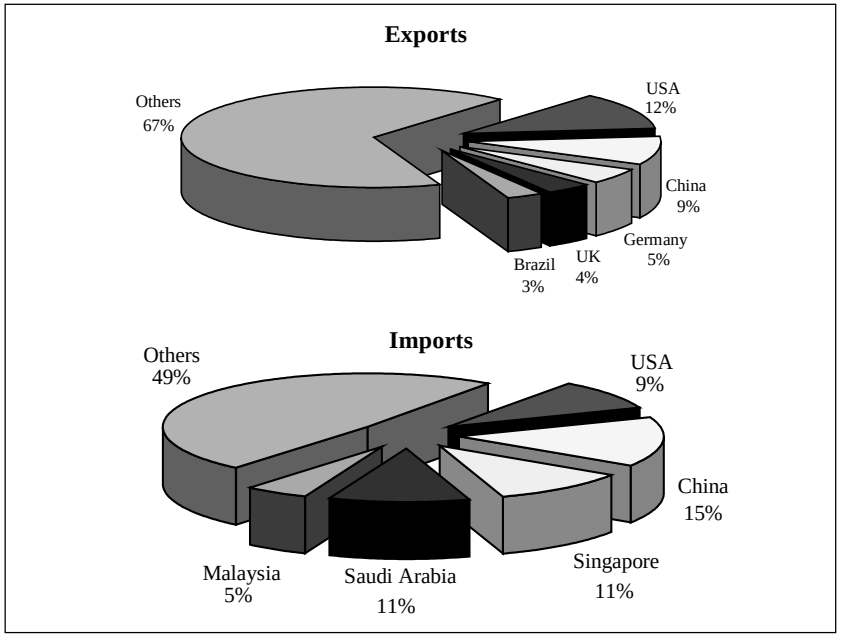
Bulk of the exports to Asia is destined to China, Singapore and Thailand accounting for 40 per cent of exports to Asia. Exports to China needs a special mention as it has grown at average annual growth rate of 100 per cent during the period between 1990-91 to 2007-08, from worth $0.1 million to $171.7 million. US accounts for more than half (54.5 per cent) of the exports to America followed by Brazil and Mexico. These three countries together account for 79 per cent of the exports to America. In terms of growth, exports to Brazil and Mexico is growing much faster than the exports to US. Export to Mexico has grown at average annual growth rate of 56.5 per cent and to Brazil at 40.9 per cent while the exports to US grew at 14.5 per cent during the period between 1990-91 and 2007-08. In Europe, Germany is the largest destination country accounting for 17.6 per cent of exports to the region followed by UK and Netherlands. Nigeria and South Africa are two major countries in Africa into which intermediates and bulk drugs are exported. These two countries accounted for 25.5 per cent of export of this category to Africa in 2007-08.

As predicted by the literature, India has been able to not only maintain its exports of intermediates and bulk drugs to western markets but accelerated its rate of growth in western markets in America and in Africa and Asia.

In imports, we already saw that there has been nine fold increase from $579.7 million in 1990-91 to $5154 million in 2007-08. There is a tremendous growth in the imports from Asia. Imports from Asia have increased by 24 times from $144.7 million to $3527.4 million resulting in the share of Asia in imports increasing from 25 per cent in 1990-91 to 68 per cent in 2007-08. China, Singapore and Saudi Arabia are the major suppliers from Asia. China alone accounts for more than one-fifth (22.3 per cent) of the imports from Asia. The share of imports from Europe and America has registered significant decline, but the value of imports has not declined. In the literature,

scholars did not express any apprehension on the import of intermediates and bulk drugs. Probably, due to the feeling that India has a strong bulk drug industry with the characteristics of low cost of production, they might not have expected any threat of increased imports.

Figure 3: Top Five Destinations of Exports and Sources of Imports Intermediates and Bulk Drugs in 2007-08



Source : DCCIS.

US is the single largest destination of exports accounting for 12 per cent of exports followed by China, Germany, UK and Brazil. These five countries account for 33 per cent of total export of intermediates & bulk drugs. Growth in export to China and Brazil is remarkable: it has grown from less than $1 million in 1990-91 to $171.7 million to China and $60.9 million to Brazil in 2007-08.

In imports, Asian countries have a predominant presence in the list of top 5 sources of supply. Four out of the five are from Asia. Whereas in

1990-91 there was only one country in the list of top five-Japan. China is the single largest source of import of intermediates & bulk drugs accounting for 15 per cent of imports. In 1990-91, the share of China was very negligible-0.3 per cent. In the intermediates and bulk drug business with China, India is increasingly becoming a net importer. Trade deficit in intermediates & bulk drugs with China is much more than the over all trade deficit in Pharma sector as a whole in 2007-08. It has grown from $1.5 million in 1990-91 to $616.4 million in 2007-08. Reducing the dependence of imports from China would have major positive impacts on the trade balance of the sector.

Report of the Task Force on Strategy for Enhancing Exports of Pharmaceutical Products[36] has pointed out that Indian pharmaceutical sector has been sourcing its requirements of chemical intermediates and bulk drugs in large quantities from China over some time; at times almost 60 to 70 per cent of our requirement of intermediates. The recent crack down of chemical industry in China in order to enforce environmental legislation resulted in shortage of supply and subsequent hike in prices affecting not only the bottom lines of Indian companies but the very existence of many firms. Due to shortage of raw materials and their rising prices, close to 50 bulk drug manufacturing units have been closed down while others have cut down manufacturing of loss making drug categories.[37] India's dependence on China is such that it does not have the adequate manufacturing capacity to meet the demand for intermediates and bulk drugs, if supplies from China are stopped for unforeseen reasons. Recently when Government of India mooted imposing safeguard duty on Chinese antibiotic bulk drugs, Indian industry resisted the move saying that there is only one manufacturer in India producing the penicillin and erythromycin bulk drugs and it does not have the capacity to meet the demand of the Indian market.[38] The report also points out that the fermentation sector, one of the segments of biotechnology that has been instrumental in shaping Indian antibiotics segment in the early decades of growth of Indian Pharmaceutical industry, has moved to China due to lower energy costs there. In general, China is stronger in biology and rapidly improving its skills. API companies in China are similar to India except that China is a dominant force in fermentation technology. Largescale state investment in research and heavily subsidized infrastructure facilities like electricity China has enabled their firms to strengthen their foothold in

the production of a range of vaccines and biologics - hepatitis vaccines, recombinant insulin, interferon and other generic therapeutic biologics. The report warns that potential opportunities if harnessed only by China in this area may mean loss of business in such APIs.

The Task Force recommended that India must reduce its dependence for these intermediates on China. India needs to identify other alternative markets which can be equally competitive and alternatively there is a strong need to review domestic capacities for supply of drug intermediates so that Indian drug industry is not over dependent on one country. India should create a policy environment where in the small and medium enterprises position themselves appropriately to address the back-end needs of the pharmaceutical industry.

5. Conclusion

Indian pharmceutical 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 - formulatins, as the share of this category has increased from about one-third in early 1990s to two-third in 2007-08. 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 2007-08 and that of the industry as a whole has increased from less than 10 per cent in 1990-91 to 35 per cent 2007-08. 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. The pharmceuticals sector is having a negative and grwoing trade balance, owing to the increased imports of intermediates & bulk drugs, may indicate the new strategy of firms to import raw matrials and intermediates and process them into formulations. Abolishion of the ratio parameter linking the production of intermediates and bulk drugs to the production of formulations

might have led to the adoption of this strategy. Though in the exports front the the industry is performing well, the expansion has been checked by various factors such as incresing competition from China, anti-counterfeit drives and application of non tariff barriers.

The expansion of exports, especially of formulations, is contrary to what has been anticipated. It was expected that the industry would focus more on the export of intermediates and bulk drugs; but the industry chose to focus more on value added segments. However, in imports there has not been any major increase in the cetegory of formulations. The limited scope of patentability in the patent law has limited the number of patented medicines and thus reduced the scope of import of formulations. The structure of imports though remain the same with 90 per cent of imports are constituted by intermediates & bulk drugs, the dependece has become focused more on one country-China. At times 60-70 per cent of the requirement of the intermediates are met by imports from China alone. India is having a huge trade deficit with China in intermediates and bulk drugs of $616.4 in 2007-08, which is more than the trade deficit of the sector as a whole in the same year. Moreover, excessive dependence on China puts the industry at the risk of any disruption in the supply from one country affecting the production base of the whole industry. In fact, this has happened in the recent past where in almost 50 Indian drug manufacturing units had to be shut down. India needs to identify other alternative markets which can be equally competitive. And at the same time there is a strong need to review domestic capacities for supply of drug intermediates so that Indian drug industry is not over dependent on imports. This is an industry with major security implications and building of domestic capabilities becomes crucial from a strategic perspective. India should create a policy environment where in the small and medium enterprises would position themselves appropriately, as it did till a few years back, to address the back-end needs of the pharmaceutical industry.

Annexure I.

ITC Chapters	Categories
300220	Vaccines for Human Medicine
300230	Vaccines for Veterinary Medicines
300410	Containing Penicillin or derivatives thereor, with penicillillanic acid structure or streptomycins or their derivatives.
300420	Containing other antibiotics
30042011-20	Cephalosporins and their derivatives
30042031-39	Fluroquinolones
30042041-50	Tetracyclines
30042061-70	Macrolide
30042091-99	Other
300430	Hormones
300431	Containing Insulin
300439	Other Hormones
30043911-19	Pituitary hormones, prednisolone, dexamethasone, danazole, other progrestogen and oestogen group hormones
30043921-22	Gonadotrophines and Luteinising hormones
30043990	Other Hormones
300440	Containing alkaloids or derivatives thereof but not containing hormones
300450	Other medicaments containing vitamines or other products of heading 2936
30049011-15	Ayurveda, Unani, homeo, Siddha, bio-chemic system medicaments
30049021-29	Anthelmintics drugs, antiamoebic and other antiprotozal drugs, antifungal drugs.
30049031-39	antihistaminics drugs, antacids preparations, antiulcer drugs, antiemitics and other gastrointestinal drugs
30049041-49	Anticancer drugs
30049051-59	Antitubercular drugs, antileprotic drugs, anti malarial drugs
30049061-69	Nonsteroidal antiinflammatory, analgesics and antipyratic drugs
30049071-79	Antihypertensive drugs
30049081-99	Other

Endnotes

[1] Private firms were denied license for production in the case of 5 bulk drugs, bulk drugs produced through the use of recombinant DNA technology and bulk drugs requiring the use of nucleic acid as active principle in the modification in DP 1986. Recently, industrial license for all kinds of drugs including those bulk drugs produced through the use of recombinant DNA technology and bulk drugs requiring the use of nucleic acid and specific cell tissue targeted formulations have been done away with.

[2] Automatic approval of investment upto 51 percent was granted in 1994. It was increased to 74 per cent in 2000 and 100 percent in 2001.

[3] An ordinance was issued on 31st December 1994 amending the Patents Act 1970 to introduce the mail-box provisions. But the amendment was not passed by Parliament. The United States dragged India into a dispute in the WTO (WT/DS50) on the failure of providing mail-box facility where the decision went against India.

[4] It introduced 64 amendments (Basheer 2005).

[5] The study was based on United States' exports (of all manufacturing industries at two digit level) to 92 countries in 1992.

[6] The *market power effect* would reduce the elasticity of demand facing the foreign firm and would ordinarily induce the firm to export less of its patentable product and *market expansion effect* would increase the elasticity of demand and firms would export more.

[7] The cost of building a new manufacturing facility in India complying with international regulatory norms is about one-fourth the cost of setting up a similar facility in the US or Europe. The cost of an Indian based laboratory analyst/chemist is one-fifth to one-eight of the US cost. Higher-level Indian scientists are well trained yet earn about a third of their Western counterparts' salaries.

[8] Issues in the trade figures for pharma sector, available from both government and industry sources have already been published. See Joseph (2009).

[9] Twenty one per cent of imports of BDMA in 2004-05 consist of intermediates. BDMA is the only source giving separate figures for intermediates. IDMA gives the list of intermediates & bulk drugs together; thus intermediates cannot be separated out from this list.

[10] The figures are same for all the years, except for the import figure for 2005-06. The DGCIS figure for import of pharmaceuticals in 2005-06 is Rs1949 crore. The DGCIS data was accessed from India Trades of CMIE.

[11] The term 'pharmaceuticals' and 'drugs' mean the same.

[12] Board here refers to the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C (relating to Ayurvedic, Siddha or Unani drug) and the Drugs Technical Advisory Board constituted under section 5 (relating to any other drug).

[13] Wikipedia, defines fine chemicals as 'pure, single chemical substances that are commercially produced with chemical reactions into highly specialized applications. Fine chemicals produced can be categorized into active pharmaceutical ingredients and their intermediates, biocides, and speciality chemicals for technical applications'. Pharmaceutical fine chemicals include both intermediates for drug production and bulk active drugs ready to be compounded with inert pigments, solvents, and fillers—called excipients—and made into dosage forms.

[14] Data for USSR has been collected only for the exports of formulations (ITC chapter 3004, 300220 & 300230) and bulk drugs of two or more chemical substances (ITC chapter 3003) as these were the categories in which India had significant trade engagement in pharmaceutical products with USSR/CIS countries. In 1993-94 the CIS countries, former USSR, accounted for 21 per cent each of exports of formulations and bulk drugs of two or more chemical substances and only 2 per cent of intermediates and bulk drugs of single chemical substances.

And imports from CIS countries was negligible in 1993-94 i.e., less than 1 per cent in different pharmaceutical categories.

15 Its share has increased from 8 per cent in 1990-91 to 9 per cent in 2007-08.

16 I am grateful to K M Gopakumar of Third World Network for providing me this data.

17 See Padmashree G Sampath (2008), 'India's Pharmaceutical Sector in 2008-Emergins Strategies and Global and Local Implications for Access to Medicines', study commissioned by DFID.

18 See Greene (2007).

19 See http://chemicals.nic.in/pharma1.htm

20 Seven years from the date of application or five years from the date of sealing of the patent, whichever is earlier.

21 See Department of Commerce, Govt. of India (2008).

22 KPMG (2006), The Indian Pharmaceutical Industry: Collaboration for Growth, p 9 in Padmashree G Sampath (2008).

23 See Department of Commerce, Govt. of India (2008).

24 These drugs have been manufactured by Schering-Plough, Abbot and Sanofi Aventis and Nycomed respectively. For details see 'Glenmark gets first to file status for three drugs', *The Times of India*, 3 July 2009.

25 See Chaudhury (2007) and *Business Standard* 'USFDA door wide open for Indian pharma cos', 6 March 2009.

26 Better known as "President's Emergency Plan for AIDS Relief", or PEPFAR.

27 For details see United States International Trade Commission (2007)

28 Economic Times, Pharma MNCs want to Take a Shot at India's Vaccine Market, 12 March 2009.

29 Trade Policy Review of EC – 2009 in WTO. Document WT/TPR/238, questions from India.

30 See: http://www.interpol.int/public/financialcrime/intellectualproperty/default.asp.

31 http://www.eac.int/customs/component/content/article/56/56.html

32 This meeting has been organized by the Pharmexcil and Ministry of Commerce and Industry, Government of India.

33 Reji K Joseph, 'The Ranbaxy model and consolidation in pharma sector', *The Economic Times*, 24 June 2008, http://economictimes.indiatimes.com/articleshow/3158463.cms

34 For a detailed discussion of NTBs facing Indian firms please see Shashank Priya and Reji K Joseph (2009), 'Review of Trade Policies of India's Major trading Partners', http://wtocentre.iift.ac.in/Books/Trade per cent20Barrier per cent20Report.pdf

35 (Export of intermediates & bulk drugs + Import of intermediates & bulk drugs) / (Total export of pharmaceutical products + Total import of pharmaceutical products).

36 See Department of Commerce, Govt. of India (2008).

37 *The Economic Times*, 'Sick Bulk Drug Cos May Get Life Support', 15 August 2008.

38 *The Economic Times*, 'Pharma Industry Against Safeguard Duty on Chinese Antibiotics', 10 April 2009.

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