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# India in the Global Vaccine Market Prior To and During COVID-19: Some Structural Issues

*Shailender Kumar\**

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**[Abstract:** India has a century long legacy in vaccine development and manufacturing. The indigenous manufacturers have provided a commendable service to the national immunisation programme and made the country self-sufficient in basic vaccines. India currently is a leading exporter of vaccines to the developing world. However, overtime, the country also became import dependent on some newer generation and basic vaccines in which domestic supply was inadequate. During the Coronavirus outbreak, India gained the status of fastest vaccinating country in the world in administering more than two billion Covid-vaccination doses through the indigenously produced vaccines and strengthened the global fight against the Coronavirus by supplying vaccines to more than 100 countries. Expectedly India prioritised vaccinating its own population over exporting the vaccines since the spring of 2021, restricting exports. China exploited this opportunity by ramping up Covid-vaccine exports. However, of late, some concerns have been raised against the efficacy and safety of Chinese vaccines. India, being a well-trusted country at WHO Prequalification platform, has a great opportunity to gain much around existing, newer generation and combination vaccines as well as those beyond Covid-19 by addressing some structural issues highlighted in the paper]

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**Keywords:** Vaccine Industry, Vaccine Export, COVID Vaccine Doses, India, China, Indigenous Manufacturing, Installed Capacity, Capacity Utilisation.

## 1. Introduction

In the past two decades, there have been significant changes in the global vaccine manufacturing landscape due to the rise in infectious diseases and the onset of endemics and pandemics around the world (Excler *et al.*, 2021; Baker, 2022). Unlike the past when five big companies (Sanofi Pasteur, GlaxoSmithKline, Merck, Pfizer, and Novartis) dominated the global vaccine market, the smaller biotech and emerging-market players have been aggressively intervening through technology transfer and contract manufacturing to change this order (Research and Markets, 2021). The outbreak of the Coronavirus (COVID-19) pandemic is likely to alter and transform the global vaccine market in a significant way as many

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countries are keen to support the recent ongoing global efforts to combat it by providing safe and affordable vaccines to the world. Many others were striving to capture the global vaccine market. China launched the 'COVID-19 Vaccine Diplomacy' programme (CSIS, 2022) to capture the market. Considering the necessity of timely supply and wider access to vaccines that could be facilitated through local vaccine manufacturing effectively (Khan, Ikram, and Hamza, 2021), several countries enforced self-reliance and self-sufficiency in vaccine production, most notably South Africa (Makenga, 2019).

Looking at the capability and necessity of vaccination in preventing infections and saving lives on the one side and widespread diversity and lack of access to and coverage of vaccination in different parts of the world on the other, some vaccine alliances (like, Gavi, a public-private global vaccine alliance that was established in 2000) have emerged to provide financial support to countries requiring vaccines recommended by the World Health Organisation (WHO). The vaccines are procured and supplied at low cost to the eligible<sup>1</sup> developing countries through the Gavi platform. The Gavi platform also facilitates the transfer of technical know-how for vaccine manufacturing to developing countries, thereby reducing inadequacy of affordable vaccines. The Developing Countries Vaccine Manufacturers Network (DCVMN)<sup>2</sup>, of which India is a member, was also established in 2000 with the goal of increasing access to high-quality essential vaccines at affordable prices to safeguard people from known and emerging infectious diseases, particularly in the UN agencies/countries. However, a manufacturer's vaccine must meet the 'vaccine prequalification' criteria determined and devised by WHO (known as WHO-PQ) for the inclusion of vaccine in the procurement tender (Dellepiane and Wood, 2015). That is, manufacturers must adhere to strict standards of quality, safety, and efficacy to ensure that the country's vaccine production lines can be relied on.

These changing regulatory and market competitive scenarios may have influenced the overall dynamics of vaccine dependency as well as of manufacturing. This paper, therefore, aims to examine India's performance in the global vaccine market both before and during the ongoing Coronavirus pandemic and to trace the dominance order of countries in the delivery of vaccines to the world. Additionally, the paper will highlight the inherent structural issues of the Indian vaccine industry and relate them with India's global position to offer some policy lessons for the growth of the vaccine industry beyond COVID-19.

In order to assess India's position in the global vaccine market, the trade statistics (export-X and import-I) from Directorate General of Commercial Intelligence and Statistics (DGCI&S) Government of India and the World Integrated Trade Solution (WITS) of World

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<sup>1</sup> Relatively high per capita income countries are not eligible for such support; eligibility is decided as per World Bank income criteria (<https://www.gavi.org/types-support/sustainability/eligibility>).

<sup>2</sup> DCVMN is the largest voluntary health-driven alliance of vaccine manufacturers from developing countries, engaged in the research, development, manufacturing, and supply of high-quality vaccines globally (DCVMN, 2021).

Bank are examined at Harmonized System HS:8-digit and HS:6(300220)-digit levels respectively. The structural issues and domestic manufacturing are highlighted using data from Annual National Health Profile (NHP) and unit level records of Annual Survey of Industry (ASI) of Government of India (GOI) respectively. To examine what proportion of a country's domestic demand (final consumption of vaccine) is met through imported vaccines, the Import Penetration Rate/Ratio (IPR) is measured as  $[IPR = I/(S-X+I)*100]$ . Where, S denotes the sale value of domestically produced vaccine, X denotes the export of vaccines, and I denotes the import of vaccines. The S-X+I is generally referred as the domestic market size (DMS) of vaccine of a country. India's changing position in the global market before and during COVID is highlighted using WITS data. Data from different vaccine trackers data are also used and cited in relevant places.

## 2. India in Global Vaccine Market Prior to COVID

The size of the global vaccine market was estimated to be around 5.5 billion doses, with a market value of US\$33 billion in 2019 (WHO/MI4A, 2020). The value of vaccine export was US\$29.86 billion, with a market volume of 43.6 million kilogram in 2019 (from Table 1). Evidence suggests that the European Union (EU) and the United States (US) supply the majority of the world's vaccines. Five advanced countries, namely Belgium (27.34%), Ireland (16.21%), France (15.95%), the United Kingdom (11.32%), and the US (8.93%), together accounted for nearly 80% share of the value of vaccine exports to the world in the past one decade, i.e. 2011–2020 (Table 1). Some of them (France, Belgium, and the US) dominate in volume supply as well, but this is not true across all countries. India ranked eighth among the top 20 exporters of vaccines in terms of value, but fourth in terms of volume of export with a share of 11.01% over the past decade. At eighth position, India's share in terms of the value of vaccine export has been very low, but its share has grown overtime to 1.55% between 2000 and 2005 from 0.78% between 1988 and 1997. With almost the same share in the initial year of the product patent regime (2006 onward), this share increased to 2.58% between 2014 and 2020 (Table 1).

The export destinations for advanced countries are generally the high-income countries (HICs) markets. In terms of the volume of export to HIC markets, France is reported to have the highest share (29.93%), followed by the US (17.47%), Belgium (15.28%), and Ireland (11.55%) (Table 2). India is found to be the top supplier of vaccines to low-income countries (LICs) markets and to low-middle-income countries (LMICs) markets with a share of 37.43% and 24.53% respectively, leaving behind all dominant EU/US players. However, India's export to HIC markets was almost negligible, accounting for only 0.29% share.

The India vs EU/US demarcation in vaccine supply to different markets explains the heterogeneity in the unit prices of vaccines across suppliers/countries. The HIC is a high price market, while LIC/LMIC are low price markets (WHO/MI4A, 2020). As per this study's estimates, in terms of volume, the HIC markets procured 0.2 billion doses annually, generating US\$12.3 billion in value in 2019. India supplies most of its vaccines through procurement platforms, especially the Gavi platform that procures vaccines through UNICEF (United Nations International Children's Emergency Fund). For instance, Indian manufacturers account for 60% of the vaccine supplies made to UNICEF (Kumar, 2017) and such platforms tend to supply high-quality vaccines at low cost/price to low-income settings. As per WHO/MI4A (2020), in 2019, the global market accounted for 41% of the volume of vaccines procured through different platforms, accounting for only 10% in value, while the remaining 59% of the market volume was self-procured by individual countries, accounting for 90% of the market value in 2019. The advanced countries tap HIC markets where they supply vaccines at relatively high prices and receive high value in return. India has been regarded as a hub of providing low-cost affordable vaccines due to its large volume of vaccines supply at low-price to low-income countries.

**Table 1: Top 20 Vaccine Exporting Countries of the World in Value/Volume of Export**

Countries	Ranking in share of <b>Value</b> of vaccine export (US\$1000)						Ranking in share of <b>Volume</b> of vaccine export (in Kg)					
	1988 to 1999	2000 to 2005	2006 to 2013	2014 to 2020	Last decade 2011 to 2020	Rank 2011 to 2020	Rank 2011 to 2020	Countries	Last decade 2011 to 2020	1 <sup>st</sup> Year of COVID-19 2020to 2021	2 <sup>nd</sup> Year of COVID-19 2021 to 2022	Two years of COVID-19 2020-21 to 2021-22
Belgium	30.68	31.75	27.70	28.02	27.34	1	1	France	24.96	76.38	31.38	61.73
Ireland	0.33	0.12	9.21	16.68	16.21	2	2	Belgium	15.52	7.09	18.07	10.67
France	22.37	23.15	17.99	14.89	15.95	3	3	US	14.32	3.58	12.75	6.57
UK	2.72	7.57	8.93	12.55	11.32	4	4	India	11.01	3.68	6.18	4.50
US	11.95	9.80	13.43	7.85	8.93	5	5	Ireland	6.90	0.51	0.00	0.34
Italy	2.31	3.98	3.01	3.92	3.60	6	6	UK	3.71	0.67	0.63	0.65
Germany	4.22	3.62	4.82	2.35	2.87	7	7	Italy	3.19	0.88	1.46	1.07
India	0.99	1.585	1.582	2.58	2.43	8	8	Germany	2.84	0.80	2.31	1.29
Netherlands	4.81	4.79	2.22	1.99	2.16	9	9	Korea, Rep.	2.45	0.48	0.00	0.32
Canada	3.29	1.80	3.71	1.85	1.99	10	10	Netherlands	2.37	0.67	2.39	1.23
Poland	0.07	0.03	0.15	1.48	1.16	11	11	Canada	2.14	0.00	0.67	0.22
Austria	1.89	2.19	1.32	0.86	0.85	12	12	Spain	1.43	0.66	9.48	3.53
Spain	0.60	0.82	0.80	0.80	0.79	13	13	Poland	1.19	0.35	0.00	0.24
Korea, Rep.	1.48	1.24	1.21	0.70	0.79	14	14	Uganda	0.93	0.35	0.00	0.23
Australia	0.29	0.89	0.78	0.41	0.52	15	15	Indonesia	0.87	0.23	0.00	0.16
Switzerland	6.50	2.74	0.62	0.34	0.39	16	16	Austria	0.70	0.96	0.43	0.79
Indonesia	0.06	0.12	0.37	0.36	0.38	17	17	Australia	0.56	0.12	0.19	0.14
China	0.07	0.25	0.13	0.40	0.33	18	18	Singapore	0.44	0.01	0.00	0.00
Denmark	0.36	0.38	0.30	0.27	0.31	19	19	Switzerland	0.39	0.18	0.69	0.35
Japan	2.99	0.85	0.21	0.09	0.11	20	20	China	0.37	0.18	10.97	3.69
Above All	98.0	97.7	98.5	98.4	98.4			Above All	95.53	97.42	85.94	93.68

Source: WITS.

### 3. Changing Pattern of Vaccine Export during COVID

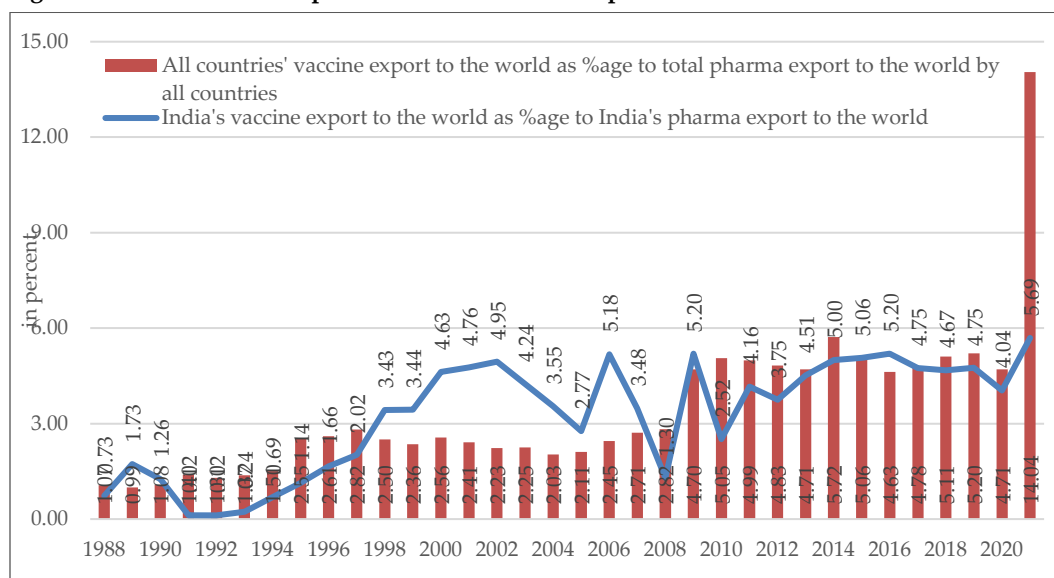
Innovation in blockbuster vaccines such as pneumococcus conjugate, rotavirus, human papillomavirus, and flu vaccines spurred the rise of the global vaccine industry following a period of weak sales growth in the early 2000s. However, due to minimal launch of newer vaccines in 2010, the growth of global vaccine sales slowed down in the later part of 2010 (WHO/MI4A, 2020). The COVID pandemic, however, rejuvenated/revived the global trade market significantly. The global export of vaccines generally accounted for 4–5% of the total global pharmaceutical exports in pre-COVID period, but reached an all-time high of 14.04% in the second year of COVID (SYC), i.e. 2021–22. India's vaccine export share in the overall pharma export increased to 5.69% in SYC (Figure 1).

India's dominance in the supply of vaccines to LMIC markets and that of EU/US to HIC markets have for long remained consistent; however, COVID-19 brought out a significant change in the export market. With significant fluctuations, France maintained its position as the world leader in terms of the volume of vaccines exported, with exports rising to 76.38% in the first year of COVID (FYC) 2020–21 from 24.96% in the pre-COVID decade (PCD) 2011–2020, before falling back to 31.38% in SYC 2021–22 (Table 1). Belgium's share in the volume of vaccine export was 15.52% in PCD, which declined to 7.09% in FYC, but again increased to 18.07% in SYC. Similarly, the US' share declined to 3.58% in FYC, but again increased to 12.75% in SYC.

India's share in the total volume of vaccine exports decreased to 3.68% in FYC from 11.01% in PCD, and again slightly increased to 6.18% in SYC. India was unable to sustain its historic vaccine exports share in double digits during the COVID period. The year-on-year growth in the value (US\$1000) of India's vaccine exports increased by 48.6% in 2021–22 against a negative growth of -3.57 in 2020–21, while the year-on-year growth rate of global exports of vaccines increased significantly to 153.8% in 2021–22 from 1.33% (from original value of Figure 1) in the previous year.

China has never been a competitor in the global vaccine market. In terms of value, its share in the vaccine exports to the world hovered just around 0.33% in PCD, and it slightly increased to 0.40% in 2014–2020 from 0.08 in 1988–1999 (Table 1). The export share in terms of volume was just 0.37% in PCD as it was mainly focused on meeting the domestic demand for its vast population; however, China emerged a major vaccine exporting country during the COVID period. China's volume of vaccine exports increased to 10.97% in SYC, securing it the fourth position globally (Table 1).



**Figure 1: Share of Vaccine Exports in the Total Pharma Exports: India and the World**

Note: For pharma export, Chapter 30 has been considered for India and the world.

Source: WITS.

While the EU and the US continued to dominate the HIC markets during the COVID period, Spain emerged as a major player with 15.54% share in volume supply in 2021–22 as compared to only 2.33% in PCD (Table 2). In the two years of COVID, China's share in HIC markets increased to 2.69% from 0.08%, while India's presence was negligible. During the COVID period, India also lost its position in the LIC and LMIC markets as a major exporter of vaccines. In LIC and LMIC markets, India's vaccine exports share was 37.43% and 24.53% respectively in PCD, which declined to 24.96% and 16.40% in 2021–22. China, however, emerged as a dominant exporter of vaccines to LIC and LMIC markets during the COVID period, with its share increasing to 37.50% and 24.72% respectively in SYC from 0.27% and 0.98% in PCD (Table 2).

An in-depth analysis of Chinese exports suggests a significant change in their export strategy as compared to India. A few years before the COVID outbreak, China began to direct its vaccine exports from LIC markets to LMIC markets, and recently to the HIC markets. Although China's export volume to HIC markets was almost negligible in 2015–16, its composition of exports saw a rising share to nearly 50% in the HIC markets in 2020–21 (Figure 2). In 2021–22, China made a notable entry in the upper-middle-income countries as well, with a share of 22.4%. We see hardly any changes in India's approach to entering the HICs markets – the high price vaccine market. There seems to be a business-as-usual approach, as India is still exploiting LIC/LMIC markets. In the recent past, China's vaccines exports constituted around 5–7% of India's global exports. China's vaccine exports reached 179.09% of India's exports in SYC. An exclusive analysis of the supply of

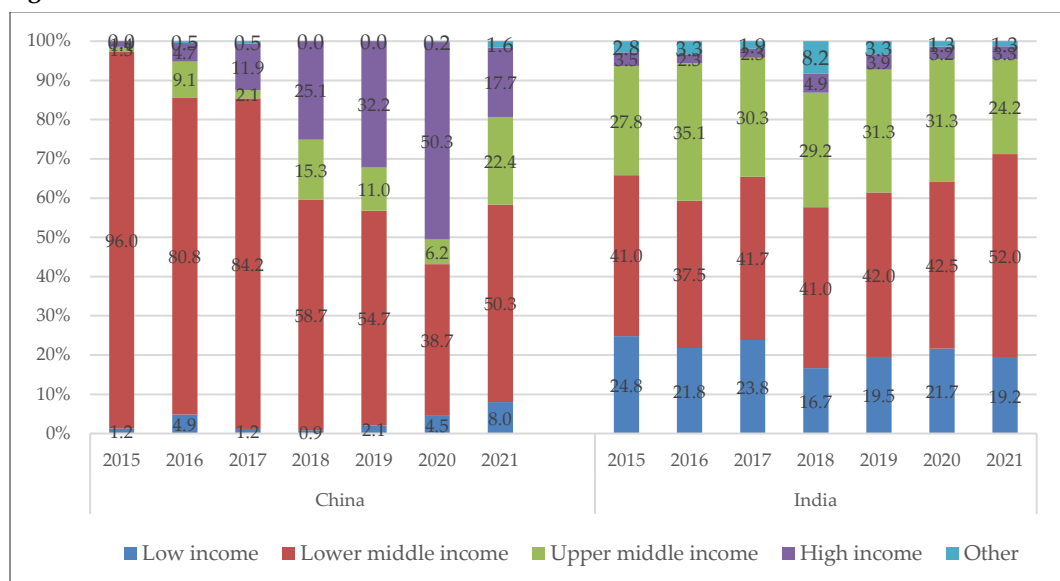
COVID vaccine doses offers a much better insight, especially where India is headed as compared to China.

**Table 2: Top Vaccine Exporting Countries in Volume of Export in Different Markets Prior to and During the COVID Period (Composition of Kg Doses)**

High-income countries (HICs) (OECD plus Non-OECD)				Low-middle Income Countries (LMICs)				Low-income Countries (LICs)			
Country	Last decade 2011 to 2020	FYC 2020-21	SYC 2021-22	Country	Last decade 2011 to 2020	FYC 2020-21	SYC 2021-22	Country	Last decade 2011 to 2020	FYC 2020-21	SYC 2021-22
France	29.93	86.04	44.53	India	24.53	28.92	16.40	India	37.43	49.79	24.96
United States	17.47	2.36	8.32	Belgium	18.09	22.39	18.31	Belgium	14.61	18.53	14.79
Belgium	15.28	4.70	17.42	France	17.71	16.03	10.10	United States	9.32	3.50	13.08
Ireland	11.55	0.57	0.00	United States	10.23	12.14	20.90	Korea, Rep.	8.17	5.22	0.00
Germany	4.12	0.87	3.04	Korea, Rep.	6.52	3.49	0.00	Brazil	5.66	0.40	0.16
United Kingdom	3.85	0.71	0.84	United Kingdom	3.12	0.25	0.29	France	5.24	6.05	2.13
Italy	3.26	0.45	1.22	Italy	2.77	2.68	1.30	Uganda	3.32	0.00	0.00
Canada	2.80	0.00	1.04	Indonesia	2.35	1.79	0.00	Indonesia	3.26	2.34	0.00
Netherlands	2.49	0.57	1.60	Netherlands	2.14	1.29	3.53	Kenya	2.00	0.29	0.51
Spain	2.33	0.75	15.54	Canada	1.33	0.00	0.11	Netherlands	1.43	2.70	3.25
India	0.29	0.04	0.16	Brazil	1.04	0.13	0.11	Bulgaria	1.34	1.82	0.00
China	0.02	0.08	2.69	China	0.98	0.90	24.72	China	0.27	0.12	37.50
Above all	93.40	97.12	96.40	Above all	90.81	90.01	95.77	Above all	92.05	90.77	96.37

Source: WITS.

**Figure 2: India and China in Vaccine Supply: A Composition Share of Different Vaccines (Doses in Kg) to Different Countries**



Source: WITS.

#### 4. Comparing Global Supply of COVID Vaccine Doses

The outbreak of COVID was an opportunity for countries to establish themselves as global leaders in the vaccine market. The global market size of the total COVID doses as of May 31, 2022 is reported to be 15.2 billion doses, of which nine billion doses were for domestic supply (in-house use) and around 6.2 billion doses were traded implicitly either through exports or imports (WTO-IMF 2022). A comparative picture suggests that as of March 31, 2022, the EU is the top global supplier of COVID vaccines (39.7%) followed by the US (about 15%) (Table 3). China, previously a marginal player in the overall vaccine exports, supplied 32.6% of the world's COVID vaccine doses (Table 3). India supplied only a fraction (5.7%) of the total COVID vaccine doses produced domestically, thus contributing only 2.3% of the total COVID vaccine doses supplied globally. The rest 94.3% doses were utilised to meet the domestic COVID vaccination requirements, although many other countries enhanced their manufacturing capacity and exported a sizable amount of COVID vaccine doses to the world. The Republic of Korea exported around 91.1% vaccine doses to the world from its total production, followed by the EU (64.8%), the US (58.4%), and China (32.1%). As on March 31, 2022, China's total dose supply (both domestically and internationally) was 6077.3 million doses, surpassing the EU (3721.0 million), India (2465.6 million), and the US (1609.8 million) dose deliveries to occupy the top position globally. China's total supply was more than twice that of India (Table 3). The EU/US and India were the biggest producers and suppliers of vaccines before the COVID pandemic, but China's entry into global vaccine supplier landscape has changed the rankings. China has altered the world order in vaccine exports.

**Table 3: Total Number of COVID Vaccine Doses Exported by Producing Economy**

<i>Producing economy (status as of March 31, 2022)</i>	<i>Number of doses exported (million)</i>	<i>Share of world exports</i>	<i>Cumulative share</i>	<i>Exports as share of total supply</i>	<i>Total supply of doses * (million)</i>
European Union	2,276.20	39.70%	39.70%	64.80%	3,721.0
China	1,869.10	32.60%	72.20%	32.10%	6,077.3
United States of America	859.1	15%	87.20%	58.40%	1,609.8
Korea, Republic of	235.8	4.10%	91.30%	91.10%	263.5
India	134.7	2.30%	93.70%	5.70%	2,465.6
Russian Federation	100.2	1.70%	95.40%	35.80%	286.2
South Africa	91.2	1.60%	97.00%	87.00%	125.2
Japan	67.0	1.20%	98.20%	99.80%	67.134
Other	105.9	1.80%	100.00%		604.5

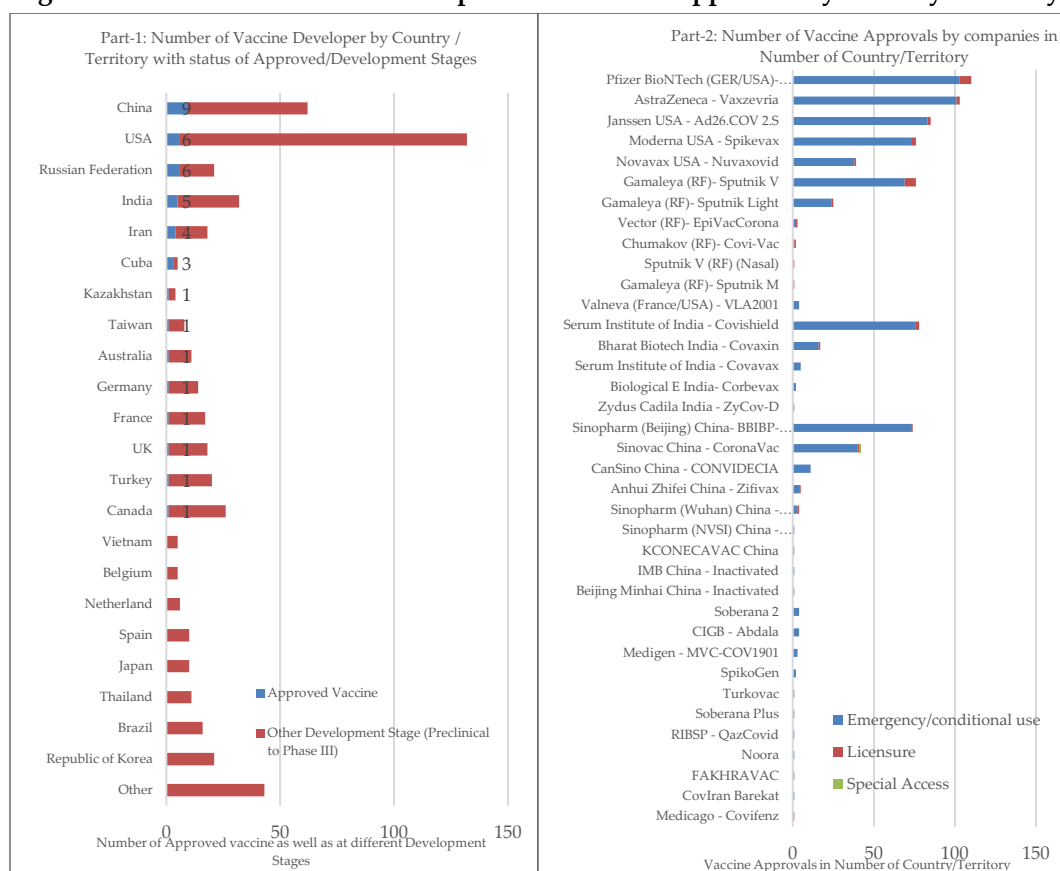
Note: \*Total supply contains both exported and domestically delivered doses.

Source: [https://www.wto.org/english/tratop\\_e/covid19\\_e/vaccine\\_trade\\_tracker\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm)

One reason why China is ahead of other countries in total supply of COVID vaccine doses could be its manufacturing capacity. China had a huge manufacturing capacity to serve its home market before the pandemic. During COVID, several Chinese companies went ahead to produce COVID vaccines and received WHO's approval for supply in the international market. In the first year of COVID 2020 itself, around 4–5 China-

manufactured COVID vaccines received approval for usage in the global market. At present (June 2022), China has the highest number of vaccine approvals (nine) for use in the international market, followed by the US (six), Russian Federation (six), India (five), Iran (four), and Cuba (three). In some of the advanced countries like Germany, France, the United Kingdom (UK), Canada, and Australia, only one vaccine was approved. China was ahead of the US and the EU in vaccine development and approval for use. However, if one takes into consideration the different stages (discovery to preclinical to clinical trial Phase III) of vaccine development in the pipeline, the US is far ahead (126 vaccine pipelines) of China (53 vaccine pipelines) and other advanced economies. In addition to five approved vaccines, India currently has 27 vaccines in the pipeline at different stages of development (Figure 3, Part-1).

**Figure 3: Number of Vaccine Developers and Vaccine Approvals by Country/Territory**



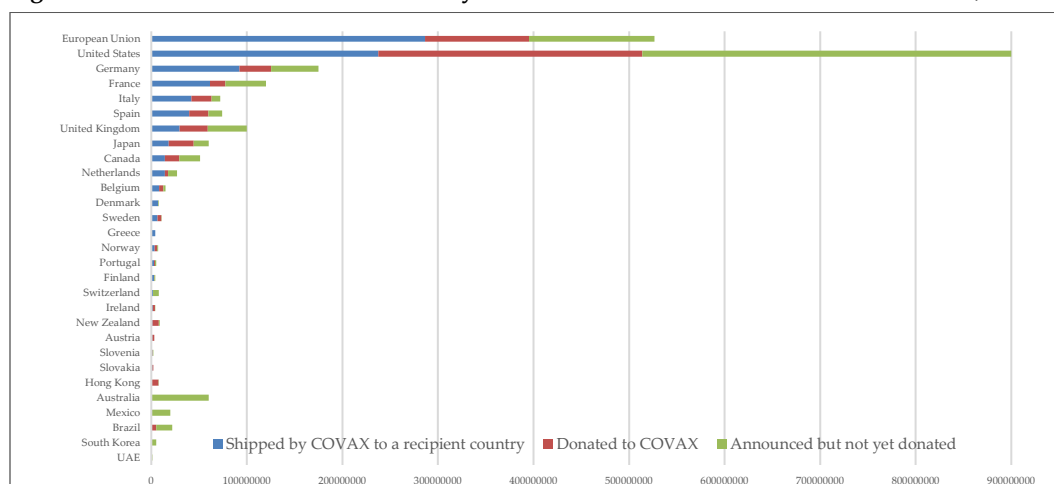
Source: UNICEF (Undated), "COVID-19 Market Dashboard." Available at: <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>; accessed on June 30, 2022.

If one considers all parameters of vaccine use such as emergency/conditional use, the Pfizer-BioNTech (Germany-US) vaccine has been approved for use in many countries (110). The UK's AstraZeneca COVID-19 vaccine is sold in 103 countries, the US'

Novavax/Moderna/Janssen vaccines taken together in 102 countries, India's SII/BE/BBIL/Zydus vaccines in 100 countries, China's Sinopharm/other vaccines in 110/85 countries respectively, and Russian Federation vaccines in 75 countries (Figure 3, Part-2). Of the total supply of COVID vaccine doses, around 90% of Indian doses went to just 20 countries in 2022. The Netherlands has the highest percentage share (around 35.64%), followed by Bangladesh (10.39%), and Myanmar (9.75%). Nigeria, Nepal, Australia, and Indonesia each have a share of around 4% (Hooda, 2022). In 2021, the top importers of Chinese vaccines were Indonesia, Brazil, Pakistan, Turkey, Iran, the Philippines, Morocco, Thailand, Argentina, Venezuela, Cambodia, Sri Lanka, Chile, Mexico, Bangladesh, Myanmar, and Afghanistan (Hooda, 2022). As of March 31, 2022, China delivered the maximum number of COVID vaccine doses across the globe through its 'COVID-19 Vaccine Diplomacy' programme (<https://chinapower.csis.org>).

## **5. The Flipside of COVID-19 Diplomacy Vs Efficacy of Chinese Vaccines**

Producers from the EU and the US continued to produce vaccines for HIC markets both before and during COVID, while India has a long history of producing vaccines for LIC/LMIC markets. During the COVID outbreak, no doubt, India enhanced its capacity of producing COVID vaccines, but when a devastating COVID wave hit in the spring of 2021, India prioritised immunising its own population over exporting vaccines. The combined vaccine production of two Indian manufacturers, namely Bharat Biotech and Serum Institute of India – the world's leading COVID vaccine manufacturer, was insufficient to meet the growing international demand as well as the domestic vaccination drive. China seized the chance when India suspended its vaccine exports in mid-April after having delivered 66 million doses to various developing countries, especially to neighbouring countries (Zeeshan, 2021). China pursued an aggressive public health diplomacy strategy to restore its image and earn goodwill, as, incidentally, the COVID virus originated in the Chinese province of Wuhan, which raised considerable doubts and questions around the world. As a first step towards vaccine diplomacy, China sought to project itself as a global health leader by making it appear that its medical supplies and vaccines are donations. However, in reality, more than 99% of the personal protective equipment (PPE) and around 96% of the vaccines exported by China in 2020 were sold rather than donated. Additionally, some of China's exported products were found to be fake or counterfeit (Lin *et al.*, 2021). China's donation of vaccines on the COVAX platform is found to be almost negligible at present (Figure 4). Few critics point out that China's prior engagement in 'COVID-19 Vaccine Diplomacy' was only a natural extension of soft power to capitalise on new economic and geopolitical opportunities and realise its aspirations to become a great power (Lee, Seow Ting, 2021).

**Figure 4: COVID Vaccine Doses Donated by Individual Countries to COVAX as of March 23, 2022**

Source: <https://ourworldindata.org/coronavirus>; accessed on July 15, 2022.

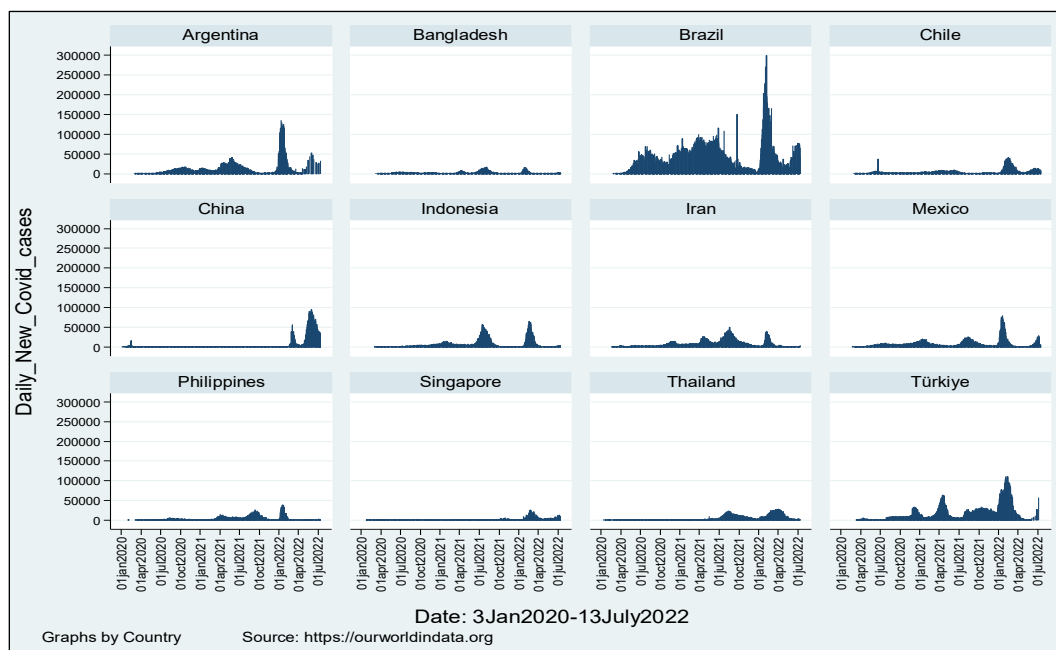
Of the eight leading vaccines (CoronaVac, Pfizer–BioNTech, Sinopharm, Oxford–AstraZeneca including SII, Moderna, Sputnik V, Johnson & Johnson and Bharat Biotech) that account for the majority of COVID-19 vaccine doses delivered globally, China’s CoronaVac and Sinopharm vaccines accounted for nearly half of all doses by the middle of 2021 (Mallapaty, 2021). Of the total vaccine doses produced in China, over two billion doses were administered within China and nearly one billion doses were exported to 110 countries (Mallapaty, 2021). China, from its non-existent presence in the international vaccine market, has emerged as a leading vaccine exporter to many developing, neighbouring, and Asia Pacific regions.

However, of late, countries that previously relied heavily on Chinese vaccines voiced concerns about the efficacy and safety of those vaccines. This is because most of the older Chinese vaccines used inactivated virus technology for vaccine development. The inactivated vaccines are easy to manufacture and somewhat safe but tend to produce weaker immune response compared to some other vaccine types (Gavi, 2020). An analysis of the association between the weekly COVID cases - adjusted for population - and vaccination rate suggests high COVID infection rates in at least six of the world’s most vaccinated countries, five of which rely mostly on Chinese vaccines (Lee, Yen Nee, 2021). Figure 5 shows the daily COVID cases of select countries, including China, that have experienced or are experiencing high burden of COVID cases and have heavily relied on Chinese vaccines at some point of time. Chinese vaccines have come under increasing scrutiny in developing, Asian, and neighbouring countries over the last eight to 12 months. Due to safety and efficacy concerns, the health authorities in at least ten countries have either suspended the use of Chinese vaccines, or recommended pairing them with non-Chinese booster shots, or taken other measures to turn away from them (Lin, 2021). Several other Asian countries that had made the Chinese vaccines a key plank in their

immunisation programmes have also announced that they will use other vaccines (Wong, 2021).

In March 2022, the COVID wave gripped China once again (Figure 5) – a country where 85.5% of the population has been fully vaccinated with its homemade vaccines. This put China's vaccine efficacy under the scanner. Researchers from China studied the data on SARS-CoV-2 (delta variant) transmission and found that given the low efficacy of the vaccines used in the country, they are unlikely to reach herd immunity by 2021 (Varshney, 2022). Concerns about the efficacy of Chinese vaccines are also being raised since they have not been as effective as Indian vaccines or other vaccines being used around the world in the fight against the Coronavirus pandemic (Liu *et al.*, 2021).

**Figure 5: Daily COVID Cases Status of Select Countries Importing Chinese Vaccines**

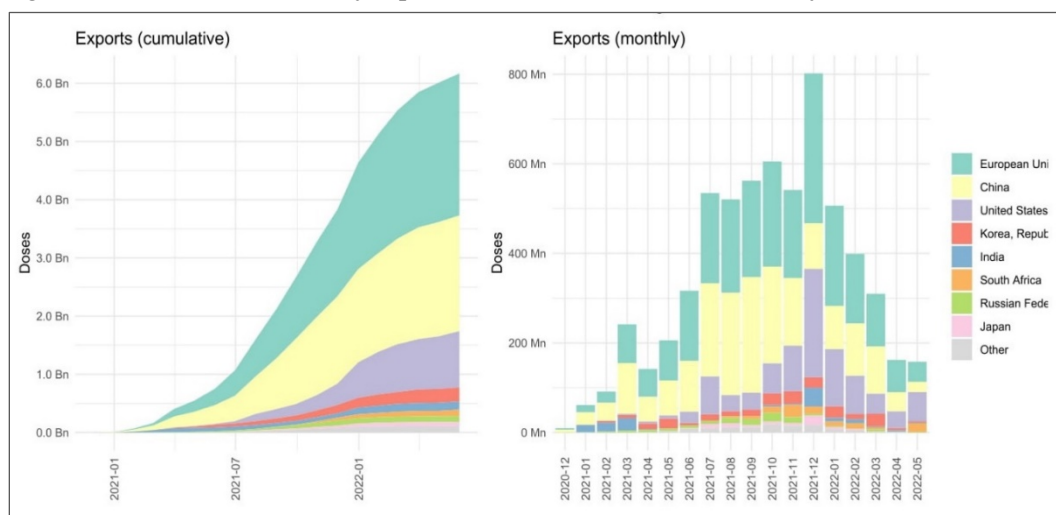


Source: Designed using data from <https://ourworldindata.org/coronavirus>; accessed on July 15, 2022.

Apart from the issue of efficacy, some countries expressed concern about the price difference. For example, the Sri Lankan government paid \$5 more than Bangladesh for each dose (Zeeshan, 2021). For some countries, China's monopoly over vaccine supply has meant the threat of Chinese political influence on strategic affairs (Zeeshan, 2021). Thus, China's exports are likely to be constrained by the willingness of countries to use their vaccines, and many have started to look for other alternatives. Initially, Chinese vaccines were distributed to 110 countries, but the number has now fallen to 85 (Mallapaty, 2021; Figure 3, Part-2). According to a survey conducted by the University of Hong Kong, about 61% of people do not want to take vaccines developed in China (*Hindustan Times*, 2021). As other countries follow suit, China's vaccine exports have decreased significantly, as

illustrated by the monthly vaccine supply shown in Figure 6. China's COVID vaccine supply declined in relative terms between October 2021 and May 2022. No doubt, China-manufactured vaccines appear to be losing favour, but whether China's vaccine diplomacy can be easily undone is a million-dollar question. If one looks at the cumulative picture of COVID vaccine exports from China, despite a recent slowdown, their supply of COVID vaccine doses to the world remains the second highest (Figure 6). In comparison to other economies, India has been a marginal player for the past 18 months, with the exception of January 2022 and some initial months of 2021 (Figure 6).

**Figure 6: Cumulative and Monthly Export of COVID Vaccine Doses as of May 31, 2022**



Note: Exports are defined as the number of doses delivered across borders from vaccine-producing economies to vaccine-administering economies.

Source: Taken directly from [https://www.wto.org/english/tratop\\_e/covid19\\_e/vaccine\\_trade\\_tracker\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm); accessed on June 30, 2022.

There is no doubt that India-manufactured COVID vaccines are welcomed around the world; however, India will have to strike a balance between domestic and global (exports) vaccine needs. On July 17, 2022, India reached the milestone of administering two billion COVID vaccine doses, nearly one-and-a-half years after launching the free vaccination drive in January 2021 (Dutt, 2022). Because India has vaccinated majority of its population with advanced buster doses to some extent, it can boost its exports when Chinese vaccines are already under scrutiny. Since manufacturers from the US and the EU tend to serve only the HIC markets, India, as a highly trusted and tested country, can reclaim its position in the LIC and the LMIC markets. The current vaccination status suggests that the world is still suffering from insufficient vaccine supply. Developing countries still have a high vaccine requirement to achieve 'fully-vaccinated' status (Table 4). As of May 31, 2022, only 14.1% population in low-income countries has been fully vaccinated, and 17.3% has received at least one dose. In LMICs, around 48% of the population still needs to be



vaccinated to achieve the ‘fully-vaccinated’ status (Table 4). Hence, there is a market out there for COVID vaccines that India can tap into.

**Table 4: Vaccination Status by Level of Development of Countries**

<i>Income group (vaccination status as on May 31, 2022)</i>	<i>Number of doses supplied (million)</i>	<i>Number of courses* supplied per 100 people</i>	<i>Percent with at least one dose administered</i>	<i>Percent fully vaccinated</i>	<i>Population (million)</i>
Low income	390.60	27.7	17.30%	14.10%	704.30
Lower middle income	4,543.70	75.8	59.30%	51.80%	2,995.40
Upper middle income	7,007.60	119.6	79.10%	73.90%	2,930.40
High income	3,211.20	129.0	78.60%	73.80%	1,244.60

Note: \* A course is defined as a series of vaccine doses required to be fully vaccinated.

Source: [https://www.wto.org/english/tratop\\_e/covid19\\_e/vaccine\\_trade\\_tracker\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm)

However, to gain a deep insight into why India was unable to deliver the required doses to the world when the need/demand was greater, why India lost its global position, and whether that position can be reclaimed, one needs to understand the inherent structural issues with the Indian vaccine industry beyond COVID-19. Especially, what Indian manufacturers produce and what manufacturing capacity is required to meet both domestic and international vaccine needs. The paper now turns to check this reality.

## 6. Some Structural Issues with the Indian Vaccine Industry

### 6.1 Dismantling the Strength of Public Sector Vaccine Manufacturing

India has a long history of vaccine development and production. During the pre-liberalisation period, there were 29 vaccine manufacturing institutions in the public sector (Madhavi, 2022). The public sector demonstrated its ability to innovate new processes and products using modern production technologies and gained expertise in manufacturing a wide range of vaccines/sera such as typhoid, cholera, diphtheria, pertussis, tetanus (DPT), diphtheria and tetanus (DT), tetanus (TT), oral poliovirus (OPV), BCG (Bacillus Calmette–Guérin), measles, MMR (measles, mumps and rubella), hepatitis B, Japanese encephalitis (JE), plague, gas gangrene anti-toxins, vaccine lymph, anti-dysentery, anti-snake venom, and anti-rabies serum (GoI, 2006-2022). The public sector made a remarkable contribution to the Universal (expanded) Immunisation Programme (UIP) that provides free vaccination for basic vaccines. At the time when UIP was introduced in 1985, the country was self-sufficient in producing basic vaccines for UIP and mostly depended on the public sector for the supply of vaccines (Madhavi, 2005; Lahariya, 2014; and, Chaudhuri, 2022). Despite providing such remarkable services to the nation, the public sector’s fortune has been on decline since 1980s. India closed seven of its public sector units by the late 1980s and another 15 in early 2000s, leaving only six units functional, namely BCG Vaccine Lab (BCGVL) Chennai, Central Research Institute (CRI), Kasauli; Pasteur Institute of India

(PII), Coonoor; Bharat Immunologicals and Biologicals Corporation Ltd (BIBCOL), Bulandshahr; Haffkine Bio-Pharmaceutical Corporation Limited (HBPCL), Mumbai; and, Human Biological Institute (HBI), a division of Indian Immunological Ltd, Gujarat.

The government's response was also less than encouraging for these six functional units. In January 2008, the Government of India revoked the manufacturing licenses of three of them (BCGVL, PII, and CRI). On the eve of their licenses being revoked, between 2004-05 and 2007-08, their share in vaccine production for four basic UIP vaccines was 100% in BCG, 78% in DT, 64.3% in TT, and 59.1% in DPT (Javid Chowdhury Committee, 2010; Madhavi, 2022). A WHO-GMP (Good Manufacturing Practice) certified public sector unit (BIBCOL) supplied polio vaccines to UNICEF and 120 million polio doses to India's UIP in 2004-05 (constituting nearly 60% of the total market share of polio vaccines in the country), demonstrating its ability to introduce monovalent oral polio vaccine (mOPV) type 1, 2 & 3 in 2009 and bivalent oral polio vaccine (bOPV) in 2014; it received WHO-GMP certification for bOPV in 2017 (BIBCOL, 2022). Despite achieving important milestones, production has not resumed since 2005-06, and since 2011-12, the company's installed capacity of 600 million doses has come to just 0.5vials/shift (GoI, 2006-2022). Similarly, a GMP-PQ certified public sector unit (HBPCL) that launched several indigenous-OPV projects, supplied OPV to UNICEF and accredited its facility for both trivalent oral polio vaccine (tOPV) and monovalent oral polio vaccine (mOPV1), did not receive UIP order for polio vaccine between 2014 and 2016 because India transitioned from tOPV to bOPV between 2012 and 2016 (GoI, 2006-2022). The company, however, made the necessary investment and upgraded its bOPV production capacity, supplying 3280 lakh doses of bOPV (constituting 100% share) to UIP in 2016-17. However, since inactivated polio vaccine (IPV) was in use in the US and some other advanced economies, India fell victim to international politics (for details, see Madhavi, 2022) and, as a part of the Global Polio Endgame Strategy, introduced IPV in UIP between 2015 and 2016. The company has yet to start and upgrade its capacity for IPV (GoI, 2006-2022). In a way, the country is losing the public sector's installed capacity potential for producing different vaccines.

## **6.2 Unutilised/Underutilised Public Sector Potential**

The country's installed capacity for vaccine manufacturing increased to 1,19,093 lakh doses in 2014-15 from 89,888 lakh doses in 2006-07, which again declined to 80,816 lakh doses in 2018-19 (Table 5). The public sector's share in the installed capacity declined to 10.2% in 2018-19 from 22.7% in 2006-07. Its share in vaccine production also declined significantly to a meagre 1.7% in 2018-19 from 29.4% in 2006-07. Capacity utilisation (measured as the share of production in installed capacity) of the public sector fell to an all-time low of 4.5% in 2018-19 from 20.7% in 2006-07. The public sector was primarily focused on meeting UIP requirements, but the demand for UIP vaccines from the public sector dropped significantly to a negligible 0.8% in 2018-19 from 32.2% in 2006-07 (Table 5). Over time, the government started redirecting UIP vaccine demand to the private sector. Currently, private firms supply over 95-99% of the UIP vaccine demand. This suggests that the

country has stopped utilising the full manufacturing potential of its public sector. In India, the public sector, which provided commendable services to the nation during epidemic emergencies ranging from plague to cholera, has lost its dominance and become a marginal player. Except for tissue culture based anti-rabies (78.32%), DPT (29.20%), and TT (1.42%) vaccines, almost the entire market for the public sector was eliminated, and the country relied heavily on the private sector for vaccine supply (Hooda, 2022).

**Table 5: Public and Private Sector Installed Capacity, Production, Demand, and Capacity Utilisation Status for All Types of Vaccines (Quantity in lakh doses)**

	<i>Total Installed Capacity (% share of Public)</i>	<i>Total Production (% share of Public)</i>	<i>Capacity Utilisation: Private (&amp; Public) sector share in%</i>	<i>Total Demand (% share of Public)</i>
2006–07	89888 (22.7)	14358 (29.4)	14.6 (20.7)	15358 (32.2)
2010–11	93293 (19.4)	24431 (1.7)	31.9 (2.29)	11756 (9.5)
2014–15	119093 (20.6)	31533 (8.9)	30.4 (11.4)	13986 (5.9)
2018–19	80816 (10.2)	21347 (1.7)	28.9 (4.5)	5804 (0.8)

Source: National Health Profile (2008, 2012, 2016, and 2021), GoI.

### **6.3 Limited Capacity of Private Sector – Conventional Centric Vaccines**

Presently, India has around 25 indigenous manufacturers in the private sector. There are a few multinational companies (MNCs) such as GlaxoSmithKline and Sanofi that primarily import vaccines and repackage them for sale in the Indian retail market (Ghosh, 2019). Indigenous private manufacturers have made commendable progress on international platforms, most notably in the WHO Prequalification (WHO-PQ) programme that sets the quality, safety, and efficacy standards for a vaccine to be used in the national immunisation programme and requires the manufacturer to adhere to GMP. Of the total 45 vaccine manufacturers listed on the WHO-PQ list, seven or eight are from India. Serum Institute of India (SII) has the most (22) PQ vaccines (WHO, 2022). Biological E obtained WHO-PQ for TT, DTP, JE, DT, measles and rubella, and typhoid conjugate vaccines between 2009 and 2020. Bharat Biotech received WHO-PQ for three vaccine types (polio, typhoid, and rotavirus) out of a total of seven vaccines between 2015 and 2021. Sanofi Healthcare, an MNC, received WHO-PQ for four vaccines, namely TT, cholera, DPT, and inactivate polio vaccine. Cadila Healthcare and Chiron Behring both received WHO-PQ for rabies vaccine. In 2012, 67 prequalified vaccines in dosage forms were being produced by seven Indian manufacturers (*The Economic Times*, 2013), and by June 2022, the number of prequalified vaccines (dosage forms) of India increased to 112 out of a total 264 prequalified by WHO (WHO, 2022). In addition, according to Developing Countries Vaccine Manufacturers Network (DCVMN), India is the most trusted vaccine manufacturer. Out of the total 41 vaccine manufacturing companies from 14 developing countries listed with DCVMN, nine are from India. India is a significant contributor to the four billion vaccine doses that DCVMN members collectively supply to about 170 countries annually (DCVMN, 2021).

It is well known that the private sector has a strong record of research and innovation. The Indian company Panacea Biotech developed, produced, and introduced the first fully liquid Pentavalent (DTwP-HepB-Hib) and the first fully liquid Hexavalent vaccine in 2008 and 2017 respectively. The first conjugated typhoid vaccine was developed and manufactured by Bharat Biotech; it was launched in 2013 and received WHO-PQ in 2017. The first thermostable rotavirus vaccine, developed by SII, became available in 2017. First Meningitis-A vaccine developed for use in Africa was manufactured by SII and prequalified by WHO in 2010 (Chaudhuri, 2022). However, most of the vaccines they manufacture are traditional/conventional in nature, unlike those produced by the India's public sector. A few of them produce (with a very low base) newer and recombination vaccines such as typhoid, meningococcal, meningitis, haemophilus influenzae (Hib), quadruple (DTwP-HepB), tetravalent (DTwP+Hib), pentavalent (DTwP-HepB-Hib), and MMR and a couple of conjugate vaccines (Hooda, 2022) whose intellectual property right protection period has already expired (Chaudhuri, 2022). The private sector has been unable to bring indigenous vaccines for seasonal influenza vaccine and inactivated polio vaccine (IPV) so far (GoI, 2006–2022). The conventional centric vaccine manufacturing, no doubt, made India a global leader in the supply of three conventional vaccines, namely DPT, BCG, and measles. India accounts for 60% of the global production of these vaccines, meeting 40 to 70% of WHO's demand for DPT and BCG vaccines, and 90% of WHO's demand for measles vaccine in 2020 (GoI, 2022). However, due to inadequate production of other UIP and non-UIP vaccines, India, which had previously been self-sufficient, could not meet the growing domestic requirements and was forced to rely on imported vaccines to fill in such gaps.

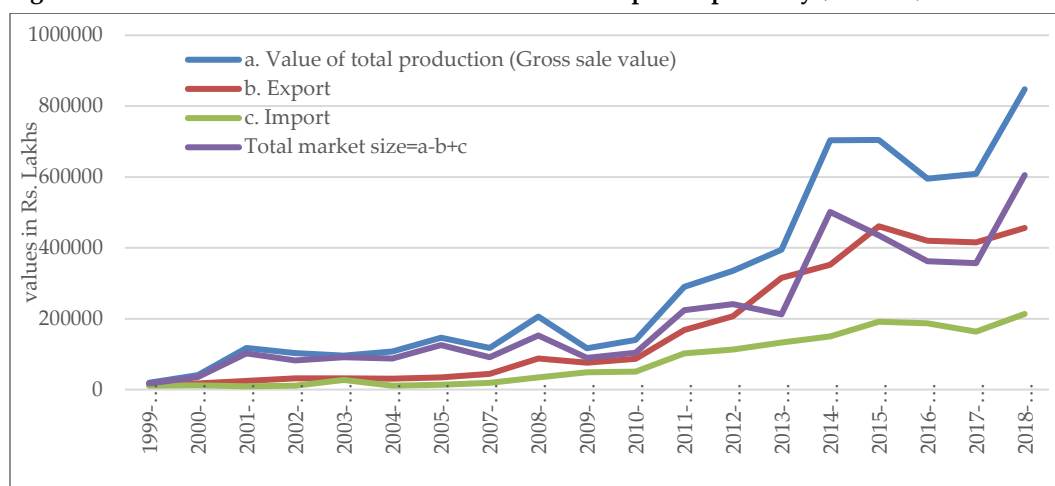
### 6.3 Growing Domestic Market Size and Import Dependency

Due to the growing population and the rising demand for vaccines, India's domestic vaccine market size [ $DMS=SV+I-X$ ] grew at a CAGR of 18.7% in the past one decade from 2009-10 to 2018-19, reaching INR 60.52 billion in 2018-19 from a low of INR 1.71 billion in 2000 (Figure 7). In 2001, around 90.95% of the domestic market requirements were met by domestically produced vaccines and the remaining 9.05% by imported vaccines, while the share of imported vaccines meeting the domestic requirements increased to 35.26% in 2018-19 (estimated from Figure 7).

Measurement of the import penetration rate/ratio [ $IPR=I/(SV-X+I)*100$ ] suggests that India has become a significant market for imported vaccines. Import penetration increased sharply to 62.5% in 2013-14 from 9% in 2001-02, recording 35.3% in 2018-19 (Figure 8). The IPR increased to 54.2% in 2009-10 from 22.4% in 2008-09, a year after India revoked the licenses of three public sector units. Coincidentally, India started importing three UIP vaccines, namely hepatitis, anti-rabies and Japanese encephalitis, from China a year after the licenses of the three public sector units, who had a certain presence there, were revoked in 2008 (Hooda, 2022). The country became largely dependent on imports of polio vaccine from Indonesia the following year when a public sector undertaking (BIBCOL) was unable

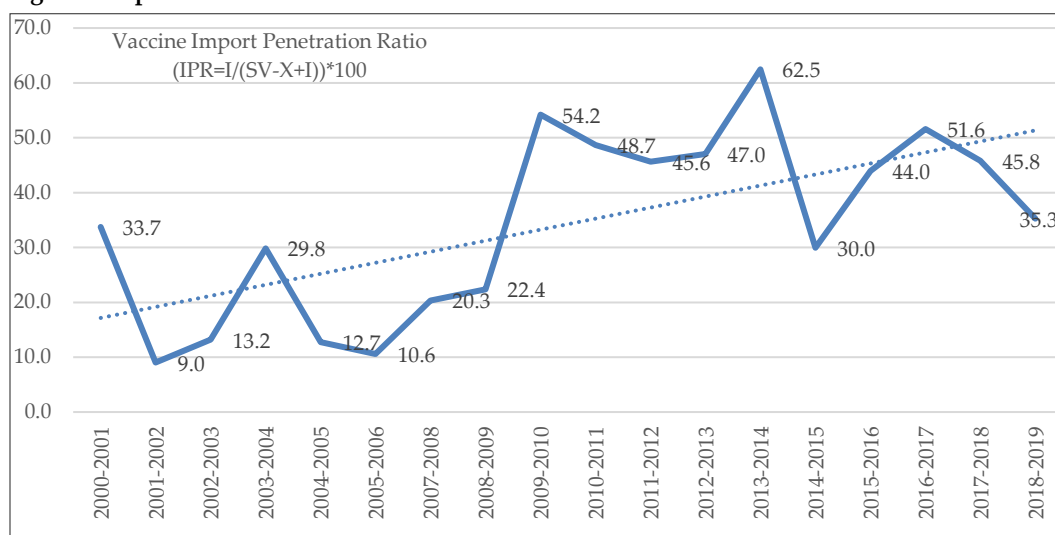
to resume manufacturing in 2005-06. It not only resulted in high import penetration, but also caused India's budget allocation for the Pulse Polio programme to nearly double in just five years to Rs 1341.48 crore in 2008-09 from Rs 659.94 crore in 2003-04 (Hooda, 2022). It is also true that several states faced vaccine shortages at the time; while the gap was filled to some extent by the private sector, the cost of procuring vaccines from the private sector increased manifold (Madhavi, 2022), pushing India's routine immunisation budget significantly up within a year to Rs 615 crore in 2008-09 from Rs 317 crore in 2007-08 (Hooda, 2022).

**Figure 7: Domestic Market Size of Vaccines in India and Import Dependency (Rs lakhs)**



Source: Sale value is estimated from ASI and export-import from DGCI&S.

**Figure 8: Import Penetration Ratio of Vaccines in India**



Source: Estimated using data from Figure 7.

Not only does India import some of the basic UIP vaccines when domestic supply is insufficient, but the increased uptake of newer generation vaccines such as pneumococcal conjugate vaccine, varicella vaccine, rotavirus vaccine, HPV, and typhoid conjugate vaccine has resulted in higher import intensity as well. The share of imported vaccines in the single vaccine category (HS-8:30022019, which also includes newer generation vaccines) increased significantly (Hooda, 2022). They are primarily high-priced vaccines, the production and sales of which are dominated by a few MNCs (GSK, Pfizer and Merck) worldwide and which are generally sold in the retail market.<sup>3</sup> In India, around 80% of the imports come from Belgium, France, and the Netherlands; Indonesia and China accounted for 15% and seven% of India's imports in 2020 (Hooda, 2022). This analysis suggests that private companies filled the vaccine gap through imports rather than domestic production.

## 7. Summing Up

Vaccine development and manufacturing have been India's core strength for over a century. In the past, the public sector had made the country self-reliant and self-sufficient in producing basic UIP vaccines, but due to the dismantling of the public sector in the post-liberalisation period, the country lost the installed capacity potential of producing different vaccines to a considerable extent. Hence, due to a lack of domestic supplies, the country became dependent on imported vaccines. The dominant private sector filled the vaccine gap through imports rather than domestic production.

In the global market, India ranked fourth in terms of the volume of vaccine supply, but eighth in terms of value of export. This distinction in value-volume ranking has long made the country a global hub for supplying affordable vaccines, especially to the LIC and LMIC markets. India, however, nearly lost its position as the world's leading supplier of vaccines to developing countries during the COVID period. China, on the other side, from a non-existent presence in the international vaccine market, has emerged as a leading player. One of the Chinese public sector units, Sinopharm, contributed significantly to making China an international player, while India had to suspend its COVID vaccines export in the spring of 2021 (most of the vaccines were used for domestic vaccination drive) due to the limited supply of vaccine manufactured by two Indian private companies. Only one Indian private company, Bharat Biotech, was able to develop indigenous COVID vaccines

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<sup>3</sup> The high-priced retail market segment dominated by MNCs accounted for 64 percent of the total vaccine sales of Rs 21,880 million in the year 2019. Of these, GSK captured the largest market share (33.2 percent), followed by Sanofi India (18.5 percent), Pfizer (7.1 percent), MSD (3.9 percent), and Abbott India (1.5 percent). The high-priced products sold widely include Meningococcal vaccine by Sanofi India (Rs 4950 per single dose), Pneumonia vaccine by Pfizer (Rs 3801), and Human Papillomavirus Bivalent vaccine by MSD (Rs 3250). As of March 2019, single dose vaccines costing more than Rs 2000 accounted for 37 percent of the sales and those costing between Rs 1000 and Rs 2000 accounted for 38 percent of the sales in 2018-19. The share of vaccines costing less than Rs 500 was only 20 percent (Chaudhuri, 2022).

(Covaxin) with scientific assistance from public sector institutions, namely Indian Council of Medical Research and National Institute of Virology. This necessitates rethinking the relevance of the public sector. We believe that if the public sector had played a complimentary role or had been involved at different levels, India could have met its domestic needs while also benefitting globally. Hence, India should consider reviving its public sector to become self-sufficient in vaccine technology and vaccine manufacturing.

Most of the manufacturers in India have conventional vaccines in their product basket. This led to an almost negligible presence of India in the supply of vaccines to the HIC markets. India has also not made any visible efforts to enter these markets. Tapping such high-priced markets generally requires new investment and innovation around a wide-range of vaccines. Indian manufacturers have several products in their R&D pipeline in different stages of development (preclinical to advance) (Hooda, 2022); it will be interesting to see how they materialise in the future.

Utilising the technology transfer and contract manufacturing options for vaccines like human papillomavirus (HPV-cervical cancer), rotavirus (diarrhoea, vomiting, fever, abdominal pain), and pneumococcal (pneumonia bacteria, etc.), conjugate vaccines could be another option to tap the HIC markets (Research and Markets, 2021). However, patent barriers, technical know-how and manufacturing complexity, lack of R&D capacity/spending, favourable local environment for research infrastructure, and other barriers may prevent the companies from entering these high-priced segments (Research and Markets, 2021).

There is need to look beyond COVID-19 and the conventional vaccine manufacturing approach. Globally, most of the vaccines to date have primarily focused on disease prevention; however, they are expected to play an increasing role in the treatment of diseases endemic to high-income regions (HIV and norovirus) as well as those endemic to low-income regions (Zika virus, tuberculosis, malaria). There are several such options, and India, as a well-trusted country on the WHO-PQ platform, may consider capitalising on such possibilities in the future for the growth of the industry.

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Shailender Hooda

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