

# Pharmaceutical Trade: India's Growth Trajectories

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T. C. James

Discussion Paper # 261



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विकासशील देशों की अनुसंधान एवं सूचना प्रणाली



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# Pharmaceutical Trade: India's Growth Trajectories

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**Abstract:** The Indian pharmaceutical industry, particularly the formulations, is one of the significantly important industries not only for its economy but also for the world economy as it is being recognised as 'Pharmacy of the World' for supplying low-cost generic drugs to the global economy, including the USA. Although this segment of the pharmaceutical industry has attained momentous growth, mainly in the last two decades, the industry requires serious policy attention from the government to resolve current challenges it is facing and to meet the standards of technological developments, such as biotechnology, gene technology, bio-similar, artificial intelligence, 3D printing, Machine Learning, AR-VR, Digital Apps, Blockchain, Organ-on-Chips, etc. which are currently happening in the global economy. The discussion paper reviews historical growth of the pharmaceutical industry and trade, mainly India's trade in formulations since 1966, how policies and programmes that in the past contributed to its development, over-time price-competitiveness with major exports, the current status and challenges and concludes with recommendations.

**Keywords:** Pharmaceuticals, formulations, trade, price-competitiveness, efficiency.

## Introduction

The pharmaceutical industry is not only one of the most important industries of the Indian economy but also it holds a distinct position in the world economy. By volume, it ranks third in the world and in terms of value it has attained 10<sup>th</sup> position (James, 2020). The contribution of this industry in India's Gross Domestic Product (GDP) was 1.72 per cent in 2019-20.<sup>1</sup> This industry employs directly and indirectly over 2.7 million people in high-skill areas like Research and Development (R&D) and manufacturing [Indian Pharmaceutical Alliance (IPA), 2019].

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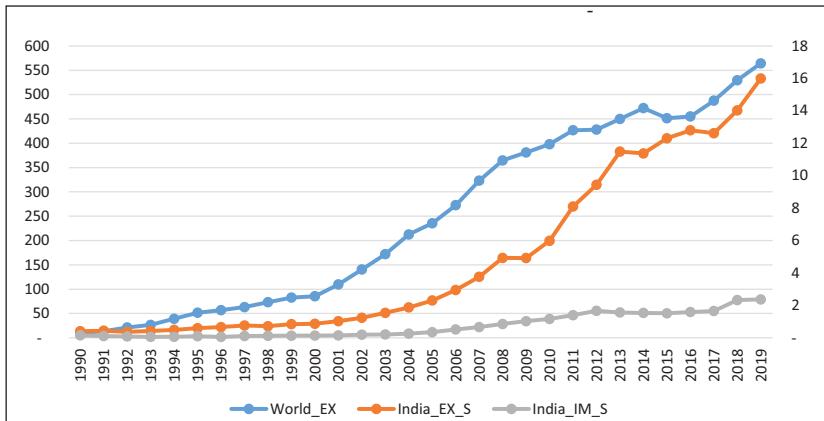
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The pharmaceutical industry comprises two sectors, drugs and medical devices. The drugs sector can further be segregated into Active Pharmaceutical Ingredients (APIs) or bulk drugs, formulations, and vaccines.

This discussion paper explores mainly formulation segment of the pharmaceutical industry, the policy and regulations contributed to its growth and other related issues and challenges it is facing currently. This segment includes both patent-protected drugs and generics.<sup>2</sup> In the generics drugs, India has been holding a strong position in the world economy for many decades. It is the second-largest producer of generic drugs, after China. India is the supplier of 60,000 generic brands across 60 therapeutic categories.<sup>3</sup> This industry fulfils more than 50 per cent of World's requirements for various vaccines and about 40 per cent of United States of America (USA) demand for generic drugs and 25 per cent of all medicines imports of United Kingdom (UK) are met by Indian pharmaceutical industry (Mishra & Sathyaseelan, 2019). In addition to this, more than 80 per cent of the antiretroviral drugs, which are used to combat AIDS (Acquired Immuno Deficiency Syndrome), is supplied globally by Indian pharmaceutical firms. In the segment of generic drugs, the major pharmaceutical companies are Sun Pharma, Cipla, Dr Reddy's Labs., Lupin, etc.

In the last three decades, the global trade in formulations<sup>4</sup>, which is one of a vital segment of the pharmaceutical industry, has grown manifolds. The global exports in formulations have increased from \$ 10 billion in 1990 to \$ 564 billion in 2019 (Figure 1). Between 2000 and 2008, the global formulation exports grew at a significant pace, registering 20 per cent compound annual growth rate (CAGR). After that, it grew at just 4.4 per cent CAGR till 2014; declined in absolute terms in the following year (2015); recovered in very next year, 2016; and since then, it has been growing at around 5.7 per cent CAGR. So, the pharmaceutical industry, like other industries, was also severely affected by the global financial crisis (2007) and the European financial crisis (2009-12).

**Figure 1: World Exports and India's Trade in Formulations:  
1990-2019 (\$ Billion)**



**Source:** Authors' estimation using WITS<sup>5</sup>, World Bank online database

**Note:** \_S denotes for the secondary axis.

In relation to value, the global formulations industry is largely dominated by Germany (15.3 per cent), Switzerland (14.6 per cent), Ireland (9.3 per cent), Belgium (9 per cent) and the United States of America [USA] (8.3 per cent) as they together accounted more than 56 per cent share in world's formulation exports (Table 1). With respect to volume, however, the sequence of the ranking of the major countries in descending order is following; Germany (13.8 per cent), France (8.9 per cent), China (8 per cent), India (5.1 per cent), Italy (5.1 per cent) etc. The two countries, the United Kingdom and France, which were a significant contributor to World's formulation exports in 1996,<sup>6</sup> both with respect to value and volume, recorded a significant decline in their share in 2019. In 1996, Ireland (7.2 per cent) was another important country, in relation to volume in exports, which registered a decline in share. Further, it is worth noting that India's share in the value of global formulation export only picked up from 2005 onwards only while its share, in relation to volume, registered consistent rise since 1996.

The difference between share in value and volume of exports of the countries also reflect prices at which pharmaceutical products are supplied by them to the world economy. For instance, Switzerland has continuously remained high price drug supplier to the world since 1996. Likewise, other countries, which were exporting pharmaceutical at high prices in 2019 were Ireland, Belgium, USA and Netherlands. On the other hand, China and India have been supplying significantly cheap drugs to the world since 1996 as reflected by significant differences between their shares in value and volume. In 2019, in terms of value, China's and India's share were 1.2 per cent and 2.8 per cent respectively whereas, with respect to volume, their respective shares were 8 per cent and 5.1 per cent. Further, between these two countries, China seems to be more price-competitive at the aggregated level, reflecting clearly that Chinese government and its pharmaceutical companies are making significant efforts to improve its position in the world economy.

**Table 1: Major Countries' Share in Value and Volume of World Exports of Formulation (%)**

Country	1996		2000		2005		2010		2015		2019	
	V	Q	V	Q	V	Q	V	Q	V	Q	V	Q
Germany	13.6	10.6	12.2	11.0	14.4	10.7	14.9	13.7	15.8	14.0	<b>15.3</b>	<b>13.8</b>
Switzerland	11.0	3.6	9.4	3.1	9.3	2.5	11.2	2.5	13.2	2.3	<b>14.6</b>	1.9
Ireland	3.9	<b>7.2</b>	4.6	6.7	6.6	5.2	7.5	4.4	6.9	3.6	9.3	4.4
Belgium	0.0	0.0	6.9	6.0	13.8	5.9	11.5	5.3	9.1	4.4	9.0	4.8
USA	8.3	9.6	11.1	12.2	8.5	10.4	9.2	5.6	9.5	4.1	8.0	4.2
France	10.6	11.7	10.6	10.2	9.0	8.1	8.2	8.2	6.5	7.8	6.2	<b>8.9</b>
Italy	5.0	5.3	6.2	4.4	4.9	5.8	4.0	5.9	4.1	5.4	5.3	5.1
UK	12.6	9.3	11.2	7.4	8.5	9.2	8.1	11.1	7.7	4.9	4.6	4.4
Netherlands	4.2	2.7	4.2	2.3	4.1	2.6	3.1	2.3	3.4	2.0	4.2	1.7
India	1.2	4.8	1.0	5.3	1.0	5.4	1.5	0.5	2.7	8.4	<b>2.8</b>	<b>5.1</b>
China	0.6	3.3	0.5	2.3	0.3	2.3	0.8	4.9	1.1	7.0	1.2	<b>8.0</b>

*Source:* Authors' Calculation using WITS, World Bank online Database.

## **The Context of the Study**

Globally, the Indian pharmaceutical industry is recognised as the ‘Pharmacy of the World’ due to its supply of low-priced drugs to the world, including developed countries, namely, the USA, etc. The recognition it has attained in the international market in this industry is a result of some of the key policies and regulations implemented in the past, viz., Patents Act 1970, Foreign Exchange Regulations Act (FERA) 1973, Drug Policy (NDP), 1978 and Drug Policy 1986. At the time of independence, however, the situation of Indian pharmaceutical Industry was not so. This industry was highly dependent on foreign countries for its domestic requirements. So, the position it has attained in the international arena is a hard-earned. In this context, the main objective of the paper is to highlight the growth trajectory of this industry, particularly on trade, since independence.

As noted in the earlier section, China has price competitiveness in this segment of the industry over India at the aggregated level. So, it would be interesting to find in which pharmaceutical products at the Harmonized System (HS) six-digit level, China has price-competitive over India and vice-versa. In this regard, the second objective of the paper is to compare India’s price competitiveness in pharmaceuticals vis-a-vis major exporting countries, including China.

Another objective of the paper is the major challenges. The paper also attempt to study currently faced by Indian pharmaceutical industry, and what sort of initiatives are required from the Indian government and pharmaceutical companies to mitigate these challenges, so that its hard-earned position in the international market could be sustained in the future. The structure of the paper is as follows: Section 3 provides an overview of the data and methodology; Section 4 discusses briefly the evolution of Indian Pharmaceutical Industry since independence and also the key policies, implemented by the Indian government, which brought out paradigm shift and ultimately contributed to its growth. Section 5 analyses India’s trade in the formulation in detail (HS six-digit level), comparison of price competitiveness with major exporting countries;

Section 6 highlights the challenges encountered by Indian pharmaceutical industry; and finally Section 7 concludes with a recap of major findings.

## Data and Methodology

In this study, pharmaceutical products or formulations referred to HS chapters from 3001 to 3004 (HS chapter at four digits) (see Appendix 1 for more detail). We have used secondary data which is available at World Integrated Trade Solution (WITS), World Bank, online database. The period considered is from 1966 to 2019. The concordance between Standard International Trade Classification (SITC) 1 and HS 1988/1992 is used to have the data from 1966 onwards. Table 2 reports products considered for formulations trade. For comparing price competitiveness, this study has used export unit values which are calculated using the value of exports divided by the volume of exports at HS six-digit level products. However, it is worth pointing out that HS products are disaggregated even further, for instance, Indian HS products are disaggregated up to eight-digit level. Therefore, unit prices calculated represents the average price for the product group at HS six-digit level.

**Table 2: Formulation Products Based on SITC1 Product Classification**

S.No.	SITC1	Description
1	54162	Organo therapeutic glands/organs & extracts
2	54163	Bacterial products, sera, vaccines
3	5417	Medicaments

*Source:* Authors' estimation using Concordance between SITC1 and HS 1988/1992.

## Indian Pharmaceutical Industry - Historical Evolution

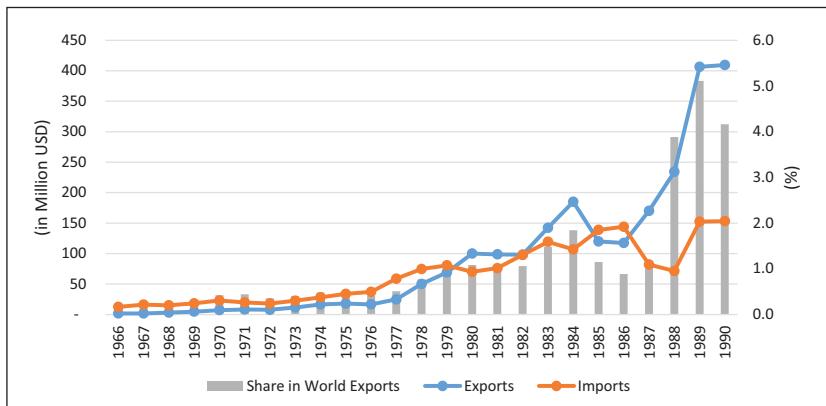
The Indian pharmaceutical industry has gone through different phases of growth since independence. Till 1972 the Patents and Design Act, 1911 was prevailing in which patent on both product and processes was permitted in all industries, including drugs and pharmaceuticals. However, this Act largely served as an obstacle in the growth of domestic drugs and pharmaceuticals industry. On one hand, MNCs used it as a tool to restrict the manufacturing of the drugs which were invented abroad

(Mueller, 2007). And on the other hand, the MNCs, themselves, were not interested in carrying out the manufacturing of pharmaceutical in India as they largely confined to formulations activities via importing most of the active pharmaceutical ingredients (APIs)<sup>7</sup> and undertaking manufacturing from the penultimate stage [Fifth FYP (Five-year plan), chapter 5]<sup>8</sup> which required relatively very less investment. Further, given the prohibition of formulations manufacturing, Indian pharmaceutical companies were reluctant to undertake investment in bulk drugs manufacturing as it required huge investment due to the highly capital-intensive nature of this industry. Owing to strenous efforts made by the government of India (GOI), basic drugs manufacturing capacity [Hindustan Anti-biotics Limited (HAL) in 1954 and Indian Drugs and pharmaceutical Limited (IDPL) in 1961] was developed in few vital bulk drugs, such as Penicillin, Streptomycin sulphate, 6-APA and Ampicillin etc.<sup>9</sup>

Furthermore, despite controlling more than 99 per cent of the patents and 80 per cent of market concentration by the MNCs, between 1947 and 1957 in India (Zambad & Londhe, 2014), indicating no competition and assurance of recouping a return on investment, and the protected environment offered to them via product patent, these hardly assisted the Indian Drugs and Pharmaceutical industry, in boosting R&D and attracting Foreign Direct Investment (FDI), technology and innovation (Mueller, 2007). On the other hand, these circumstances, surprisingly assisted the MNCs in charging relatively exorbitant prices<sup>10</sup> for most of the drugs.

Therefore, as a result of the aforementioned developments, India had to depend heavily on the MNCs of pharmaceuticals for its domestic requirements of both formulation and bulk drugs which were importing most of them. The underdevelopment of the Indian pharmaceutical industry and dependence on the foreign countries for the same is very well depicted in Figure 2. The import value of formulation stood at \$ 12 million in 1966 which increased further close to \$ 18 million in 1972. In comparison to imports, exports of formulations were significantly lower, resulting in the trade deficit.

**Figure 2: India's Global Trade in Formulations (Million USD) and Share in World Exports (%): 1966 to 1990**



*Source:* Authors' Calculation using WITS, World Bank online Database

In 1970, India through the new Patents Act, 1970 which replaced the earlier Patents and Designs Act, 1911, brought out a paradigm shift in patenting of drugs, such as permitting only process patent in food and drug substances for seven years only. The Patents Act, 1970 assisted significantly in the flourishing domestic pharmaceutical industry as it allowed them to manufacture the formulations, which were patented abroad, through reverse engineering technology. Further, India introduced the Foreign Exchange Regulation Act (FERA) in 1973 which made a distinction between FERA companies and non-FERA companies based on MNCs equity share in the companies. In addition to this, in 1978, India launched its first Drug Policy (NDP) that included compulsory provisions, such as ratio parameter, the supply of bulk drugs to non-associated formulators, etc. which statutorily bounded all pharmaceutical companies to produce bulk drugs from the basic stage. Further, all these series of developments created a favourable environment for raising R&D expenditure, resulting in the jump of R&D units significantly. The number of R&Ds units increased significantly from 40 (Private: 35 & PSUs: 5) during third five-year plan (1961-66) to 270 (Private: 230 & PSUs: 40) during sixth five-year plan (1980-85). As a result of increased R&D expenditure and R&D units, the number of indigenously developed

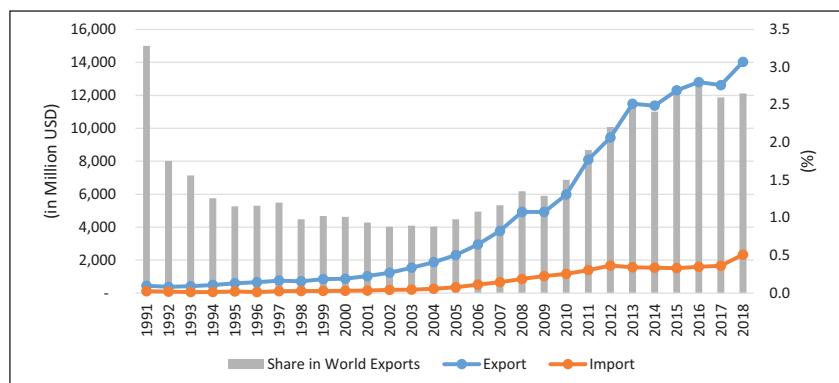
technology for bulk drugs production got a significant boost. Concerning technological capabilities, top 10 MNCs introduced technology for six bulk drugs during 1978 to 1982; four PSUs developed technology for eleven bulk drugs while top 10 Indian private companies introduced technology for only one bulk drugs boost (Mehrotra, 1989)<sup>11</sup>. All these aforementioned developments changed the course of the development path of the Indian pharmaceutical industry. This industry started being recognised as foreign exchange earning industry from foreign exchange consuming (trade-deficit). This can easily be seen from the trend of exports and imports of formulations presented in Figure 3. The formulations exports grew at around 21 per cent CAGR during 1973-77, and, after that, they rose to 33 per cent CAGR until 1984. In the following two years (1985 and 1986), however, the exports of formulation sharply declined in absolute terms. The main reason behind this dramatic slump in formulations exports was the decline in exports to the Soviet Union which was importing almost 50 per cent of India's formulation exports in 1984. In addition to this, formulations exports to the Netherlands, US, France and Nigeria also declined in 1985.

The formulations exports recorded major turnaround from 1986 onwards, when it started growing at a much higher pace and reached \$ 409 million in 1990 in just four years: from \$ 117 million in 1986, accounting for 37 per cent CAGR. As a result, India embarked on a consistent and growing trade surplus in formulation since 1986. In 1989, the share of Indian formulation exports in the world economy recorded a sharp jump to 5 per cent from less than 1 per cent in 1986.

Even after liberalisation, Indian exports of formulations grew remarkably well (Figure 3). Considering the share in the world's exports of formulations, however, India's experience was not satisfactory as it registered a continuous decline until 2004 and fell to 0.9 per cent. This decline might be due to rising competition, particularly from developed countries and the emergence of new competitors in this segment of the industry, namely, Belgium, Ireland, China (Table 1). From 2005 onwards, the Indian pharmaceutical industry again changed its growth trajectory also as well as its performance in the world's exports of formulations.

India's global share grew consistently and reached to 2.8 per cent in 2019. The exports of formulations increased from less than \$ 0.5 billion in the early 1990s to \$ 1.9 billion in 2004; after that, it enlarged almost six times until 2013 and reached approximately \$ 11.5 billion. In next four years (up to 2017), it increased just by \$ 1 billion (\$ 12.6 billion); since then, it again grew enormously and reached \$ 16 billion (2019) in just two years. Consequently, India's trade surplus in this segment of the industry has increased from merely from around \$ 300 million in the early 1990s to more than \$ 14 billion in 2019. This amplification in both value of exports and share in world's exports of formulations is significant as it took place in post-Trade Related Aspects of Intellectual Property Rights (TRIPs) regime when Indian pharmaceutical industry domestically faced intense competition from foreign companies. The implementation of various policy measures by the GOI during this phase, viz, Special Economic Zone (SEZ) (2005), various export promotion schemes (EXIM Bank, 2020), have played one of the key roles in expanding India's exports of formulations. Further, to some extent, M&As has also played some role in enlarging India's exports of formulation as one of the main objectives of the acquired Indian pharmaceutical companies by foreign companies is largely increasing exports to developed countries.

**Figure 3: India's Global Trade in Formulations (Million USD) and Share in World Exports (%): 1991 to 2018**



*Source:* Authors' Calculation using WITS, World Bank online Database.

# A Detailed Analysis of India's Trade of Formulations and its Price Competitiveness

## ***Major Export Destinations***

In 1996, the Russian Federation was India's prime export destination both with respect to value (14.7 per cent) and volume (13.7) (Table 3). With respect to value, other important destinations were Germany (7.3 per cent), US (7.2 per cent), Hong Kong (5.4 per cent), Nigeria (5 per cent). Concerning volume, however, the sequence of other major countries in descending order was Nigeria (8.4 per cent), Nepal (7 per cent), Sri Lanka (6.6 per cent), Germany (6 per cent), US (5.8 per cent). In 2018, the US has emerged as the most important destination for India's formulation exports both with respect to value (35 per cent) and volume (18 per cent) (Table 4). The United Kingdom and South Africa each accounted for almost 4 per cent share in the value of formulation exports while Nigeria and the Russian Federation each had about 3 per cent share. The comparative ranking of exports destinations, be it value-wise or volume-wise have changed considerably between 1996 and 2018 as could be seen from a comparative reading of Tables 3 and 4. The comparative ranking of a particular destination differs depending on whether the norm is value or volume. For instance, in 2018 South Africa was the third major destination in relation to the value of formulation but it was at sixth position with respect to volume (Table 4).

**Table 3: Major Destinations for Formulations in terms of Value and Quantity in 1996**

S.No.	Country	Share in value (%)	Rank with respect to value	Share in quantity (%)	Rank with respect to quantity
1	Russian Federation	14.7	1	13.7	1
2	Germany	7.3	2	6.0	5
3	United States	7.2	3	5.8	6
4	Hong Kong, China	5.4	4	1.9	13

*Table 3 continued....*

Table 3 continued....

5	Nigeria	5.1	5	8.4	2
6	Netherlands	3.9	6	3.0	8
7	Vietnam	3.7	7	3.0	7
8	Nepal	3.2	8	7.0	3
9	United Kingdom	3.2	9	2.2	10
10	Sri Lanka	3.1	10	6.6	4
	Total	56.8		57.6	

Source: Authors' Calculation using WITS, World Bank online Database

**Table 4: Major Destinations for Formulations in terms of Value and Quantity in 2018**

S.No.	Country	Share in value (%)	Rank with respect to value	Share in quantity (%)	Rank with respect to quantity
1	United States	35.1	1	18.0	1
2	United Kingdom	3.9	2	4.4	3
3	South Africa	3.8	3	2.6	6
4	Nigeria	3.0	4	5.1	2
5	Russian Federation	2.9	5	2.2	10
6	Brazil	1.8	6	0.7	35
7	Australia	1.7	7	1.4	20
8	Canada	1.7	8	0.6	38
9	Kenya	1.6	9	2.5	8
10	Philippines	1.5	10	2.1	11
	Total	57.0		39.6	

Source: Authors' Calculation using WITS, World Bank online Database

### **Major Pharmaceutical Products Exported (at HS six-digit)**

Within formulation, HS 300490 (other medicaments of mixed or unmixed products) alone accounted for almost 46 per cent share in India's formulation exports (USD 659 million) in 1996 (Table 5). The major

destinations for this product were Russian Federation (20.2 per cent), Germany (7.5 per cent), United States (6.8 per cent), Nepal (5.1 per cent), Nigeria (3.9 per cent) etc. In India's export basket of formulations, the other important products were HS 300390, HS 300420 (Medicaments of other antibiotics) and HS 300410 (Medicaments of penicillin) which together constituted around 42 per cent share. These products were largely exported to the US, Russian Federation, Germany, Hong Kong China, Vietnam, Nigeria etc. Between 1 to 4 per cent share was captured by HS 300450 (Other medicaments of vitamins), HS 300439 (Medicaments of other hormones), HS 300220 (Vaccines for human medicine) and HS 300440 (Medicaments of alkaloids or derivatives).

In 2018, however, it is significant to note that the US acquired a major share in most of the leading pharmaceuticals products exported by India (Table 6). For instance, the US captured more than 40 per cent share in other medicaments of mixed or unmixed products (HS 300490); 35 per cent share in medicaments of other antibiotics (HS 300420) exports; 24 per cent in medicaments of penicillin (HS 300410); 23 per cent share in other medicaments (HS 300390) etc. As in 1996, HS 300490 (other medicaments of mixed or unmixed products) dominated India's exports of formulations in 2018 also as this product alone accounted for more than three-fourth share in India's global exports of formulations (\$ 14 billion). Further, it is worth to note that this product is exported by India to 203 countries, including US (39 per cent), UK (4 per cent), South Africa (4 per cent), Russian Federation (3 per cent) and Nigeria (2.4 per cent). Medicaments of other antibiotics (HS 300420), vaccines for human medicine (HS 300220) and medicaments of penicillin (HS 300410) together constituted 16 per cent share and they were exported to 187, 172 and 181 countries respectively. For medicaments of other antibiotics (HS 300420), most important destinations were US (36 per cent), South Africa (4 per cent), Belgium (3.4 per cent), Nigeria (3.3 per cent) and Russian Federation (3.3 per cent) while for vaccines for human medicine (HS 300220) key destinations were Nigeria (8 per cent), Indonesia (7 per cent), Pakistan (5.4 per cent), Brazil (5.2 per cent) and Iraq (4 per cent).

**Table 5: Major Formulations Exported in 1996, their Share and Main Destinations**

S. No.	HS code	Description	Share (%)	Count of Countries	Top Five Destination
1	300490	Other medicaments of mixed or unmixed products	45.9	147	Russian Federation (20.2%), Germany (7.5%), United States (6.8%), Nepal (5.1%), Nigeria (3.9%)
2	300390	Other medicaments with >=2 constituents, not fo	17.8	129	United States (14.4%), Russian Federation (12%), Germany (6.1%), United Kingdom (4.7%), Nigeria (4.6%)
3	300420	Medicaments of other antibiotics, for retail sa	12.4	112	Hong Kong, China (22.3%), Iran, Islamic Rep. (10.8%), China (9.5%), Vietnam (5.9%), Russian Federation (5.7%)
4	300410	Medicaments of penicillins... or streptomycins.	11.5	101	Germany (13.9%), Nigeria (11.1%), Vietnam (8.2%), Russian Federation (4.9%), Netherlands (4.6%)
5	300450	Other medicaments of vitamins or other products	4.2	99	Nigeria (15.8%), Russian Federation (10.5%), Germany (9.6%), United Kingdom (6.3%), Sri Lanka (6.3%)

*Table 4 continued....*

Table 4 continued....

6	300439	Medicaments of other hormones, for retail sale,	2.9	76	Netherlands (22%), Russian Federation (11.2%), South Africa (10.9%), Vietnam (8.2%), Sri Lanka (5.6%)
7	300220	Vaccines for human medicine	1.7	76	Brazil (19.5%), Bahrain (12.6%), Egypt, Arab Rep. (8.6%), Bangladesh (8.4%), United States (6.7%)
8	300440	Medicaments of alkaloids or derivatives thereof	0.9	50	Russian Federation (44.2%), United States (27.5%), Hong Kong, China (3.5%), Mexico (3.1%), Ghana (1.6%)
9	300290	Human and animal blood; microbial cultures; tox	0.8	75	Russian Federation (16%), Italy (10.4%), Netherlands (7.9%), United Kingdom (7.2%), United States (4.5%)
10	300431	Medicaments of insulin, for retail sale	0.4	5	Russian Federation (97.9%), Uganda (1.4%), Tanzania (0.4%), Sri Lanka (0.1%), Maldives (0.1%)

**Source:** Authors' Calculation using WITS, World Bank online Database

**Table 6: Major Formulations Exported in 2018, their Share and Main Destinations.**

S. No.	HS code	Description	Share (%)	Count of Countries	Top Five Destination
1	300490	Other medicaments of mixed or unmixed products,	76.7	203	US (39.3%), UK (4.2%), South Africa (4.2%), Russian Federation (3.2%), Nigeria (2.4%)
2	300420	Medicaments of other antibiotics, for retail sa	7.2	187	US (35.6%), South Africa (3.9%), Belgium (3.4%), Nigeria (3.3%), Russian Federation (3.3%)
3	300220	Vaccines for human medicine	4.8	172	Nigeria (8.1%), Indonesia (6.9%), Pakistan (5.4%), Brazil (5.2%), Iraq (3.7%)
4	300410	Medicaments of penicillins... or streptomycins.	3.5	181	US (24.1%), UK (5.8%), South Africa (5.4%), Nigeria (4.9%), Australia (3.9%)
5	300390	Other medicaments with >=2 constituents, not fo	2.2	170	US (23%), Netherlands (5.4%), Germany (4.9%), UK (4.2%), Brazil (3.5%)
6	300450	Other medicaments of vitamins or other products	1.7	162	Nigeria (11.5%), Congo, Dem. Rep. (7.7%), US (7.3%), Myanmar (5.3%), Ghana (5%)

*Table 6 continued....*

Table 6 continued....

7	300290	Human and animal blood; microbial cultures; tox	1.4	169	US (11.9%), Ethiopia(excludes Eritrea) (5.9%), Canada (5.8%), UK (5.4%), Sri Lanka (4.5%)
8	300431	Medicaments of insulin, for retail sale	0.9	162	US (26.5%), Germany (7.3%), South Africa (6%), Malta (4.2%), Thailand (3.2%)
9	300439	Medicaments of other hormones, for retail sale,	0.6	168	US (20.5%), UK (10%), Singapore (6.1%), Nigeria (5.4%), Russian Federation (4%)
10	300432	Medicaments of adrenal cortical hormones, for r	0.4	141	US (33.9%), South Africa (6.2%), Nepal (4.7%), Algeria (4.5%), Myanmar (2.9%)

**Source:** Authors' Calculation using WITS, World Bank online Database

As noted earlier, India's imports in formulations are insignificant in comparison to its exports. In 2018, India imported about \$ 2.3 billion of formulations and the majority of them came from the US, Switzerland and Germany (Table 7). In this, \$ 2.3 billion imports, 39 per cent share was captured by HS 300490 (other medicaments of mixed or unmixed products), 21 per cent by HS 300290 (Human and animal blood; microbial cultures), 16 per cent by HS 300220 (vaccines for human medicine), 10 per cent by HS 300431 (medicaments of insulin) while HS 300439 (medicaments of other hormones), HS 300420 (medicaments of other antibiotics), HS 300190 (Substances of human or animal origin), HS 300390 (other medicaments with  $\geq 2$  constituents) accounted share between 2 per cent to 4 per cent share.

**Table 7: Major Formulations Imported in 2018, their Share and Main Sources**

S. No.	HS code	Description	Share (%)	Count of Countries	Top Five Sources
1	300490	Other medicaments of mixed or unmixed products,	39.1	81	US (22.8%), Switzerland (18.9%), Germany (13.5%), UK (5.7%), Singapore (4.8%)
2	300290	Human and animal blood; microbial cultures; tox	21.2	62	US (21.2%), Switzerland (17.4%), Germany (14.9%), France (8.3%), Italy (6.3%)
3	300220	Vaccines for human medicine	15.9	29	Belgium (32.1%), Indonesia (22.1%), France (21.2%), UK (6.3%), China (5.1%)
4	300431	Medicaments of insulin, for retail sale	9.8	18	Brazil (32.4%), Denmark (22.5%), Italy (15.5%), Germany (14.9%), Belgium (8.8%)
5	300439	Medicaments of other hormones, for retail sale,	3.4	17	Switzerland (33.7%), US (11.7%), Germany (11.3%), Belgium (10.5%), Netherlands (9.5%)
6	300420	Medicaments of other antibiotics, for retail sa	2.5	29	Belgium (24%), Switzerland (22.8%), US (17.8%), Netherlands (7.5%), Other Asia, nes (6.6%)

*Table 7 continued....*

Table 7 continued....

7	300190	Substances of human or animal origin, for proph	2.4	9	China (87.6%), US (7.2%), Belgium (4.7%), Germany (0.3%), Brazil (0.1%)
8	300390	Other medicaments with >=2 constituents, not fo	2.4	28	Germany (25.4%), Canada (16%), China (15.4%), Belgium (14.3%), Nepal (12.5%)
9	300239	Other vaccines for veterinary medicine (excl. f	1.2	14	Netherlands (27.7%), Israel (24.4%), US (13.8%), Belgium (8.8%), Brazil (6.8%)
10	300410	Medicaments of penicillins... or streptomycins.	0.8	31	US (55.2%), China (11.4%), UK (8%), Spain (7.5%), Italy (6%)

Source: Authors' Calculation using WITS, World Bank online Database

### **Price Competitiveness**

For price comparison over time among major pharmaceutical exporters, namely, China, France, Germany, India, Ireland, Italy, Netherlands, Spain, Switzerland, United Kingdom and the United States, this study has used HS 1992 product classification under which the exports of all formulations are clubbed into twenty one pharmaceutical product groups at HS six-digit lines (For detail see Appendix 2). For 1996, trade data is available for all 21 pharmaceutical products. However, for 2019, trade data is only available for 19 HS six-digit tariff lines. There are two HS tariff lines, HS 300110 (glands and other organs, dried, whether or not powdered), 300210 (antisera, other blood fractions and immunological products), for which trade data is not available due to following reasons. From 2007 onwards, HS 300110 (glands and other organs, dried, whether or not powdered) has been clubbed with HS 300190 (other). While, HS 300210 (antisera, other blood fractions and immunological products) has been separated into HS 300211, 300212, 300213, 300314, 300315 and 300319 since 2017. Therefore, to have comparable figures for 1996 and

2019, this study has compensated the loss in India's price competitiveness in 2019 for the aforementioned tariff lines for which data doesn't exist in 2019. While compensating for this loss, the assumption is made that India has been able to maintain price competitiveness in those two HS lines for which data doesn't exist (Table 8).

In 1996, India had price competitiveness in most of the pharmaceutical products over major exporters of pharmaceutical products and it was able to maintain this competitiveness in 2009 (Table 8). In the last 10 years, however, India has lost the price competitiveness with almost all major exporters in the number of pharmaceutical products. When India's price competitiveness is compared with China, this loss is quite significant. Between 1996 and 2019, India has lost price competitiveness in four pharmaceutical products over China. This data analysis further supports our earlier analysis of the difference between share in the value of global exports and volume which has indicated that China is more price competitive over India at an aggregated level (Table 1). With Spain, France and the US, India has lost price competitiveness in three pharmaceutical products during the same reference period. Concerning the UK and Ireland, this loss includes two pharmaceutical products. Table 9 presents pharmaceutical products, along with their share in India's global exports of formulation in 2019, in which India did not price competitive in 2019 *vis-a-vis* major exporting countries.

**Table 8: Number of Pharmaceutical Products with India's Price Competitiveness over Major exporters**

Country	1996*	2000	2005	2009 @	2015 @	2019 #	2019 (After compensating for non-existence of Trade data for 2 HS tariff lines)
World	19	21	19	20	18	14	16
China	12	16	9	14	6	6	8
France	18	20	19	20	17	13	15
Germany	21	20	19	19	17	17	19

*Table 8 continued....*

Table 8 continued....

Ireland	18	21	19	19	16	14	16
Italy	17	19	18	20	17	16	18
Netherlands	18	17	17	6^	18	17	19
Spain	16	17	17	17	15	9	11
Switzerland	20	20	19	20	18	17	19
UK	16	21	21	19	19	14	16
USA	16	19	18	20	17	11	13

**Note:** \* out of 21, @ out of 20, # out of 19, ^ Data unavailability

**Source:** Authors' Calculation using WITS, World Bank online Database

**Table 9: Pharmaceutical Products in which India was Non-competitive in Price in 2019**

S. No.	HS 1992	Description	Share in India's global Exports of formulation (%)	India's Non-competitiveness in Price
1	300490	Other Medicine Put Up For Retail Sale	78.0	China, France, Spain
2	300420	Other, Containing Antibiotics	6.9	China, Spain, US
3	300220	Vaccines For Human Medicine	4.8	France
4	300410	Mdcmnts Cntng Pencllns/ Drvtvs Throf Wth A Penclnc Acid Strctr/ Strptmycns Or Thr Dervtvs Put Up For RTL Sale	3.4	China, France, Germany, Ireland, Spain, Switzerland, UK, US
5	300390	Othr Medicants(Excl Headng 3002,3005,3006) For Therapeutic Prophylactic Uses Not Put Up For Retail Sale	1.9	China, Ireland, Spain

Table 9 continued....

Table 8 continued....

6	300450	Other Medicaments Containing Vitamins Or Other Products Of Heading 2936 :	1.5	China
7	300290	Toxns,Culturs Of Microrgnsm And Smllr Prodt	1.4	China, France, Spain, UK
8	300439	Other : Pituitary Hormones; Prednisolone; Dexamethasone; Danazol; Other Progestogen And Oestogen Group Hormones :	0.5	Spain
9	300432	Medicaments Containing Corticosteroid Hormones, Their Derivativeandstructural Analg	0.5	China
10	300440	Medicaments of alkaloids or derivatives thereof	0.1	China, Ireland
11	300239	Other vaccines for veterinary medicine	0.1	China, Italy, Spain, Switzerland, US
12	300320	Medicaments Cont. Other Anti-Biotics	0.1	China, France, Spain, UK, US
13	300339	Other	0.0	China, Ireland, Italy, Spain, UK, US
14	300120	Extrcts Of Glnds/Othr Orgns/Of Thr Secrtns	0.0	US
15	300340	Medicaments of alkaloids or derivatives thereof	0.0	China, France, Germany, Netherlands, US
16	300331	Containing Insulin	0.0	China, Ireland, Italy, Netherlands, Spain, UK, US

**Source:** Authors' Calculation using WITS, World Bank online Database.

This study has also attempted similar price comparison analysis for the formulations based on HS 2017 product classification because of the following two reasons. First, this product classification is most recent and data for those products in which countries are currently trading is available. Secondly, HS 2017 product classification is much broader in comparison to HS 1992 as it includes 32 HS six-digit products while at HS 1992 product classification, there are only 21 products.

Based on HS 2017 product classification, Table 10 provides details of the pharmaceutical products at HS six-digit tariff lines in which India has price competitiveness over major pharmaceutical exporting countries, namely, China, France, Germany, Ireland, Italy, Netherlands, Spain, Switzerland, United Kingdom and the United States, along with the number of HS eight-digit products included in each six-digit products and their share in India's global exports of formulation in 2019-20. As noted earlier, there is one significantly vital pharmaceutical product, HS 300490 (other medicine put up for retail sale)<sup>12</sup>, in India's export basket as it constituted more than a three-fourth share of India's pharmaceutical exports in 2019-20, i.e. \$ 12.3 billion (77 per cent) out of \$ 16 billion. Concerning this product, India has price competitiveness over France, Germany, Ireland, Netherlands, Switzerland and the United States but it is not competitive with China, Italy, Spain and the United Kingdom. In pharmaceutical product, HS 300420 (other containing antibiotics), which accounted around 7 per cent share in India's pharmaceutical exports, India is price-competitive only with four major countries (France, Germany, Ireland and Switzerland) out of ten. In vaccines for human medicine (HS 300220), which acquired 5 per cent share in India's pharmaceutical exports, India is competitive with five major exporting countries, namely, China, Germany, Ireland, Switzerland, United Kingdom. Like-wise, India has price-competitiveness in HS 300410 (MDCMNTS CNTNG PENCLLNS/DRVTVS THROF WTH A PENCLLNC ACID) over five major countries, viz, France, Italy, Netherlands, Switzerland and the United States. Further, it is worth to highlight here that five HS products, HS 300490 (77 per cent), HS 300420 (6.8 per cent), HS 300410 (3.4 per cent), HS 300390 (1.9 per cent) and HS 300450 (1.4 per cent), accounted

more than 90 per cent share in India's global exports of formulation in 2019-20 in which India was found non-competitive in price *vis-à-vis* China.

**Table 10: Price competitive Pharmaceutical Products at HS Six digit (HS 2017) of India**

(along with count of eight digit tariff line and share in India's pharmaceutical global exports)

S. No.	HS 2017	Description	No. of 8 digit codes	2018-19	2019-20	Share in India's exports of formulation	India's Price Competitiveness
1	300490	Other Medcne Put Up For Retail Sale	70	11,207	12,322	76.9	France, Germany, Ireland, Netherlands, Switzerland, United States
2	300420	Other, Containing Antibiotics	29	1,040	1,090	6.8	France, Germany, Ireland, Switzerland,
3	300220	Vaccines For Human Medicine	14	651	807	5.0	China, Germany, Ireland, Switzerland, United Kingdom,
4	300410	Mdcmnts Cntng Penclns/Drvtvs Throf Wth A Pen-clinc Acid Strctr/ Strptmycns Or Thr Dervtvs Put Up For Rtl Sale	8	520	541	3.4	France, Italy, Netherlands, Switzerland, United States,

*Table 10 continued....*

Table 10 continued....

5	300390	Othr Medicants (Excl Heading 3002,3005,3006) For Therapeutic Prophylactic Uses Not Put Up For Retail Sale	14	296	296	1.9	France, Germany, Italy, Netherlands, Switzerland, United States,
6	300450	Other Medicaments Containing Vitamins Or Other Products Of Heading 2936 :	11	233	229	1.4	France, Ireland, Spain, Switzerland, United States,
7	300215	Immunological Products, Put Up In Measured Doses Or In Forms Or Packings For Retail Sale	1	89	123	0.8	France, Germany, Ireland, Switzerland,
8	300431	Medicaments Containing Insulin	2	114	117	0.7	China, Germany, Ireland, Spain, Switzerland,
9	300460	Other, Containing Antimalarial Active Principles Described In Subheading Note 2 Of Chapter 30	1	7	113	0.7	France, Germany, Italy, Netherlands, Switzerland, United States,
10	300432	Medicaments Containing Corticosteroid Hormones, Their Derivativeand- structural Analg	1	61	90	0.6	France, Germany, Ireland, Netherlands, Switzerland, United Kingdom,

Table 10 continued....

Table 10 continued....

11	300439	Other : Pituitary Hormones; Prednisolone; Dexamethasone; Danazol; Other Progestogen And Oestrogen Group Hormones :	8	84	93	0.6	China, France, Italy, Netherlands, Switzerland,
12	300212	Antisera And Other Blood Fractions:	5	58	61	0.4	France, Germany, Ireland, Netherlands, Switzerland, United States,
13	300190	Heparin Slts;Othr Human/ Anml Substns Fr Thruptc/ Prophylactic Use Nes	3	21	44	0.3	China, France, Ireland, Spain, United States,
14	300290	Toxns,Culturs Of Microrgnsm And Smlr Prodtcs	5	42	33	0.2	Germany, Ireland, Netherlands, Switzerland, United Kingdom, United States,
15	300211	Malaria Diagnostic Test Kits	1	7	13	0.1	France, Germany, Ireland, Spain, United Kingdom,
16	300230	Vaccines For Veterinary Madicine	1	10	11	0.1	France, Germany, Ireland, Netherlands, Switzerland, United Kingdom,
17	300320	Medicaments Cont. Other Anti-Biotics	1	8	9	0.1	France, Germany, Italy, Switzerland,

Table 10 continued....

Table 10 continued....

18	300449	Other: Medicaments Of Mixed Or Unmixed Products	8	14	16	0.1	France, Germany, Italy, Netherlands, Switzerland,
19	300120	Extrets Of Glnds/ Othr Orgns/Of Thr Seccrtns	4	5	2	0.0	China, Germany, Italy, Switzerland,
20	300213	Immunological Products, Unmixed, Not Put Up In Measured Doses Or In Forms Or Packings For Retail Sale:	1	8	0	0.0	France, Germany, Ireland, Netherlands, Spain, Switzerland,
21	300214	Immunological Products, Mixed, Not Put Up In Measured Doses Or In Forms Or Packings For Retail Sale:	1	1	0	0.0	Germany, Ireland, Netherlands, Spain, Switzerland,
22	300219	Other: Human Blood; Animal Blood; Antisera, Etc	1	9	3	0.0	France, Ireland, Netherlands, United Kingdom, United States,
23	300310	Mdcmnts Cntng Pnclns/Thr Drvts With A/Pnclnc Acd Strctre, Strptmcns/ Thr Drvts	1	2	2	0.0	China, France, Italy, Netherlands, United Kingdom, United States,
24	300331	Containing Insulin	1	0	0	0.0	France, Germany, Italy, Switzerland,
25	300339	Other: Medicaments With >=2 Constituents Mixed Together	1	5	6	0.0	France, Netherlands, Switzerland,

Table 10 continued....

Table 10 continued....

26	300341	Containing Ephedrine Or Its Salts	1	-	-	0.0	France, Italy, Switzerland, United Kingdom, United States,
27	300343	Containing Norephedrine Or Its Salts	1	-	0	0.0	Italy, Netherlands,
28	300349	Other: Medicaments With >=2 Constituents Mixed Together	1	0	0	0.0	France, Ireland, Netherlands, Spain, United Kingdom,
29	300360	Other, Containing Antimalarial Active Principles Described In Sub Heading Note 2 Of Chapter 30	1	0	-	0.0	Italy, Netherlands, United Kingdom,
30	300441	Containing Ephedrine Or Its Salts	1	0	1	0.0	France, Germany, Italy, United Kingdom,
31	300442	Containing Pseudoephedrine (Inn) Or Its Salts	1	1	0	0.0	China, Italy, Netherlands, Switzerland, United States,
32	300443	Containing Norephedrine Or Its Salts	1	-	-	0.0	France, Italy, Spain, United Kingdom,
			200	14,494	16,023		

**Source:** Authors' calculation using WITS, World Bank online Database and Export-Import data Bank of Ministry of Commerce.

## Current Challenges

**Price Competitiveness:** From the data analysis, it has emerged that in 1996, India had price competitiveness in most of the pharmaceutical products over major exporters of pharmaceutical products and it was able to maintain this competitiveness until 2009. In the last 10 years,

however, India has lost the price competitiveness with almost all major exporters in the significant number of pharmaceutical products. When India's price competitiveness is compared with China, this loss is quite significant. The five HS products, HS 300490 (77 per cent), HS 300420 (6.8 per cent), HS 300410 (3.4 per cent), HS 300390 (1.9 per cent) and HS 300450 (1.4 per cent), accounted for more than 90 per cent share in India's global exports of formulation in 2019-20 in which India was found to be non-competitive in price vis-à-vis China. The draft of pharmaceutical policy [Government of India (GOI), 2017] made a similar observation in its report. The report highlighted that the Indian pharmaceutical industry is facing increasing competition from foreign countries, especially from neighbouring countries like Vietnam, Korea, Sri Lanka and Bangladesh. It further added that the comparative advantage of the Indian pharmaceutical companies got weak due to takeover (mergers and acquisitions - M&A) of Indian pharmaceutical companies. The theoretical argument in support negative relationship between the increase in M&As and decline in price competition is that increase in M&As result an increase in prices due to shortages of the product and decline in price competition (Gagnon & Volesky, 2017). The US economy experienced a significant increase in the prices of generic drugs during that period in which a significant number of M&As took place.<sup>13</sup> Similarly, India, in the post-TRIPS period has experienced increased in prices in a number of drugs in several therapeutic groups (Chaudhuri, 2019). Further, in the Indian case, it is worth noting that the loss of competitiveness followed the period of M&As. Most of these M&As took place between the late 2000s and early 2010s and Indian pharmaceutical companies have lost comparative advantage in the last ten years, as noted earlier in the data analysis. Based on observed facts and figures, it can be said that M&As is one of the reasons for declining price competitiveness of Indian pharmaceutical Industry.

**Bulk Drugs or APIs:** Although India is known as 'Pharmacy of the world' because of supply of low-cost formulations or generics, it is highly dependent on global imports for its requirement (domestic & exports) of Active Pharmaceutical Ingredients (API), particularly

on one country, China (James, 2020). India is importing APIs largely from China, which is now the largest, in terms of volume<sup>14</sup>, supplier of the bulk drugs in the world.<sup>15</sup> So, to attain a higher profit margin in the manufacturing of formulations or finished pharmaceutical products and cheap supply of the same to the world, India has to depend largely on China for APIs. Given that China is cheap producer and supplier of API to the world economy, the formulations manufactured and exported by China using its APIs obviously would also be cheap. Therefore, over time rising dependence of India on China for API could be another reason for the decline in price competitiveness mainly *vis-à-vis* China.

**Efficiency:** The Indian pharmaceutical industry has been encountering challenges in relation to output efficiency (Mazumdar et al., 2012). This problem of output efficiency is mainly pertaining to small firms while big firms have been able to do quite better comparatively. Similarly, James (2020) highlighted that Indian pharmaceutical companies have lower cost efficiency particularly, in manufacturing of bulk drug in comparison to China despite enjoying a lower labour cost labour. Consequently, Indian bulk drug producers face serious competition from their Chinese counterparts<sup>16</sup>. It is important to note that China has not attained this cost-efficiency overnight, but it is a result of the implementation of important policies in the past, such as relaxed environmental and pollution restrictions, cheaper electricity, and large-scale production. Another reason for lower cost-efficiency of the Indian pharmaceutical industry is the presence of a large number of small firms in the increasing returns to scale zone (Mazumdar et al., 2012). Some other issues highlighted in the available literature such as lack of manpower, the gap between university curriculum and industry requirements and insufficiency of R&D expenditure could be additional reasons for lower-cost factors and output efficiency.

**Quality and standards of the Drugs:** Another major concern of the Indian pharmaceutical industry is the issue related to the quality and standards of the drugs. This issue is largely pertaining to SMEs which largely cater to domestic consumption. Indian pharmaceutical producers

are increasingly facing the issues of supply of low quality, spurious and substandard drugs owing to lack of transparency in the licensing procedures of drugs (Mishra & Sathyaseelan, 2019). About 30 per cent of drugs in the Indian market are spurious, substandard, counterfeit drugs, as per the observation of the Mashelkar Committee.<sup>17</sup> Even, the Indian government itself found that, in the Indian market, about 8-10 per cent of drugs are substandard and 0.3 per cent to 0.5 per cent.<sup>18</sup> Following are the main reasons cited in the draft Pharmaceutical Policy (2017). First, India does not have a sufficient number of Nationally Accredited Laboratories (NABL) for conducting frequent regular tests and also the audit of these NABLs is not conducted regularly. Second, established drugs manufacturers are given sanction for manufacturing drugs by State Drug Administrators without any Bio-Availability and Bio-Equivalence test of the claimed products; and third, most of the manufacturing units are not following standards of World Health Organisation's (WHO) Good Manufacturing Practices (GMP) or the Good Laboratory Practices (GLP).

## **Distribution of Generic Drugs**

India is the second-largest producer of generic drugs, after China, and, it is also one of the major generic distributors across the world. Despite this, the experience of India in relation to the distribution of generic drugs in its economy is not encouraging as it has been beset with some of the serious challenges, such as doctors are not prescribing generic drugs.<sup>19</sup> These drugs are still not easily accessible to a large chunk of the Indian population as few government regulatory bodies take care of the availability of the generic medicines. Retail pharmaceutical stores largely sell branded drugs, which come at premium prices (Mishra & Sathyaseelan, 2019).

## **Major Findings and Way Forward**

The global recognition of India as a source for affordable quality generic drugs is the result of key policies and regulations implemented in the past, viz. Patents Act 1970, FERA 1973, Drug Policy, 1978, Drug Policy 1986. In the last two decades, Indian pharmaceutical industry has attained phenomenal growth as reflected by its continuous increasing

share in global exports in terms of both value and volume. In terms of value, India's share in global exports has increased to 2.8 per cent in 2019 whereas, with respect to volume, it has accounted for 5.1 per cent. Despite this phenomenal growth and the bright prospects in near future, this industry is currently facing some major challenges, such as price-competitiveness, efficiency, distribution of generics, quality and standard of the drugs (as discussed in detail in Section 6 of this paper). Although all the issues discussed in this study are important for the Indian pharmaceutical industry, the issue of loss of price-competitiveness is most significant as India has lost the price competitiveness with almost all major exporters in a large number of pharmaceutical products in the last 10 years. This loss in price competitiveness is quite significant when compared with China.

To sustain the growth of the pharmaceutical industry in future and preserve its hard-earned position in the international market, the India needs to implement key policies to resolve these aforementioned challenges. Recently, the GOI launched some schemes for the development of drugs and pharmaceutical industry, such as the production-link scheme for encouraging domestic manufacturing of critical bulk drugs<sup>20</sup> and medical devices, setting-up of clusters or parks, for bulk drugs<sup>21</sup> and medical devices. The availability of bulk drugs domestically would no doubt assist the Indian economy in attaining health security, particularly during an emergency, as it would not have to depend on foreign countries for its domestic requirements. On the other hand, the provision of common infrastructure facilities would make sure that bulk drugs to be produced is cost-efficiently via economies of scale as well as maintain high quality and standards which, in turn, would help in improving the competitiveness of both bulk drugs and formulations. Further, to improve its position in relation to competitiveness in the international market, these policies will have to be complemented with relevant measures in the direction of new technological developments, such as biotechnology, gene technology, bio-similar, artificial intelligence, 3D printers, machine Learning, AR-VR, digital apps, blockchain, organ-on-chips, etc.

Some of the specific steps that can be taken are suggested below:

The loss of competitiveness is linked with a number of factors such as costs of labour production, raw material, transportation and marketing. Most of the areas will have to be addressed by the industries themselves. They will have to introduce appropriate management techniques to reduce cost. The scale of production has much to do with cost and, therefore, companies will have to study how best to enhance their markets to scale of manufacturing. Limiting the market to high-end ones may not be very conducive for this. Both high and low-end markets will have to be covered. Digital technologies and artificial intelligence can be used in a significant way in this regard. At a policy level, the government can initiate steps for labour law reforms and increase of transport and transportation facilities. It can also initiate policies that would reduce the cost of energy, water, etc.

Technology up-gradation is a major challenge. While the pharmaceutical industries will have to take major steps in this regard, the government can also initiate several schemes for technology up-gradation, including technology parks, special funds for technology up-gradation by MSME units, etc. Medium and large industries can consider tie-ups with technology firms and big companies. Banks may also extend special interest-free or nominal interest loans for such purposes.

Continuous research and development is a most essential in the pharmaceutical formulation industry. This will have to focus on cost reduction. For this manufacturing units can join hands with local or other technology institutions and universities. The government should exempt all expenditure on R&D from the purview of income tax and give extra rebates for the same. Advance buying agreements for public healthcare facilities can also contribute to R&D investments. Domestic agreements will attract such agreements from abroad.

Quality standards are an important concern globally. All medicines and other medical products of India will have to be safe and of the highest quality levels. While the responsibility is with the manufacturing

firms governments can provide quality and standard checking facilities near industry units. The cost of such facilities should be nominal. The government may also take steps to provide large publicity to Indian quality standards. Efforts should also be made to change the general perception across countries that Indian pharmaceutical products are the best in the world. Government and industry organisations may from time to time get studies done for products imported in select countries from time to time and also organise Indian pharmaceutical exhibitions, fairs, seminars and workshops.

Continuous skill up-gradation of workers and chemists in pharmaceutical units is a necessity. India may launch special schemes for this in association with regulatory authorities, universities, technical institutions and industry associations.

Indian pharmaceutical industry has been built up over decades with dedication and commitment by all stakeholders. Through concerted efforts, it can continue to serve both at national and international levels, especially in its efforts to achieve health and well being of all by 2030.

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## Appendix

S.No.	HS 4 digit	Description
1	3001	Glands etc dry & ext, heparin, hum etc subst nesoi
2	3002	Human blood, animal blood, antisera, vaccines etc
3	3003	Medicaments nesoi of mixtures, not dosage etc form
4	3004	Medicaments nesoi, mixed or not, in dosage etc form

S.No.	HS 1988	Description
1	300110	Glands and other organs, dried
2	300120	EXTRCTS OF GLNDS/OTHR ORGNS/OF THR SECRTNS
3	300190	HEPARIN SLTS;OTHR HUMAN/ANML SUBSTNS FR THRUPTC/PROPHYLACTIC USE NES
4	300210	Antisera and other blood fractions
5	300220	VACCINES FOR HUMAN MEDICINE
6	300239	Other vaccines for veterinary medicine (excl. f
7	300290	TOXNS,CULTURS OF MICRORGNSM AND SMLR PRODTS
8	300310	MDCMNTS CNTNG PNCLNS/THR DRVTVS WITH A/PNCLNC ACD STRCTRE,STRPTMCNS/THR DRVTS
9	300320	MEDICAMENTS CONT. OTHER ANTI-BIOTICS
10	300331	CONTAINING INSULIN
11	300339	OTHER
12	300340	Medicaments of alkaloids or derivatives thereof

13	300390	OTHR MEDICANTS(EXCL HEADNG 3002,3005,3006)FOR THERAPEUTIC PROPHYLACTIC USES NOT PUT UP FOR RETAIL SALE
14	300410	MDCMNTS CNTNG PENCLLNS/DRVTVS THROF WTH A PENCLLNC ACID STRCTR/STRPTMYCNS OR THR DERVTVS PUT UP FOR RTL SALE
15	300420	OTHER, CONTAINING ANTIBIOTICS
16	300431	MEDICAMENTS CONTAINING INSULIN
17	300432	MEDICAMENTS CONTAINING CORTICOSTEROID HORMONES, THEIR DERVATIVEANDSTRUCTURAL ANALG
18	300439	OTHER : PITUITARY HORMONES; PREDNISOLONE; DEXAMETHASONE; DANAZOL; OTHER PROGESTOGEN AND OESTOGEN GROUP HORMONES :
19	300440	Medicaments of alkaloids or derivatives thereof
20	300450	OTHER MEDICAMENTS CONTAINING VITAMINS OR OTHER PRODUCTS OF HEADING 2936 :
21	300490	OTHER MEDCNE PUT UP FOR RETAIL SALE

## Endnotes

<sup>1</sup> <https://www.expresspharma.in/market-pharma/indian-pharma-industry-backbone-of-indian-economy-in-the-current-pandemic/>

<sup>2</sup> According to World Health Organization (WHO) generic medicines are “those produced without a licence from the innovator company when the patent or other market exclusivity rights on the innovator product has expired” (Generic Medicines in WHO Drug Information, 2016, p. 370). These generic drugs are bioequivalent to the innovator drug and become available only after the approval of drug controller on the satisfaction of proof of bioequivalence. The generic drugs are also therapeutically equivalent to the original drug in that there is no significant difference in rate and extent to which the API or moiety becomes available at the site of drug action when administered in the same dose (James, 2020).

<sup>3</sup> <https://www.investindia.gov.in/sector/pharmaceuticals>

- <sup>4</sup> The formulations sector of pharmaceutical industry includes Harmonized System (HS) Chapters from 3001 to 3004.
- <sup>5</sup> World Integrated Trade Solution (WITS)
- <sup>6</sup> Only Since 1996, consistent data on both value and volume is available in WITS, World Bank database.
- <sup>7</sup> According to First Five Year Plan (FYP), Chapter 32, India had spent annually more than Rs. 10 crore value of essential drugs and raw materials such as penicillin, streptomycin and other antibiotics, sulpha drugs, gland products, vitamins, anti-leprosy drugs and insecticide. Penicillin and streptomycin constituted nearly 35 per cent share in total value of imported drugs.
- <sup>8</sup> Fifth FYP: Chapter 5, note 75.
- <sup>9</sup> For more details see James (2020).
- <sup>10</sup> Concerning drugs prices “India was among the highest priced nations in the world” see Chaudhuri (2005), pp. 132.
- <sup>11</sup> The United Nations Industrial Development Organization (UNIDO) categorized India “as one of the most advanced amongst developing countries with respect to technological development (Mehrotra, 1989).
- <sup>12</sup> This HS 300490 product includes 70 lines at HS eight digit.
- <sup>13</sup> *ibid*
- <sup>14</sup> In relation to volume, China acquired almost one-fourth share in World’s exports of API in 2018.
- <sup>15</sup> *Ibid.*
- <sup>16</sup> *Ibid.*
- <sup>17</sup> *ibid*
- <sup>18</sup> *Ibid.*
- <sup>19</sup> In 2002, the Medical Council of India (MCI) brought the clause 1.5 (Professional Conduct, Etiquette and Ethics) Regulations, 2002, under which physicians were asked to prescribe drugs to patient by their generic names only and avoid mentioning branded names(Mishra & Sathyaseelan, 2019). Those found violating this clause, suitable disciplinary action by MCI would be undertaken against that individual. However, MCI’s 2016 notification has amended this clause.
- <sup>20</sup> For more detail see <https://pharmaceuticals.gov.in/sites/default/files/Gazettee%20notification%20of%20bulk%20drug%20schemes.pdf>
- <sup>21</sup> For more detail see [https://pharmaceuticals.gov.in/sites/default/files/Guidelines%20of%20the%20Scheme%20Promotion%20of%20Bulk%20Drug%20Parks\\_1.pdf](https://pharmaceuticals.gov.in/sites/default/files/Guidelines%20of%20the%20Scheme%20Promotion%20of%20Bulk%20Drug%20Parks_1.pdf)



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