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Vaccine Manufacturing Industry of India: Structure, Size and Competitiveness

Shailender Hooda [*]

[***Abstract***: *Vaccine manufacturing in India has historically been centered around producing a wide-variety of conventional vaccines that made the country self-sufficient as well as a net exporter of basic vaccines. However, overtime, other safe and efficacious vaccines that follow technologically more advanced manufacturing processes became available in the market against some high burdened diseases, their increased uptake made the country import dependent. In the second half of 2000s when manufacturing capacity of public sector was being dismantled, India became a big market for imported vaccines (e.g., import penetration rate increased from 10.6% to 62.5% between 2007-08 to 2013-14) since then and export got affected adversely. Despite such repercussions, India continued to enjoy comparative advantage (RCA>1) and trade surplus due to high acceptability of Indian vaccines in developing countries market. High R&D intensity and active State support are critical for making the country self-reliant and self-sufficient in vaccine development and manufacturing, and addressing future health challenges like the Coronavirus.*]

Keywords: *Vaccine Industry, Indigenous Manufacturing, Capacity Utilisation, Domestic Market Size, Import Penetration, Export Efforts, Revealed Comparative Advantage, Universal Immunisation Programme (UIP), Public Sector, R&D.*

1. Introduction

Vaccines have been highly cost-effective medical intervention in reducing death and morbidity caused by infectious diseases (GoI 2011). Some of the viral and bacterial infections that traditionally affected millions of children have been reduced drastically, like smallpox[1] eradicated completely (Henderson 2011), polio[2] almost disappeared worldwide (WHO 2022a). The vaccination against diphtheria, tetanus, pertussis, measles and influenza alone save at least 3.5–5.0 million lives every year worldwide (WHO, undated) and prevent almost 6 million deaths from vaccine-preventable-diseases (VPDs) (Ehreth 2003; Rodrigues and Plotkin 2020). These numbers are projected to increase further if all children are vaccinated

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[1] In the 20th Century, smallpox killed "at least 300 billion people" which have been eradicated (between 1959-1980) completely by 1980 (Henderson, 2011).

[2] Poliovirus have decreased by over 99% since 1988, from an estimated 3,50,000 cases then, to 6 reported cases in 2021 (WHO 2022a).

as per recommended vaccination schedule of World Health Organisation, as VPDs are still responsible for 1.5 million deaths worldwide each year (Vanderslott 2018) and around 19.5 million infants are still at of their risk because they miss out on basic vaccines (Vanderslott et al. 2019). The recent vaccination drive could curtail Coronavirus (COVID-19) infection, reduced hospitalization burden (Barro, 2020) and prevented almost 14.4 million deaths from COVID-19 (henceforth, Covid) in first year itself between December 2020-2021 (Watson et al. 2022). Despite the fact of great imperative of vaccination in preventing infections and saving lives, many countries lack access to and coverage of recommended vaccination. For instance, coverage rate of third dose of DPT (Diphtheria-Pertussis-Tetanus) was below 50% in low- and middle-income countries (LMICs) as compared to more than 90% in most of the rich countries in 2018 (Watson et al. 2022). The global average coverage rate of a vaccine like the third dose of DPT was 86% in 2018, while children received rotavirus (35%) and pneumococcal (47%) vaccines that protects millions of children from diarrheal and pneumonia diseases, was low (ibid). In the recent global efforts of combating Covid-19, as of May 31, 2022, only 14.1 percent population from low-income countries and 52 percent from LMICs could be fully vaccinated with Covid-19 vaccine as against the 74% in high-income countries (Hooda 2022).

Evidences suggest that countries having robust vaccine-manufacturing base, in the public sector, could make independent decisions on vaccine manufacturing and supply, provision and introduction of vaccine in their respective health system and achieved relatively high vaccination status (Khan 2021) as compared to countries that have no/inadequate manufacturing capacity and largely rely on imported vaccines (Kumraj et al. 2022). It is argued that timely and wider access to vaccines can be facilitated effectively through the local vaccine manufacturing. Vaccine development and manufacturing, however, is laborious and costly endeavour (Plotkin et al. 2017) and often viewed as a less profitable product of pharmaceutical companies (Tull 2021). Therefore, a majority of vaccine manufacturers are from high-income countries where they get a strong state support for vaccines research and development (Steven 2011; Xue and Quellette 2020; Mani 2021; Cross et al 2021), while many low-income countries, due to their financial and technological capacity constraints, have not been able to establish own manufacturing units (Khan 2021).

In 2010, nearly 200 countries committed to a shared global health vision called '*Decade of Vaccine Initiative (DVI) 2010-2020*' to stimulate the discovery, development and delivery of life-saving vaccines and achieve 90% vaccination coverage in developing countries. All countries were supposed to play a significant role in these initiatives, however, manufacturers from developed countries, that used to supply majority of prequalified vaccines to the world, have shown least interest in EPI supplies (Expended Programme on Immunisation) and increasingly focuses on the production of vaccines that are primarily used in developed countries (Jadhav et al. 2014). In order to address such gaps, unlike the past where five-big manufacturers (Sanofi Pasteur, GlaxoSmithKline, Merck, Pfizer, and Novartis) accounted for majority of vaccine production in the world, smaller biotech and emerging-market players have been intervening aggressively through new R&D (Research

and Development), contract manufacturing[3] and technological transfer to exploit vaccine manufacturing and investing more to enhance domestic manufacturing capacity (ResearchandMarkets 2021).

The significance of having local manufacturing capacity gained prominence during Covid emergency when widespread lockdown and vaccine nationalism disrupted the vaccine supplies in developing countries especially in the South African countries (Makenga 2022). Many countries were keen to play key role in combating the Coronavirus pandemic by supplying safe and affordable vaccines to the world including India. China even launched a 'Covid-19 Diplomacy Project' to capture the world vaccine market[4] (CSIS 2022). The vaccine supply to international market however must satisfy certain strict norms of quality, safety and efficacy to make sure that country's vaccine production lines are efficacious and safe and can easily be trusted. These stringent regulatory norms are devised and determined in 'vaccine prequalification' (PQ) criteria of World Health Organisation that was introduced in 1987 (Dellepiane and Wood 2015). These norms have undergone through refinement and changes overtime due to the desire of having a more efficient and technologically advanced manufacturing process for ensuring vaccine's quality and manufactures to follow Good Manufacturing Practice (GMP) (Ulmer et al. 2006).

Globally, around 25 effective vaccines are available against the 28 human diseases[5]. Given the necessity and public good characteristics, some of the vaccines are entrusted through Universal Immunization Programme (UIP)[6] that were added in respective Country's UIP at different points, while several newer generation vaccines that became available in market overtime remained out of UIP ambit. The vaccines listed under UIP vary widely, influenced either by variation in strain across regions, degree of disease prevalence or/and limited supply and capacity to manufacture all kind of quality vaccines[7]. For instance,

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[3] In 2020, global commercial vaccine contract manufacturing market alone accounted for over 64 percent ResearchandMarket (2021).

[4] However, countries that had relied heavily on Chinese vaccines voiced concerns about efficacy and safety of their vaccines and reiterated that they have not been as effective as Indian vaccines or other vaccines being used around the world in the fight against the Coronavirus pandemic. Recently, China's Covid vaccine losing out favour across developing countries due to the quality and efficacy issues (Hooda 2022).

[5] Cholera, Dengue fever, Diphtheria, Haemophilus influenzae type b, Hepatitis A, Hepatitis B, Hepatitis E, Human papilloma-virus, Influenza, Japanese encephalitis, Malaria, Measles, Meningococcal disease, Mumps, Pneumococcal disease, Pertussis, Poliomyelitis, Rabies, Rotavirus gastroenteritis, Rubella, Tetanus, Tick-borne encephalitis, Tuberculosis, Typhoid fever, Varicella, Yellow fever, Shingles (Herpes Zoster), and Smallpox. https://ourworldindata.org/vaccination

[6] UIP committed for universal access to all relevant vaccines to control infectious diseases and achieve better health for all population everywhere and generally delivered through public health system/programme.

[7] For instance, national health system funds rotavirus vaccine in Germany but not in Spain. Japanese encephalitis, cholera, and yellow fever vaccines are recommended in some Asian countries like India and Thailand while Australia funds for meningococcal C conjugate vaccines.

Contd…

India launched EPI in 1978 with four (BCG, DPT, OPV and typhoid)[8] vaccines. For almost two decades since its beginning, no additional vaccines was added in EPI (GoI 2011). Its ambit was increased with the inclusion of measles vaccine (typhoid vaccine was discontinued) in 1985 and the programme was renamed as UIP in the same year. By 1990, UIP, in phased manner, aimed to target all infants with primary immunization and all pregnant women with TT (Tetanus Toxoid) immunization (4 plus TT). India, over time, added several other vaccines like the Hepatitis B (2007-08), second dose of measles (2010) and Japanese Encephalitis (JE) (2011) vaccines in UIP. Recently, few more vaccines like yellow fewer in 2015, IPV (Inactivated poliovirus vaccine), replacing OPV, in 6 states in 2015 and across India since 2016, Rotavirus diarrhea in 2016 in 11 states and since 2019 at all India level and the PCV (Pneumococcal Vaccine) in five Indian states in 2017, were added in UIP (GoI, undated). A number of other safe and efficacious vaccines became available for most deadly diseases like pneumonia and diarrhea, Typhoid and Rubella that are being used in the immunization programmes of many countries. A few other vaccines like Haemophilus influenzae type b (Hib) vaccines, Pneumococcal conjugate vaccines, Rotavirus vaccines, HPV (Human Papillomavirus) vaccines that became available in the market have an estimated high burden and possible role in reducing child mortality in India (GoI 2011). If domestic manufacturers do not have enough production capacity to cover the entire annual requirement of these vaccines, the country has to place a parallel purchase contract from different indigenous sources and also use import mechanism to procure them (GoI 2011). Considering these facts in advance, first ever *National Vaccine Policy 2011* of India strongly felt the need of making the country self-reliant and self-sufficient in development and manufacturing of vaccines listed under UIP and strives to enhance manufacturing capacity around newer and expensive vaccines that are available in the market (GoI 2011)[9]. It stressed that an enhanced capacity of producing a wide range of vaccines is not only important for increasing affordability and vaccine coverages in the country but they can be exported to other nations. However, if supply fall short from domestic producers; they must be imported, which leave the UIP vulnerable to price and supply shortages (GoI 2011).

Keeping in view of the dynamics of growing requirements of different types of UIP and newer vaccines, changing and more stringent regulatory pathways for ensuring safety and

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https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization; https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year.

[8] Bacille Calmette-Guerin (BCG) – a vaccine for tuberculosis (TB) disease; OPV- Oral Poliovirus Vaccine

[9] The policy document states that there is abundance of new and expensive vaccines on one hand and limitations of resources on the other where most of the new vaccines are used by one segment of the population who can afford them, while vulnerable segment, which are serviced through UIP, misses out on this opportunity. In such situation, it becomes imperative that the country to have a strong vaccine manufacturing capacity, including of producing more complex and newer vaccines (GOI 2011).

efficacy of vaccines, growing competition from emerging market players and significance of having local manufacturing capacity, it is worthwhile to map vaccine manufacturing landscape of India across UIP and non-UIP vaccine categories. An analysis across vaccine categories helps us to assess indigenous manufacturing capacity and lack thereof as well as contribution of indigenous manufacturing in serving the national and international market. We have placed the analysis in historical perspective that begins with analysing the structural change in producing different type of vaccines across public and private sector in India and review key policy initiatives/decisions that might have affected the overall vaccine manufacturing in the country. It then seeks to evaluate domestic vaccine market size across UIP and non-UIP vaccines, especially to assess emerging pattern of import dependency on vaccines in which domestic supply is limited/inadequate. Lastly, it analyses how India has fared its position in the competitive global vaccine market and identifies who dominate in vaccines supply to different markets of the world. Overall, this paper provides a detail analysis around the structure and growth of manufacturing capacity, size of vaccine consumption meeting through domestic and imported vaccines and export competitiveness in vaccine segment. A study around these issues assume imperative for exploring the future growth potential of vaccine industry in a situation when outbreak of Coronavirus pandemic have already transformed the world vaccine market in a significant way. Secondly, understanding India's manufacturing landscape is important to trace why India had to suspend its vaccine export during Covid emergency, especially in the spring of 2021, which it used to export to developing country market (Hooda 2022).

The structure of the paper is as follow. Followed by the introductory section, the paper provides a brief description on data and method. The analytical section covers structure and growth of vaccines manufacturing, domestic consumption market size and import dependency, and export performance. The last section summaries the findings and discusses the future growth potentials for vaccine industry of India.

2. Data and Method

The information are collected from Annual Report of National Health Profile (NHP), Ministry of Health and Family Welfare, the Annual Survey of Industry (ASI), Ministry of Statistics & Programme Implementation, the Directorate General of Commercial Intelligence and Statistics (DGCIS)[10], Department of Commerce, Ministry of Commerce and Industry, Government of India and the World Integrated Trade Solution (WITS) data of World Bank.

The Annual Report of NHP captures information on production (Y), installed capacity (C), supply and purchase/demand order (PO or D) placed by the government for UIP vaccines from public and private manufacturers. These information are available in doses form

[10] https://tradestat.commerce.gov.in/eidb/default.asp

between 2006 to 2021, except for some earlier (2001 to 2003) reports, and utilized to present the changing manufacturing structure as well as capacity-utilisation status [U = Y/C*100] across public and private manufacturers. The essential component of assessing the size of vaccine manufacturing is the value of vaccine output. This is estimated using unit level data of ASI from past two decades (1999-2000 to 2018-2019). Since vaccine industry is a sub-sector of pharmaceutical industry, therefore, estimation of value of output is not straightforward mere by filtering National Industry Classification (NIC) code of pharmaceutical activity. To arrive at the value of output, we used product level codes, classified as Annual Survey of Industry Commodity Classification (ASICC) up to 2009-10 and National Product Classification for Manufacturing Sector (NPCMS) since 2010-11 to till recently. The vaccines specific ASICC and NPCMS codes (Table 1) were filtered against the NIC code of pharmaceutical activities using NIC-1998&2004 (24231, 24232, 24233, 24234, 24235, 24236, 24239) and NIC-2008 (21001, 21002, 21003, 21004, 21005, 21006 and 21009).

Instead of using Gross Value Added (GVA) as a measure of value of output of vaccine, we used sale (and ex-factory) value of vaccines, simply because estimation of GVA was not possible by using vaccine specific product (ASICC/NPCMS) codes. The GVA is generally estimated at industry level[11]. In our case, not all pharmaceutical units are exclusively producing vaccines. They produce different products including vaccines, drugs, medicines and medical devices, etc. Therefore, Sale value (S) is used as a proxy while estimating the growth and size of domestic manufacturing industry. The sale value is estimated at vaccines level using ASICC/NPCMS codes, described in Table-1.

The size of final (consumption) demand of vaccine is another important measure to understand the extent to which the domestically produced vaccines are able to satisfy the domestic consumption requirements and how much the gap is filled through import (I). The final demand of vaccine in a given country is defined as the production output (assessed through sale) less exports (X) plus vaccines imported (I) from abroad and expressed as (S – X + I). This is known as final demand (FD) or domestic market size (DMS) of vaccines in a country.

The estimated DMS is further used to measure the import penetration rate (IPR) in vaccines and expressed as:

$$\text{IPR} = \frac{\text{I}}{\text{S} - \text{X} + \text{I}} * 100$$

This is a frequently used but traditional measure of IPR that indicates what share of domestic demand is met through imported vaccines (Fronczek 2017). For a given country, an IPR's value close to 0 means self-sufficient, i.e. domestic demand is mainly satisfied by

[11] For instance, the latest ASI 2018-19 schedule takes information from J, G, F, H and I blocks for estimating the GVA as: (J12,13) (+) (G1,3+ G2,3+ G3,3+ G4,3+ G6,3+ G7,3+ G8,3+ G11,3+ F7,3) (-) (F1,3+ F2(i),3+ F2(ii),3+ F3,3+ F4,3+ F6,3+ F7,3+ F8,3+ F11,3) (-) (H23,6) (-) (I7,6). The block G and F contain information at industry level and not at product level.

domestic production and a value close to 100 implies that domestic demand is mainly fulfilled through imports (OECD 2011).

For estimating the DMS and IPR across different categories of vaccines, a concordance is done between product (ASICC/NPCMS) codes and HS-8 trade codes (see Table 1). The trade (export and import) data by type of vaccines is extracted from DGCIS using HS-8 digits level information against vaccines codes described in Table-1 for 'vaccines for human medicine'.

Table 1: Vaccines for Human Medicine: Concordance of ASICC (1999-00 to 2009-10), NPCMS (2010-11 to 2018-19) and HS-8 Code

ASICC	*NPCMS*	*Descriptions*	*HS-8 under 300220*
		Single vaccines	
33341	3527065	Vaccine For Cholera and Typhoid	30022011
33354	3527068	Vaccine for Hepatitis A (Hep-A)	30022012: Vaccine for Hepatitis
33351	3527069	Vaccine for Hepatitis B (Hep-B)	
33342	3527079	Vaccine for Tetanus (TT)	30022013
33344	3527075	Vaccine for Polio (OPV/IPV)	30022014
33346	3527078	Vaccine for T.B (BCG)	30022015
33357	3527076	Vaccine for Rabies	30022016
33356	3527071	Vaccine for Japanese Encephalitis (JE)	30022017
33347	3527081	Vaccine for Whooping Cough	30022018
33348	3527082	Vaccine for Yellow Fever (YF)	30022019: Other Single Vaccine
33355	3527070	Vaccine for Influenza	
33361	3527072	Vaccine for Measles	
33362	3527074	Vaccine for Meningococcal Meningitis	
		Mixed vaccines	
33358	3527066	Vaccine for Diphtheria, Pertussis and Tetanus (DPT)	30022021
33343	3527067	Vaccine for Diphtheria / Diphtheria Toxoid (DT)	30022022: Vaccine for Diphtheria and Tetanus (DT)
33352	3527073	Vaccine for Measles, Mumps & Rubella (MMR)	30022023
33345	3527077	Vaccine for Typhoid-Paratyphoid (TAB) or Typhoid Paratyphoid-Cholera (TABC)	30022024
33369(89)	3527083	Vaccine others & other Microbial Culture. N.E.C	30022029: Mixed vaccines

Note: HS-8: 30022019 is 'Other Single Vaccine' may also include other newer vaccines.

The export performance is assessed by estimating India's vaccines export share in total vaccine export of the world as well as by measuring the export efforts made by a country from its domestic production (as export share in domestic production/sale). The export to sale ratio (X/S) highlights the export effort. This ratio shows the importance of the foreign market for a given industry in a country, under the supply and demand conditions that usually changes overtime in foreign and domestic markets.

To judge the competitiveness of Indian vaccines export, the Revealed Comparative Advantage (RCA) index/ratio is estimated. The country A is said to have a revealed

comparative advantage in a given product i when its ratio of exports of product i to its total exports of all commodities (products j) exceeds the same ratio for the world as a whole. It is calculated by using the following formula:

$$RCA = \frac{\frac{XAi}{\Sigma XAj}}{\frac{Xwi}{\Sigma Xwj}}$$

where, X_{Ai} is the country A's exports of product i (here i is vaccine), X_{wi} is the worlds's exports of product i, ΣX_{Aj} is the country A's total exports (of all products j), and ΣX_{wj} is the world's total exports (of all products j). The RCA may take value from zero to infinity, however, when a country has a revealed comparative advantage greater than one for a given product (RCA >1 for i), it is inferred to be a competitive producer and exporter of that product relative to a country producing and exporting that product. The higher the value of a country's RCA>1 for product i, the higher its export strength in product i. For comparing the vaccines export pattern of different countries and estimating the RCA as well as export efforts, data are explored from WITS at HS-6 (300220) digit level.

3. Structure of Vaccine Industry

India has over a century long legacy in vaccine development and manufacturing, dating back to 1890 (Lahariya 2014). During the period up to 1980s, the indigenous manufacturers, especially the public sector, provided commendable services to the nation during epidemic emergencies starting from plague to cholera. There have been around 29 public sector vaccine institutions (PSIs) in the country at different points of time (Madhavi 2022). Of the total, seven came into existence after India independence. The PSIs demonstrated their ability to innovate new processes and products through modern production technologies and gained expertise in manufacturing of a wide range of vaccines/sera such as, typhoid, cholera, DTP, DT, TT, OPV, BCG, measles, MMR, Hepatitis B, rDNA (Recombinant Deoxyribonucleic Acid), plague, gas gangrene anti-toxins, vaccine lymph, anti-dysentery, anti-snake venom, anti-rabies and anti-rabies serum, etc. The public sector made a remarkable contribution to the Expended Programme on Immunization (EPI). At the time when EPI was introduced in 1978, the country was self-sufficient in producing basic vaccines for EPI and depended mostly on public sector for vaccine supply (Madhavi 2005; Lahariya 2014; Chaudhuri 2022). Despite providing such remarkable services to the nation, their number has been on the decline since 80s (Appendix 1). India closed-down seven of its public sector vaccine manufacturing institutions (PSIs) in the late 1980s. The decade of 2000s further brought out a major setback to PSIs when most closed-down exercised. Around seven other PSIs were closed-down in the first half of 2000s and eight more in the early second half of 2000s (Appendix 1).

This was precisely the time when WHO introduced vaccines prequalification (PQ) programme in 1987 with the aims of ensuring that the vaccines purchased by UNICEF (United Nations International Children's Emergency Fund) and other UN (United

Nations) procurement agencies/countries be safe and effective under conditions of use in national immunization programmes (Dellepiane and Wood 2015). The procedures of prequalification were being revised overtime to strengthen the regulatory assessment that the manufacturers to follow GMP. Meeting these norms need necessary investment for upgrading the manufacturing processes. The declining number of public sector units in India during the time of stringent regulatory norms corroborate that necessary investment might not have taken place for necessary upgradation[12]. Madhavi (2022) study highlights that PSIs faced major neglect around the liberalisation phase of Indian economy. Of the total 29 PSIs, the country left with only 6-7 functional PSIs by the end of 2000s (Appendix 1). Three are Centre/States Governments undertaking, two are PSUs and one operates under National Dairy Development Board and one (King Institute of Preventive Medicine) turned as training institute. Currently, the BCG Vaccine Lab (BCGVL), Chennai, Bharat Immunologicals and Biologicals Ltd. (BIBCOL), Bulandshar, Haffkine Bio-Pharmaceutical Corporation Limited (HBPCL), Mumbai, Central Research Institute (CRI), Kasauli, Pasteur Institute of India (PII), Coonoor, and Human Biological Institute (HBI), *A division of Indian Immunological Ltd*, Gujarat are functional public sector units (Figure 1).

There have been 25 vaccine-manufacturing companies in the private sector in India (Figure 1). They are of two types, the MNCs and the indigenous manufacturers. The MNCs, like GSK and Sanofi, primarily import vaccines and repackage them for sales in India (Ghosh 2019, pp 7-8), while indigenous manufacturers do a wide range of activity ranging from vaccine development to manufacturing. The private sector companies manufacture around 24 types of vaccines (Figure 1). The SII produces a large number of vaccines (16), followed by Shantha Biotech (acquired by Sanofi in 2009) (9), Bharat Biotech (7), Panacea Biotech (7), Biological E (6), etc. A list of licensed vaccines with the individual indigenous public and private manufacturers is presented in Appendix-2.

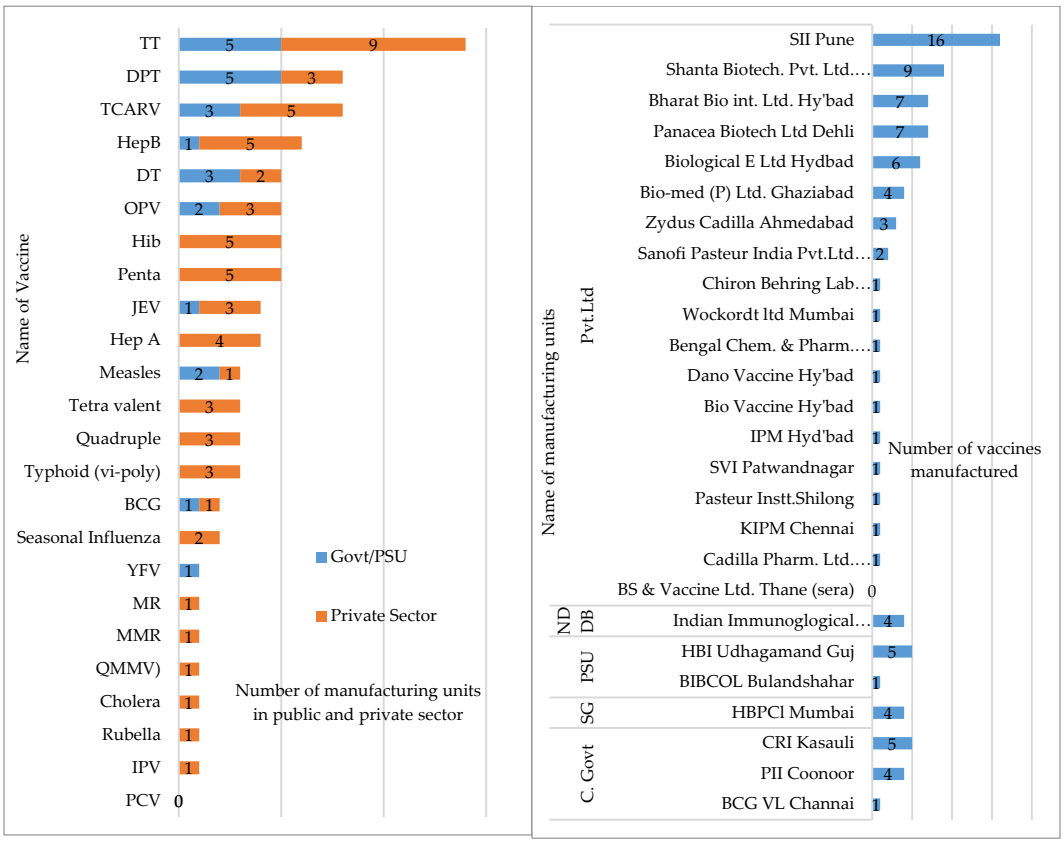
The public sector manufacture around 10 traditional type of vaccines namely, DPT, DT, TT, JE, YF, OPV, BCG, Measle, Hep-B, and TCARV (Figure 1). A large number of private companies manufacture basic UIP as well as anti-rabies, Hep-B, Hib, Pentavalent vaccines. Some companies have monopoly in producing a few newer vaccines (Figure 1).

The contribution of India in research and innovation has been significant in some of the conventional and traditional vaccines, which is well documented in Madhavi (2022). From the individual company websites, we observed that first fully liquid Pentavalent (DTwP-HepB-Hib) as well as first fully liquid Hexavalent vaccine were developed, manufactured and launched by Indian company Panacea Biotech in 2008 and 2017 respectively. The first conjugated typhoid vaccine was developed and manufactured by Bharat Biotech, which was launched in 2013 and prequalified by WHO in 2017. The first thermostable rotavirus vaccine,

[12] It is important to note that this was also a time when country was in the process of amending its patent law to make them compatible with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) replacing earlier process patent regime with the product patent in 2005, which however cannot directly be attributed with the shutting down process.

developed by Serum Institute of India, became available in 2017. First Meningitis-A vaccine developed for the use in Africa, manufactured by SII and prequalified by WHO in 2010. The Bharat Biotech developed indigenous Covid-19 vaccine (Covaxin) in collaboration with the Indian Council of Medical Research (ICMR) and National Institute of Virology Pune (NIV) and got an approval for the use in international market. Serum Institute of India could lead in manufacturing world large number of Covid-19 vaccine doses through technology transfer from AstraZeneca and Novavax. The SII has robust manufacturing capacity of producing several other conventional and some recombination vaccines as well.

Figure 1: Vaccine Manufacturing in Public and Private Sector: Number of Vaccines and Units in 2019-2020



Source: https://dghs.gov.in/content/6_1_Institutes.aspx; Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India.

Globally, other than Covid vaccine, around 25 effective vaccines are available against the 28 human diseases[13]. The count of vaccines manufactured in India is more or less same

[13] Namely, Cholera, Dengue fever, Diphtheria, Haemophilus influenzae type b, Hepatitis A, Hepatitis B, Hepatitis E, Human papilloma-virus, Influenza, Japanese encephalitis, Malaria, Measles, Meningococcal disease, Mumps, Pneumococcal disease, Pertussis, Poliomyelitis, Rabies, Rotavirus

Contd…

(Figure 1). The manufacturers either produce them indigenously or repackage the imported vaccines for sale in India. Analysis suggests that most of the vaccine manufacturing in the country is centered around the traditional/conventional type of vaccines (Figure 1). Only a few units engaged in producing some recombination vaccines and a couple of conjugate vaccines. It is important to note that most of vaccines that are in use across the world were developed in the 20th century. For many of them, IPR protection period has already been exhausted. It is clear from the Appendix-3 that, in the recent past decade of 21st century, most of the vaccines that have been manufactured are recombination in nature, which are produced using modern technology. The matching of vaccines produced in India with the trajectory of vaccine development (Appendix 2&3) suggest that Indian manufactures mostly produce vaccines in which IPR protection period has already been exhausted. Analysis of manufacturing capacity across individual vaccine, discussed in next section, also corroborate the same.

4. Manufacturing Capacity

The public and private manufactures taken together have a robust capacity of producing different types of vaccines and sera. The total installed capacity of producing vaccines/sera in the country was 90223.4 lakh doses in 2006-07, which declined slightly (9.2%) to 81918.7 lakh doses in 2018-19 (Table 2). Of the total, the share of public sector in total installed capacity declined from 22.76% in 2006-07 to 17.77 percent in 2018-19. Their installed capacity for a few UIP vaccines (like DPT, TT, anti-rabies and Hepatitis B) however shows an increasing trend (Table 2). Public sector demonstrated their ability to produce serums/sera like Anti Scorpin Serum, Anti Tetanus Serum, Anti Snake Serum, and Anti Diphtheria Serum, however, their share in installed capacity and in producing of IHR (International Health Regulation)[14]/newer vaccines remained negligible (Table 2).

The installed capacity of producing UIP vaccines declined around 23.3 percent between 2006-07 to 2018-19, while installed capacity of IHR (International Health Regulation) and newer vaccines increased by 122.7% during this period (Table 2). The compositional share of UIP segment in total installed capacity reported to be around 90.25% in 2006-07, the rest 9.65% and 0.10% was newer/IHR vaccines and sera. In 2018-19, the share of IHR/newer vaccines increased (recorded 17.34%), while UIP share declined (recorded 82.46%) (Figure 2), indicating that manufacturing capacity has been moving from conventional type of UIP vaccines to producing the IHR/newer/combination vaccines. This is a healthy indication as they follow technologically more advanced manufacturing processes, however, majority of the installed capacity still centred around conventional types of vaccines.

The overall production of vaccine increased (about 46.3%) from 14,373.3 lakh doses in 2006-07 to 21,030.9 lakh doses in 2018-19. The share of public sector in total production however

gastroenteritis, Rubella, Tetanus, Tick-borne encephalitis, Tuberculosis, Typhoid fever, Varicella, Yellow fever, Shingles (Herpes Zoster), and Smallpox. https://ourworldindata.org/vaccination

[14] IHR is mandatory vaccines to be used while international travel to 196 countries

declined significantly from 44.37 percent in 2006-07 to 1.78 percent in 2018-19 (Table 2). The installed capacity for some vaccines shows an increasing trend, while production declined in some other cases, which might have affected the capacity utilisation of total installed capacity of producing different type of vaccines. The capacity utilisation of vaccines/sera taken together increased from 15.93% in 2006-07 to 25.67% in 2018-19. The capacity utilisation shows an increasing trend for UIP and IHR/newer vaccines, while it declined for four basic UIP vaccines namely BCG, DPT, measles and anti-rabies. The capacity utilisation of public sector reached at abysmally low level of 2.57 percent in 2018-19 from 31.05 percent in 2006-07, while capacity utilisation of private sector increased to 30.67 percent in 2018-19 from 11.47 percent in 2006-07 (Table 2).

Table 2: Installed Capacity, Production and Capacity Utilisation of Vaccines in India

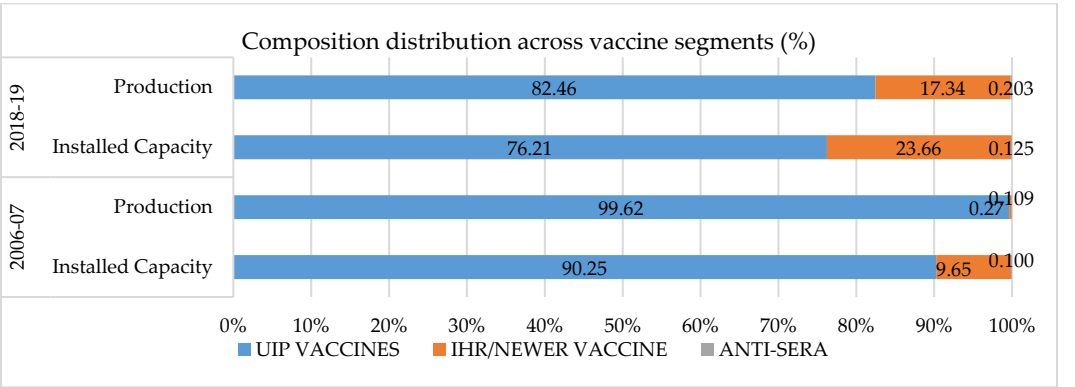
	Total Installed Capacity (Qt. in lakhs of doses)	*Total production (Qt. in lakhs of doses)*	*Capacity Utilisation ratio (%)*	*Share of public sector in total installed capacity (in %)*	*Share of public sector in total production (in %)*	*Total Installed Capacity (Qt. in lakhs of doses)*	*Total production (Qt. in lakhs of doses)*	*Capacity Utilisation ratio (%)*	*Share of public sector in total installed capacity (in %)*	*Share of public sector in total production (in %)*
	2006-07 (NHP, 2008)					**2018-19 (NHP, 2021)**				
A. UIP VACCINES	**81430.7**	**14319.3**	**17.58**	**25.1**	**44.5**	**62433.4**	**17341.9**	**27.78**	**23.29**	**2.13**
BCG	2000	1726.47	86.32	40.0(100)	48.0(100)	2800.0	1836.2	65.58	28.57	0.00
DPT	8898	1739.75	19.55	23.6	44.5 (25.7)	5558.0	634.5	11.42	33.25	29.20
DT-Diphtheria& Tetanus (Td)	1705	379.32	22.25	64.8	92.7	2000.0	1200.0	60.00	0.00	0.00
TT- Tetanus Toxoid	19592	3040.38	15.52	18.6	35.3(47.7)	13297.0	3953.9	29.74	33.93	1.42
Polio (OPV)	38280	4339.81	11.34	31.9(42.6)	26.6(51.3)	28200.0	7139.4	25.32	21.28	0.00
Measles	3300	2107.74	63.87	9.09	100	4600.0	1550.0	33.70	13.04	0.00
JE Vaccine	2011.1	2.31	0.11	0.552(100)	100(100)	174.0	5.0	2.87	0.00	0.00
Tissue culture based anti-rabies vaccine (TCARV)	284	147.86	52.06	22.9	26.4	494.0	159.4	32.27	36.44	78.32
YF Vaccine#	0.55	0.738	134.18	100	100(100)	0.4	2.6#	650.0	100.00	50.0
Hepatitis-B	5360	834.89	15.58	3.7	4.8	5310.0	860.9	16.21	11.30	0.21
B. IHR/NEWER VACCINE	**8702.5**	**38.28**	**0.44**	**0.43**	**0.00**	**19383.2**	**3646.3**	**18.81**	**0.00**	**0.00**
Typhoid (Vi-Poly)	400	8.34	2.09	7.5	0.0	433.0	23.0	5.31	0.00	0.00
Typhoid (AKD)	NA	NA	NA	NA	NA	940.0	19.0	2.02	0.00	0.00
Quadrivalent Meningococcal Meningitis Vaccine (QMMV)	17.08	1.79	10.48	0.00	0.00	40.0	18.0	45.00	0.00	0.00

	Total Installed Capacity (Qt. in lakhs of doses)	*Total production (Qt. in lakhs of doses)*	*Capacity Utilisation ratio (%)*	*Share of public sector in total installed capacity (in %)*	*Share of public sector in total production (in %)*	*Total Installed Capacity (Qt. in lakhs of doses)*	*Total production (Qt. in lakhs of doses)*	*Capacity Utilisation ratio (%)*	*Share of public sector in total installed capacity (in %)*	*Share of public sector in total production (in %)*
Haemophilis (Hib) Influenzae Vaccine	1040	6.0	0.58	0.00	0.00	1287.5	52.8	4.10	0.00	0.00
Quadruple Vaccine (DTwp-HepB)	2250	0.00	0.00	0.00	0.00	2000.0	42.6	2.13	0.00	0.00
Tetravalent Vaccine (DTwp+Hib)	4500	8.29	0.18	0.00	0.00	2015.0	4.4	0.22	0.00	0.00
Pentavalent Vaccine (DTwp-HepB-Hib)	250	13.86	5.54	0.0	0.00	6875.7	2533.5	36.85	0.00	0.00
MMR	245.37	0.00	0.00	2.85	0.00	5000.0	513.5	10.27	0.00	0.00
MR	NA	NA	NA	NA	NA	650.0	40.0	6.15	0.00	0.00
IPV -Inactivated Polio vaccine#	NA	NA	NA	NA	NA	30.0	330.0#	--	0.00	0.00
Seasonal Influenza Vaccine (SIV)	0.00	0.00	0.00	0.00	0.00	106.0	3.5	3.30	0.00	0.00
Cholera Vaccine#	NA	NA	NA	NA	NA	6.0	66.0#	--	0.00	0.00
C. ANTI-SERA	**90.20**	**15.71**	**17.42**	**66.90**	**32.22**	**102.09**	**42.69**	**41.82**	**16.65**	**11.07**
ATS- Anti Tetanus Serum	3.7	0.00	0.00	48.65	0.00	8	9.19	114.88	62.50	0.07
ADS- Anti Diphtheria Serum	2.2	0.075	3.41	77.27	100.0	2.1	0.111	5.29	100	100
ASVS- Anti Snake Serum	73.2	11.29	15.42	68.03	30.5	38.74	11.03	28.47	15.75	22.70
ASVS- Anti Scorpion Serum	0.95	0	0.00	94.74	0.00	22.14	1.309	5.91	6.775	2.291
ARS- Anti Rabies Serum	7.4	3.3	44.59	45.95	15.2	31.1	18.59	59.77	7.40	1.42
Diagnostic Antigen (MV)#	2.75	1.04	37.82	100.00	100.0	0.01	2.463#	--	as per demand	73.604
Total (A+B+C)	**90223.4**	**14373.3**	**15.93 (11.47: 31.05)$**	**22.76**	**44.37**	**81918.7**	**21030.9**	**25.67 (30.67 : 2.57)$**	**17.77**	**1.78**

Note: Figures in parenthesis are for 2000-01 for some select UIP-vaccines; #- production figure in most cases are imported values for 2018-19, therefore capacity utilisation ratio turned higher than 100%; $ -private : public sector share respectively.

Source: NHP 2001, 2008 and 2021.

Figure 2: Distribution of Installed Capacity and Production across Vaccine Categories



Source: From Table-2

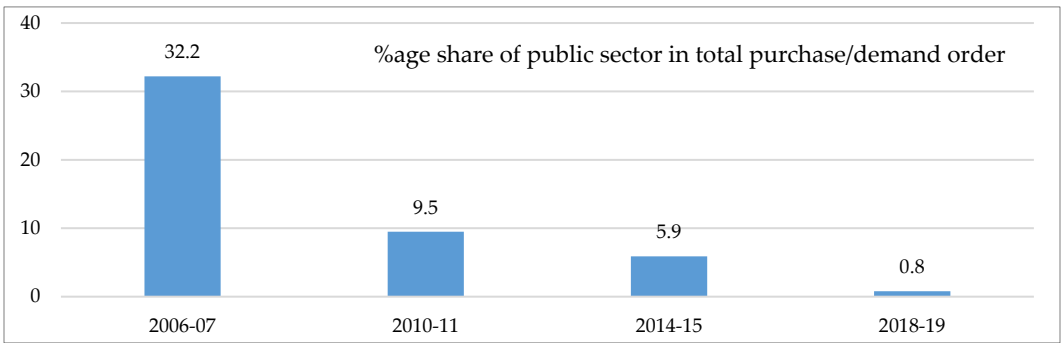
In some of the UIP vaccines, public sector was dominating in 2000. They demonstrated their ability to produce even more than their installed capacity by running/working extra hours for some vaccines, depending on the size of purchase order placed by the government for UIP vaccines. For instance, public sector contributed 44.5% in total UIP-vaccine production with an installed capacity of just 25.1% with them in 2006-07 (Table 2). However, by 2018-19, its share in installed capacity and production of UIP-vaccine reduced to 23.29% and 2.13%, respectively. In 2006-07, public sector share in installed capacity of sera and its production was 66.9% and 32.2% respectively, which declined to 16.65% and 11.07% respectively by 2018-19 (Table 2).

Of the total 10 listed UIP vaccines, public sector share in production of at least five vaccines reported to be nil in 2018-19. Their share in production in other listed UIP vaccines was almost negligible, except for tissue culture based anti-rabies (78%) and DPT (29%) vaccines (Table 2). In the total vaccines/sera listed in Table-2, public sector did not manufacture 17 out of 28 vaccines/sera in 2018-19. They found producing none of the IHR/newer/combination vaccines (typhoid, meningococcal meningitis, haemophilis (Hib) influenzae, DTwp-HepB), DTwp+Hib, DTwp-HepB-Hib, MMR, MR (Mumps & Rubella), inactivated polio vaccine, and seasonal influenza vaccine) in 2018-19 (Table-2). In this context, it is important to highlight that the UIP vaccines that are generally purchased at the central level for distribution to the states and procured under the broad overarching General Financing Rules using Annual Rate Contracts against which Supply Orders are issued (GoI 2011), the public sector used to supply UIP vaccines as per the contract, as they were established mainly to feed into UIP requirements following the no-profit-no-loss principle. Therefore, they must have not exposed themselves to produce vaccines beyond UIP. A study highlights that public sector that used to receive state funding for continuing research and development and manufacturing of vaccines, anti-toxins, sera and anti-venoms around the prevailing diseases (like, malaria, kala-azar, cholera, typhoid, polio, rabies, influenza, smallpox, tuberculosis, etc.) in pre liberalisation period, did not receive

such support in the post liberalisation period (Madhavi 2022). This might have refrained them to enter in to other segments that are reported in Table-2.

In addition, in UIP vaccine category, where public sector was generally dominating, the private players, through lobbying and other means, managed to incapacitate the public sector and took over the UIP vaccine market. Some of the projects that the government of India started overtime, the private sector took the main advantage to grow not only in the older vaccines but also in the new vaccines often by taking help from government laboratories (Chaudhuri 2022). In this context it is important to mention that the contribution of public sector in fulfilling almost 100% UIP requirements duly acknowledged in the past (Lahariya 2014) and government used to place entire purchase order of UIP vaccines from public sector. However, the share of purchase order of UIP vaccines from public sector declined significantly overtime. In 2006-07, in total purchase order placed by the government for UIP vaccines, the share of public sector was 32.2%, which declined to almost negligible level of 0.8 percent in 2018-19 (Figure 3), indicating that the government has almost stopped buying major UIP vaccines from public sector. That is, government is redirecting majority of UIP purchasing from public to private firms. This leads to concentration of entire manufacturing capacity towards private sector in the country, while manufacturing potential of the public sector remained un(der)utilised, due to which public sector almost lost its dominance and presence.

Figure 3: Public Sector in Purchase Order of UIP vaccines placed by Government



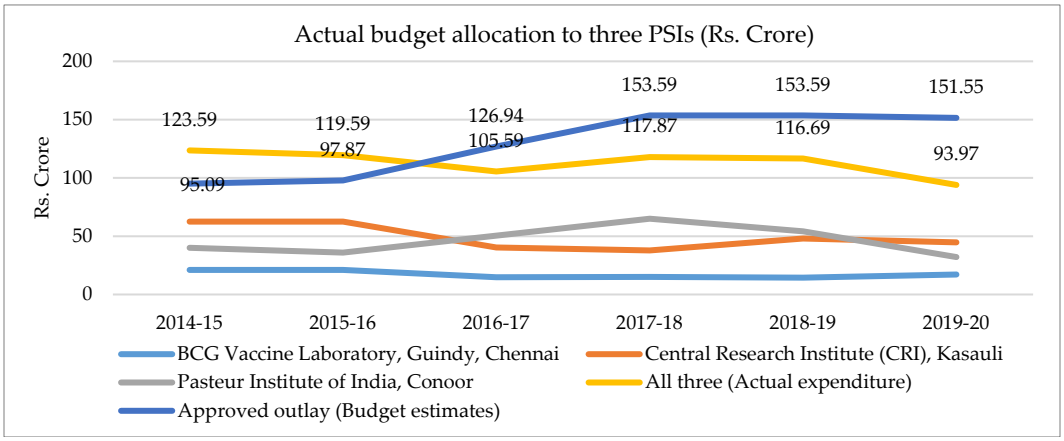
Source: NHP - 2008, 2012, 2016 and 2021.

In order to understand the dilemma of dominance to declining share of public sector in vaccine supply, one needs to decode what went wrong with the public sector units that were functional till the recent past. A detail analysis of the existing PSIs, presented in Madhavi (2022) and Chaudhuri (2022), reveals that they are facing numerous constraints and consistent neglect since 2007-08. Government of India cancelled licences of three major functional public sector vaccine-manufacturing units in January 2008, namely BCGVL, PII and CRI. On the eve of their licences cancellation, during 2004-05 to 2007-08, the share of these units in vaccine production of four-basic UIP vaccine was 100 percent in BCG, 78 percent in DT, 64.3 percent in TT and 59.1 percent in DPT (Jawad Chowdhury Committee, 2010). Despite such a contribution, their licences were cancelled on the ground that they

were not confirmed to the Good Manufacturing Practice of WHO guidelines. The then constituted Parliamentary Standing Committee (PSC, 2009a & 2009b) reports, however, stated that government did not allocate extra fund to qualify the WHO-GMP. The reports stressed that there was no basis of licences-cancelation, rather official choose to cancel the licences (Chaudhuri 2022). With the suspension of licences, these units had to stop production and entire market for the public sector was eliminated immediately. Effectively, public sector lost its dominance since then.

Based on the recommendations of Jawad Chowdhury Committee, the licenses of BCGVL, PII and CRI were revived between 2010/11 to 2013/14, but they have not been revived in good sprit. The fund allocation by the government towards these units rather declined after revival of their licences. Actual budgetary allocation of the government towards these units declined from Rs. 123.59 crore in 2014-15 to Rs. 93.97 crore in 2019-20 (Figure 4). In 2014-15, the actual spending was almost 30% higher than the approved budget (Budget Estimate-BE), while actual spending noticed to be almost 38% less than the BE in 2019-20 (Figure 4). A closer look of NHP 2021 reveals that commercial production for many vaccines have not been started in these units until recently, except for a few vaccines like the DPT. The approval for commercial production of many other vaccines is still pending

Figure 4: Recent Trends in Government's Budgetary Allocation towards three PSIs



Source: Union Budget (2014-15 to 2021-2022), Government of India.

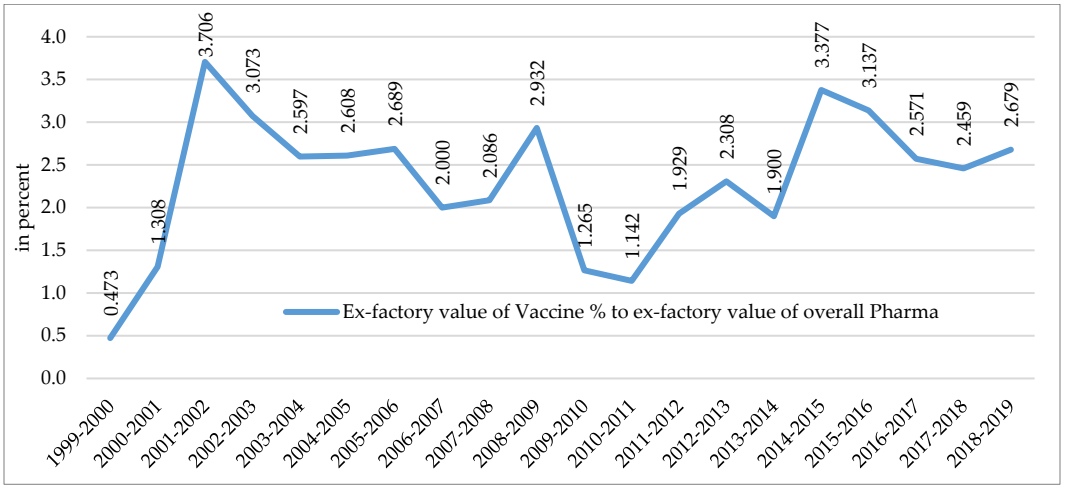
with the department of Drugs Controller General of India (DCGI), Ministry of Health and Family Welfare, Government of India (NHP 2021). Therefore, it is not surprising that public sector lost its dominance in vaccine segments in the country.

5. Indigenously Produced Vaccines: Size and Growth Pattern

Estimates suggest that vaccine industry is a tiny sub-sector of pharmaceutical industry. The share of ex-factory value of vaccine produced in ex-factory value of pharmaceutical industry just hovered around 2.0–3.5% in past two decades (between 2000 to 2019), except

for the years 2009-2011. This share showed a declining trend between 2001-02 to 2010-11, though increased sharply thereafter to till 2014-15. It declined slightly from 3.38% in 2014-15 to 2.68% in 2018-19 (Figure 5).

Figure 5: Size of Vaccine Segment in overall Pharmaceutical Manufacturing (%)



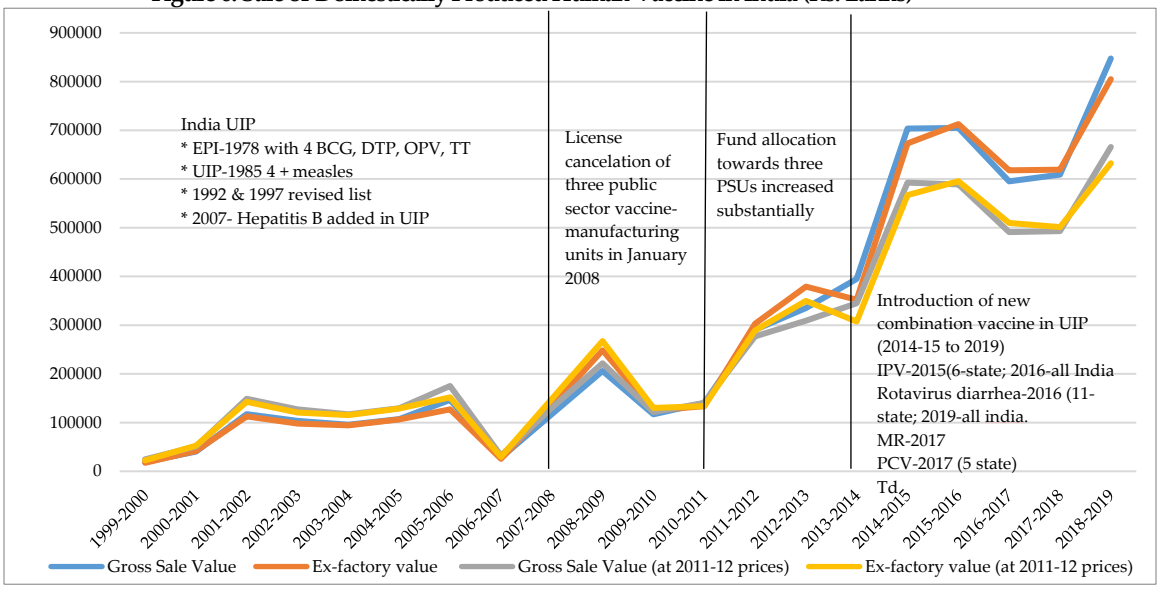
Source: Unit level data of ASI since 1999-2000 to 2018-19.

The size of vaccines produced in the country, in terms of nominal sale, is estimated to be around Rs. 84.75 billion in 2018-19. It had a very low base of around Rs. 1.92 billion in 1999-00. The inflation-adjusted sale value increased from Rs. 2.46 billion in 1999-00 to Rs. 66.57 billion in 2018-19 (Figure 6). The growth in sale value of vaccine output remained almost stagnant up to 2008 (except for 2006-07[15] and two initial years of study period). This was a time when public sector units had a large share in manufacturing of at least four basic (BCG, DPT, Measles, TT) UIP vaccines. Since, they usually supplied vaccines at low prices, following the no-profit-no-loss principle, against the purchase/demand order placed for UIP. This can be a plausible reason for the negligible share of these basic vaccines in overall vaccines produced in the country in that particular period (Figure 7). The sale value of domestically produced vaccines though rises sharply in recent decade. Between 2009-10 to 2018-19, the nominal sale value of domestically produced vaccines grew at a compound annual growth rate (CAGR) of nearly 20.92% and inflation-adjusted sale at 15.46% (Figure 6). The high growth may be because, in the recent past decade, along with four basic UIP vaccines, a few more vaccines such as Hepatitis B (2007-08), second dose of measles (2010) and Japanese Encephalitis (2011), yellow fewer (2015), IPV (Inactivated poliovirus vaccine) (2015-2016), Rotavirus diarrhea (2016-2019) and PCV (Pneumococcal Vaccine) (2017) were added in UIP. Since government started redirecting demand order for basic and other UIP-vaccines to private sector, and the private sector must have supplied such vaccines at high price. It is reported that since after the capturing of BCG market by the private sector after the BCGVL's licence cancelation, price of BCG vaccine increased many folds in the country.

[15] The sale value in this year was reported under others vaccine categories in ASI data with a very low value.

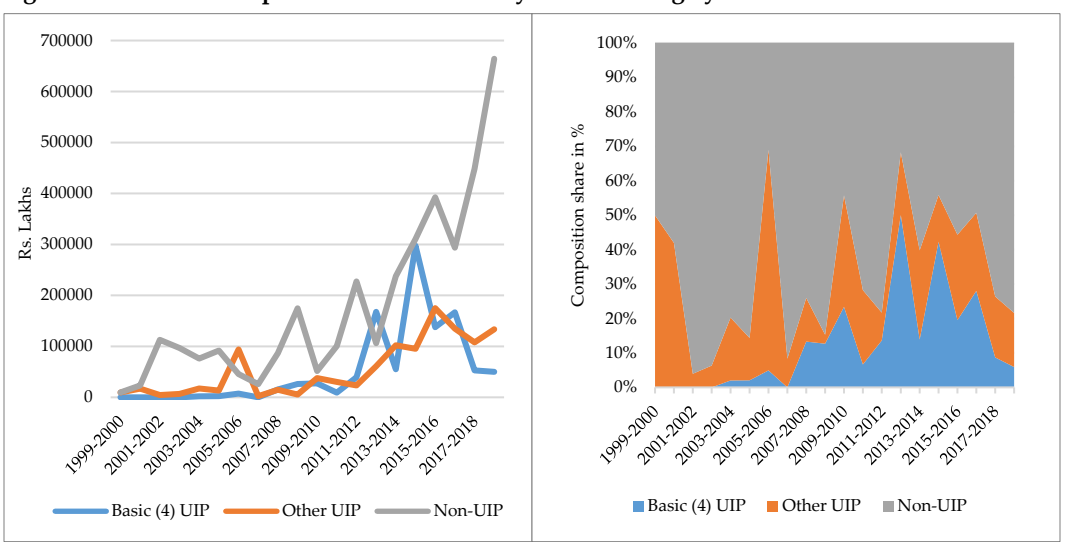
The private company (SII) supplied BCG vaccine for UIP with almost double rate of US$0.63 per 10 doses (Madhavi, 2022), while BCGVL's procurement price was US$0.3 for a 10-dose vial supplied to UIP in 2007-08. Our estimates from ASI data suggest that the unit price of per kg polio vaccine increased to manifolds (around 4.77 times higher) between 2008-09 to 2018-19. Therefore, overall sale as well as its compositional share of basic and other UIP vaccines might have shown a rising trends in the recent past decade (Figure 7).

Figure 6: Sale of Domestically Produced Human Vaccine in India (Rs. Lakhs)



Source: Unit level data of ASI since 1999-2000 to 2018-19.

Figure 7: Trends and Compositional Share of Sale by Vaccines Category



Source: Unit level data of ASI since 1999-2000 to 2018-19.

In addition, the installed capacity of producing a few other safe and efficacious vaccines like the typhoid, Hib, pentavalent, MMR, MR and influenza in the non-UIP category, which have an estimated high mortality burden in India, were made available in the retail market. The increase in their production, especially in the private sector, presented in Table-2. Most of these non-UIP vaccines are high priced, therefore, sale value of this segment shows a sharply rise in the recent period (Figure 7). Recently, it is the non-UIP vaccine category that dominant in overall sale in the country (Figure 7). The analysis across vaccines suggests that the share of MMR vaccine's sale and other mixed vaccines increased in the recent past (Appendix 4). The sale value of anti-rabies, polio, meningococcal vaccines appears to be almost constant since 2012-13 to 2018-19 (Appendix 4). Thus, increase in availability of vaccines listed under UIP as well as other high priced non-UIP vaccines resulted in sharp rise in overall sale value of vaccine in the country[16].

Some vaccines primarily are the imported ones for which a few of MNCs repackage them for sales at high price in India. Chaudhuri (2022) study reported that the high priced retail market segment dominated by MNCs accounted for 64% of total vaccine sales of Rs. 21,880 million in the country in 2019. Of which, GSK capture the largest market share (33.2%), followed by Sanofi India (18.5%), Pfizer (7.1%), MSD (3.9%) and Abbott India (1.5%). Among the high-priced products sold widely are Meningococcal vaccine sold by Sanofi India (Rs. 4950 per single dose), Pneumonia vaccine sold by Pfizer (Rs. 3801) and Human Papillomavirus Bivalent vaccine sold by MSD (Rs. 3250). As on March 2019, the vaccine products with single doses costing more than Rs. 2000 accounted for 37% of the sales and those costing between Rs. 1000 and Rs. 2000 constitute 38% of the sales in 2018-19. The share of products costing less than Rs. 500 was only 20 percent. This might have put upward pressure on overall size of vaccine's consumption in the country, discussed in next section.

6. Domestic Consumption and Import Dependency

The final consumption demand (or domestic market size – DMS) of vaccines in the country, measured as value of domestically produced vaccines (S) less exports (X) plus vaccines imported (I) from abroad, has been on the rise. The size of consumption demand (DMS) reached to almost Rs. 60.52 billion in 2018-19 from its low base of Rs. 1.71 billion in 1999-2000 (Table 3). The growth in domestic consumption of vaccines was almost stagnant between 2001 to 2009, however, its grew with a CAGR of nearly 18.7% in the recent decade (between 2009-10 to 2018-19). The measure of DMS reflect that when domestically produced vaccines fall short of the national requirement, the gap is filled through imported

[16] Note that we observed quite inconsistent sale data across different vaccines produced in the country before 2010-11. The sale value found subsumed under other single or other mixed vaccine categories. The availability of more consistent data since 2010 across different vaccines may be because, in 2010, nearly 200 countries including India shared a common global health vision called 'Decade of Vaccine Initiative 2010-2020' with an aim to achieve 90% vaccination coverage across all UIP vaccine so as to achieve full immunisation across countries. The country might have put some efforts to achieve immunisation across all vaccines, which has not been discussed here.

vaccines. It is found that in the overall vaccine consumption in the country, the size of imported vaccines also increased sharply in the past decade. Vaccines import grew at a CAGR of 10.9% between 1999-00 to 2008-09, while it grew with a CAGR of 15.9% in recent decade (Table 3) which is almost equivalent to the CAGR (15.46%) of inflation-adjusted sale value of vaccines.

The share of domestically produced vaccines in fulfilling the final consumption demand of vaccines in the country was around 90.97% in 2001-02, the rest fraction of demand was met through imported vaccines (from Table 3). The share of imported vaccine in meeting the domestic market requirement increased to almost four times since 2001-02 to 2018-19 (from Table 3). On average, around 59% of domestic vaccine requirements were met through domestic production in recent past five years and remaining 41% of the requirements met through imported vaccines.

The measure of import penetration rate (IPR) suggests a rise in import penetration of vaccines in the country. Import penetration rate increased from 9.05% in 2001-02 to a highest level of 62.47% in 2013-14 (Table 3). The year 2008-09 seems to be the breakeven point, when IPR increased from 22.4% in 2008-09 to 54.2% in 2009-10. This was the period when government of India cancelled licence of three major vaccine manufacturing unit in the public sector, the detail on which has already been provided earlier especially how they were neglected overtime. Since then to till recently, the IPR remained consistently high, except for the year 2018-19 in which it was recorded around 35.27 percent. The overall trend line of IPR suggests that India's dependency on imported vaccines has been on the rise (Table 3). That is, India has emerged as a big market of imported vaccines overtime.

An analysis by type of vaccines suggests that import share of basic/traditional vaccines in the UIP remains very low, simply because India have robust manufacturing capacity within the public as well as in the private sector. The import dependency in other (non-basic) UIP vaccines category, however, is very high, in which import of polio vaccine constitutes a major share (Table 4). The share of polio vaccine import was close to 50% in total vaccine import in 2014[17], though its share is declining overtime (Table 4). The import share of 'other single vaccine' in both UIP and non-UIP categories reported to be around 20% in 2012-13 which increased to around 45.68% in 2018-19. The share of import of 'other mixed vaccine' category declined from 29% in 2012-13 to 16% in 2018-19 (Table 4), though its shows a highly fluctuating pattern during the past two decades. The import share of Japanese Encephalitis (JE) vaccine in total import has been low (ranges between 3-6%) in recent past few years. The estimates of import penetration rate (IPR), which measure the degree to which a country is import dependent on a particular vaccine, suggest that the country is fully dependent on imported JE vaccine. The IPR value turned out to be 100 for JE vaccine (Table 4). The IPR estimates across different categories of vaccines suggest that

[17] India received 'Polio Free Certification' on 27 March 2014

India has become high import dependent on hepatitis, polio and 'other single' and 'other mixed' categories of vaccines.

Table 3: Domestic Market Size, Import Penetration and Trade Surplus of Vaccine in India (Rs. Lakhs & Ratio)

	Sale value (S)	*Export (X)*	*Import (I)*	*Domestic Market Size (DMS)= (S-X+I)*	*Import Penetration Rate (IPR) = (DMS/I)*100*	*Export Intensity ratio =X/S*	*Domestically produced vaccine consumed within the country = (S-X)/S*100*	*Export to Import ratio (X/I)*	*Trade surplus (X-I)*
1999-00	19180.8	12755.0	10704.1	17129.9	62.49	0.66	33.50	1.19	2050.9
2000-01	40397.5	16927.5	11951.1	35421.1	33.74	0.42	58.10	1.42	4976.4
2001-02	117415.1	24487.8	9221.5	102148.7	9.03	0.21	79.14	2.66	15266.4
2002-03	103358.6	31957.9	10838.6	82239.3	13.18	0.31	69.08	2.95	21119.3
2003-04	95528.7	31815.0	27100.0	90813.7	29.84	0.33	66.70	1.17	4715.0
2004-05	107196.0	30719.4	11136.6	87613.2	12.71	0.29	71.34	2.76	19582.8
2005-06	146637.8	34728.3	13265.3	125174.9	10.60	0.24	76.32	2.62	21463.0
2007-08	117065.6	44292.0	18578.4	91351.9	20.34	0.38	62.16	2.38	25713.6
2008-09	206016.7	87213.5	34263.6	153066.9	22.38	0.42	57.67	2.55	52949.8
2009-10	116830.2	75811.1	48543.5	89562.6	54.20	0.65	35.11	1.56	27267.5
2010-11	140132.1	87061.7	50363.4	103433.8	48.69	0.62	37.87	1.73	36698.3
2011-12	290301.0	168333.5	102403.9	224371.5	45.64	0.58	42.01	1.64	65929.6
2012-13	334908.5	207257.5	113294.1	240945.0	47.02	0.62	38.12	1.83	93963.5
2013-14	394800.0	315187.1	132522.5	212135.5	62.47	0.80	20.17	2.38	182664.5
2014-15	703509.2	352356.5	150212.2	501364.9	29.96	0.50	49.91	2.35	202144.3
2015-16	704885.1	460816.8	191576.1	435644.4	43.98	0.65	34.63	2.41	269240.7
2016-17	595212.7	419896.9	186834.3	362150.1	51.59	0.71	29.45	2.25	233062.5
2017-18	608985.1	415748.7	163476.6	356713.0	45.83	0.68	31.73	2.54	252272.1
2018-19	847481.7	455708.5	213456.2	605229.4	35.27	0.54	46.23	2.13	242252.3

Note: Value of S for 2006-07 in ASI data is not under-presented, therefore excluded from analysis here.

Source: X&I - from DGCIS (https://tradestat.commerce.gov.in/eidb/default.asp) at vaccine level; S- from ASI Unit level data

The IPR reported to be high (around 17.23% in 2018-19) in three basic UIP (DPT, BCG, TT) vaccines category (Table 4). Due to the uptake of DPT (triple antigen) vaccine which is being imported from abroad, the IPR in basic UIP category had also risen. This suggests that India also import UIP vaccines where domestic supply is inadequate. The increased uptake of other newer generation of vaccines like Pneumococcal conjugate vaccine, Varicella vaccine, Rotavirus vaccine, HPV and typhoid conjugate vaccine has also resulted in high import and import penetration in vaccine in the country.

Analysis suggests that India started import of three vaccines namely Hepatitis, Anti Rabies and Japanese Encephalitis from China in the following year when licence of three public sector units were cancelled and India started neglecting other PSIs between 2005-06 to

2008-09 (Appendix 5 & 6). The import share of these vaccines in total vaccine import ranges between 6-12%, though IPR remained very high, in the recent past (Table 4).

Table 4: Import Penetration Rate of dominant Vaccines in total Import (%)

	Vaccines for hepatitis (A&B)	*Vaccines for polio*	*Anti-rabies vaccine*	*Vaccine for Japanese encephalitis*	*DPT+ BCG +TT*	*Hepatitis -A&B +JE+ Polio+ Rabies*	*Other single /mixed UIP/ Non-UIP vaccines*	*All vaccines*
	Import Penetration Rate							
2012-2013	31.16	57.55	12.19	97.28	0.11	51.32	43.28	47.02
2013-2014	44.57	59.10	8.71	100.00	0.16	53.06	84.38	62.47
2014-2015	85.42	61.65	13.12	100.00	0.12	58.54	18.24	29.96
2015-2016	20.74	84.51	5.38	100.00	1.08	50.45	37.88	43.98
2016-2017	47.10	89.44	2.97	100.00	1.06	55.29	48.44	51.59
2017-2018	24.00	95.92	7.13	100.00	7.91	71.15	35.61	45.83
2018-2019	22.37	79.92	7.48	100.08	17.23	58.62	28.29	35.27
	Vaccines for hepatitis (A&B)	*Vaccines for polio*	*Anti-rabies vaccine*	*Vaccine for Japanese encephalitis*	*Other single vaccines*		*Other UIP & Non-UIP including mixed vaccines*	
	Compositional share of Selected Vaccines that dominate in Total Import							
2012-2013	1.34	44.61	1.70	3.14	19.87		29.35	
2013-2014	3.69	49.74	1.29	4.68	22.17		18.42	
2014-2015	5.79	44.23	1.77	5.03	22.30		20.89	
2015-2016	5.64	42.85	1.43	5.69	24.61		19.78	
2016-2017	3.65	35.67	0.97	9.02	25.84		24.85	
2017-2018	3.24	36.01	0.49	4.90	33.62		21.75	
2018-2019	1.94	32.35	0.98	2.95	45.68		16.10	

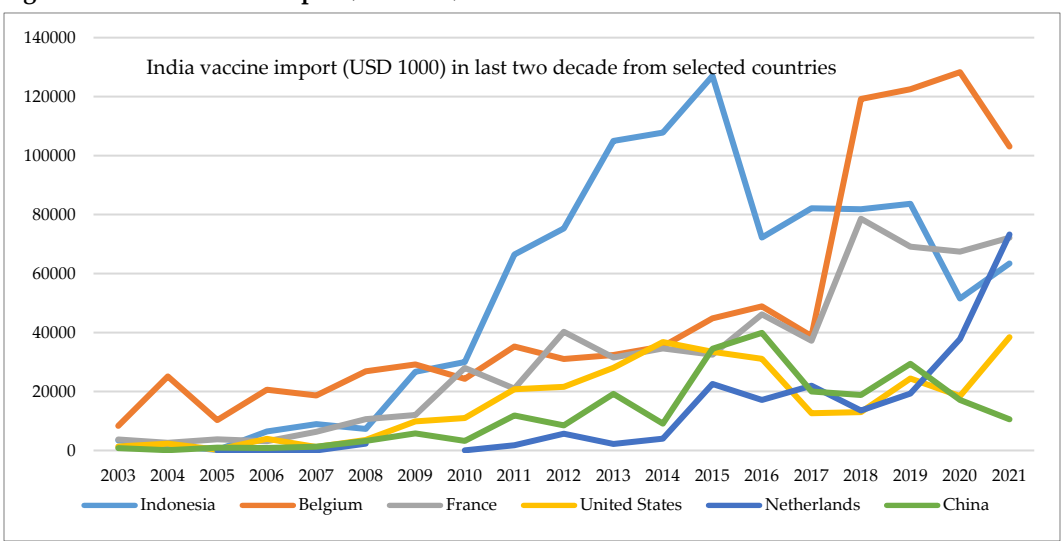
Source: Table-3

In the past two decades, more than 50 percent of India's import came from Indonesia (27.17%) and Belgium (24.5%), followed by France 16.30%), United State (8.47%), China (6.39%) and Netherlands (6.02%) (from note of Figure 8). India import Polio vaccine majorly from Indonesia, due to comparative price/cost advantage, since, Polio vaccine constitutes a major share in total vaccine's import, therefore, share of import is reported to be high from Indonesia. Between 2011-12 to 2015-16, imports from Indonesia were substantially very high (Figure 8). This was the period when WHO recommended transitioning from the use of tOPV polio vaccine to bOPV in 2012. By April 2016, 145 countries switchover to bOPV including India. This led to substantial increase in import from Indonesia. It is important to note that a public sector unit (HBPCL) used to supply majority of polio vaccine for UIP, the unit did not receive any order of polio vaccine from government for few years when India transitioned from tOPV to bOPV. The HBPCL, however, enhanced its manufacturing capacity to produce bOPV and supplied 3280 lakh doses of bOPV to UIP in 2016-17 that constituted 100 percent share in installed capacity as well as production of bOPV in 2016-17 in the country (Appendix 7). As one can see from Figure 8, the import from Indonesia decreased substantially since then. The import of polio

vaccine that constituted a share close to 50% in total vaccine import around the time when India was declared a polio free country in 2014, declined to 32.35% in 2018-19 (as discussed in Table 4). However, a newer version polio vaccine called Inactivated Polio Vaccine (IPV) was in use in US and some other advance countries, as part of Global Polio Endgame strategy, India introduced IPV to prevent re-emergence of polio in six states on 30 November 2015 and from April 2016 across country. The HBPCL, so far, has not been able to enhance its manufacturing capacity to IPV[18]. However, a private company (SII) made a commitment to start supplying IPV in UIP from September 2021, but we did not find any information on the company website whether it has started suppling IPV, this might be the reason of high import share of polio vaccines.

However, recently, in 2020, almost 80% of imports came from developed countries such as Belgium, France, and the Netherlands (from Figure 8). The import from these countries were mainly for newer vaccines, the production and sales of which are dominated by few MNCs (GSK, Pfizer, MSD) worldwide (WHO/MI4A 2020). Most of their imported vaccines are sold in the retail market are high priced (discussed above) which might have contributed to India's high import penetration.

Figure 8: Trends in vaccine import (USD 1000)



Note: India imported around 90% of vaccines from 6 countries in last two decades namely, Indonesia (27.17%), Belgium (24.5%), France 16.30%), United State (8.47%), China (6.39%) and Netherlands (6.02%).

Source: WITS

Low pace of research and development in newer generation vaccines alongside of the not utilizing the fullest potential of public sector could be other reasons of high import penetration. However, public sector, in other part of the world, has been major developer of vaccines. It is reported that in the US, the public sector research institutions have created

[18] https://www.vaccinehaffkine.com/about-us/milestones.html

all the important, innovative vaccines (of around 15 FDA approved vaccines) that have been introduced during the past 25 years (Steven 2011). The underlying technology of Moderna's and Pfizer/BioNTech's mRNA vaccine technology for Covid-19 vaccine have benefited from more than 20 years of public funded scientific research (Mani 2021). Similarly, at least 97 percent of the funding for the development of Oxford/AstraZeneca Covid-19 vaccine came from public and charitable finances (Cross et al 2021). Usually, developed country spend a sizeable amount on vaccine's R&D. The R&D intensity in European vaccine industry is reported to be high, for instance, vaccine industry in Europe invested €1.8 billion in R&D in 2006 which was around 18.4% of total revenues (EVM 2008). The estimates from ASI data suggest that R&D intensity (R&D spending percentage to sale) of vaccines in India was around 7.56 percent in 2018-19. R&D intensity, in some of the vaccines cases like the meningococcal, TB and Hep-B, however, found to be over 20 percent in 2018-19 in India. The R&D intensity reported to be slightly higher (9.52%) in private sector as compared to the public sector (6.05%) in 2018-19, as per the estimates from ASI data. The R&D intensity in Indian pharmaceutical reported to be around 4.96 percent (as % to sale turnover) in 2017-18[19], indicating that R&D intensity in vaccine in India is higher than overall R&D intensity of pharmaceutical industry[20]. India has several (around 38) public sector research institutions under DBT (Dept of Biotechnology), ICMR (Indian Council of Medical Research), CSIR (Council of Scientific & Industrial Research) and recently, around 25 institutions name were displayed on Ministry of Science and Technology (DST)[21] website that were indulging in Covid-19 vaccines development, though, their R&D spending needs to be studied separately. Mani (2021) attempted to compare the vaccine R&D investment in the US and India, however, research and development expenditure on various vaccine projects running under the above listed institutions of DST have not been studied in this study.

7. Export's Performance and Competitiveness

7.1 International Acceptability of Indian Vaccines

Assessing the international acceptability of vaccines produced in the country is the first step to understand India's performance and competitiveness in export market. A detail analysis of vaccines produced in India and a list of Indian vaccines that have qualified WHO-

[19] https://dst.gov.in/sites/default/files/Research%20and%20Deveopment%20Statistics%202019-20_0.pdf

[20] However, it is important to note that the R&D intensity for vaccine might be over-represented, as R&D figures are available at industry level (NIC of pharmaceutical activities) while sale data (the denominator here) represents the vaccine's sale value at product (ASICC/NPCMS) level. However, the estimates suggest that vaccine R&D intensity in India still lower than other countries discussed in the text.

[21] https://www.indiascienceandtechnology.gov.in/covid-19-vaccine/institutes-labs-involved-vaccine-development; https://dbtindia.gov.in/schemes-programmes/research-development/medical-biotechnology/vaccine-research-and-development

prequalification norms suggest that of the total 45 vaccine manufacturers that are listed at WHO-PQ[22] platform, 7-8 are from India (WHO 2022b). In 2012, India had seven vaccine manufacturers producing 67 prequalified vaccines in dosage forms (Economic Times 2013). By June 2022, Indian vaccine manufacturers made a commendable progress and presently producing 112 prequalified vaccines in dosage forms out of total 264 dosage forms prequalified presentations for WHO's listed 166 vaccines (WHO 2022b). The Serum Institute of India has large number (around 63 PQ in dosage forms) of vaccines prequalification presentations in the world, followed by GlaxoSmithKline Biologicals SA (26). Other Indian companies that has vaccines prequalification presentations in doses form are Biological E (23), Bharat Biotech (10), Sanofi Healthcare India (7), Panacea Biotec (4), Haffkine Bio Pharmaceutical Corporation (3), Cadila Health Care (1) and Chiron Behring Vaccines (1).

In the past two decades, the progress of Indian manufacturers towards listing their vaccines at WHO-PQ platform is highly encouraging. SII was the first Indian company to get WHOPQ for Measles vaccine in 1993 (WHO 2022b). By 2006, SII had 9 more vaccines under PQ including for Diphtheria Tetanus (DT), Tetanus Toxoid (TT), Measles, Mumps and Rubella, Hepatitis-B. By 2022, SII registered largest number of PQ vaccines (22). Amongst the other companies, Biological E get PQ for TT, DTP, JE, DT, Measles and Rubella, and Typhoid conjugate vaccines between 2009-2020. Bharat Biotech received PQ for three type of vaccines viz., Polio, Typhoid and Rotavirus starting from 2015 to 2021. The MNC, Sanofi Healthcare has PQ for four vaccines viz., TT, Cholera, DTP, and inactivate Polio vaccine. Cadila Health Care and Chiron Behring Vaccines both has PQ for Rabies vaccine (WHO 2022b). Haffkine Bio Pharmaceutical Corporation is the only public sector firm that has PQ for three types of polio vaccines. However, it is important to note that majority of the Indian manufacturers that have received international acceptability status of their vaccines most of them are traditional and conventional vaccines in nature.

India has not only largest number of vaccines prequalification presentations (WHO-PQ) in the world, but also a most trusted vaccine manufacturer at DCVMN (Developing Countries Vaccine Manufacturers Network) platform (DCVMN 2020). DCVMN – a largest voluntary private health-driven alliance of vaccine manufacturers from developing countries, firmly engaged in research, development, manufacturing and supply of high-quality vaccines globally that came into existence in 2000 with an aim to increase supply of quality essential vaccines at affordable prices particularly in the United Nation countries/agencies. Around 14 emerging countries are listed at DCVMN and they supply vaccines to almost 170 countries (DCVMN 2020). Of the total 41 vaccine manufacturing

[22] WHO vaccines prequalification (WHO-PQ) is a service provided by WHO to UNICEF and other UN agencies that procure vaccines. In prequalifying vaccines, WHO applies international standards to comprehensively evaluate and determine whether vaccines used in immunization programmes are safe and effective (WHO 2022b).

companies from these countries[23], nine companies are from India. SII is the most trusted vaccine manufacturer as well as the largest vaccine manufacturer by number of doses produced and sold through the DCVMN platform (DCVMN 2020). To some extent, these progresses must have placed India internationally competitive, which is discussed below under export efforts and revealed comparative advantage (RCA) section. A comparative analysis of India's global position in value and volume terms, prior to and during Covid-19, and to what extent Chinese Covid-19 Vaccine Diplomacy affected the vaccine's export of India has been discussed in Hooda (2022).

7.2 Export Efforts and Revealed Comparative Advantage Analysis

A simple growth and trend analysis of vaccines export suggests that Indian export grew with a CAGR of 23% in the past three decades (1991-2020), which is more than the CAGR of world vaccine's export (16%) (from Figure 9). A decadal CAGR estimates suggest that growth in Indian vaccines export has always been higher than the world vaccine's export. In the recent past decade, Indian export grew with a CAGR[24] of 13.7%, while world vaccines export grew at 4.14% (from Figure 9).

Figure-9 shows that Indian vaccines export share in the world vaccine export shows an increasing trend over the past three decades with a fluctuating pattern. There was a major setback to export during the period when India cancelled licences and started neglecting its public sector vaccine manufacturing institutions (PSIs) around 2007-2008. For instance, India's vaccines export share in total vaccines export of the world increased from 0.26% in 1991 to 2.22% in 2006, but declined to 0.06% in 2008 – the year in which licences of three PSIs were cancelled (Figure 9). Indian vaccine export took around 5-6 years to resume to its previous level. The export share reached at all-time high at 3.16 percent in 2016, however, shows a declining trend since then to till recently (Figure 9).

The Indian vaccines export share in value term noticed to be around 1.55% prior to the product patent regime (2000-2005) and almost same in the initial years of product patent regime, but increased to 2.58% in the recent half decade 2014-2020 (Figure 9). Overall, India's share in world vaccine export remained low around 2.43% in past one decade though grew overtime.

The export efforts, export share in value of production (sale), is an important measure to show the importance of foreign market for a given industry in a country. There has been a consistent rise in India's export share in value of vaccines production in the country, indicating that India's efforts in international market are consistent and growing. (Figure 10). These estimates indicate that more than half of the turnover of vaccine industry in

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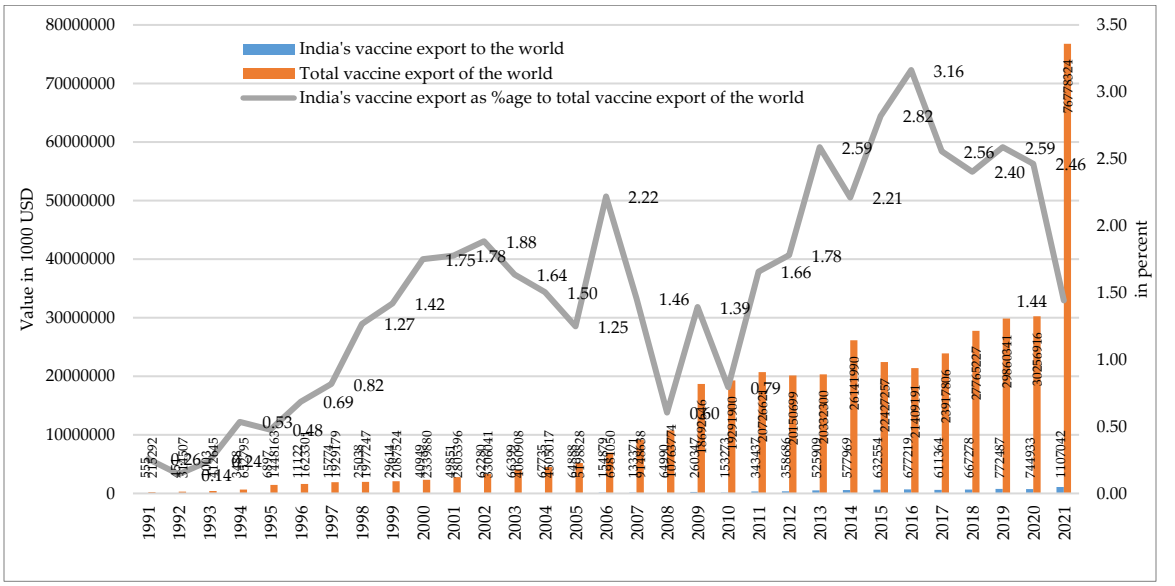
[23] Currently roughly, 30-40 countries manufacture vaccines https://www.unido.org/sites/default/files/files/2017-12/Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf

[24] Export value in USD 1000 million were considered while estimating the CAGR.

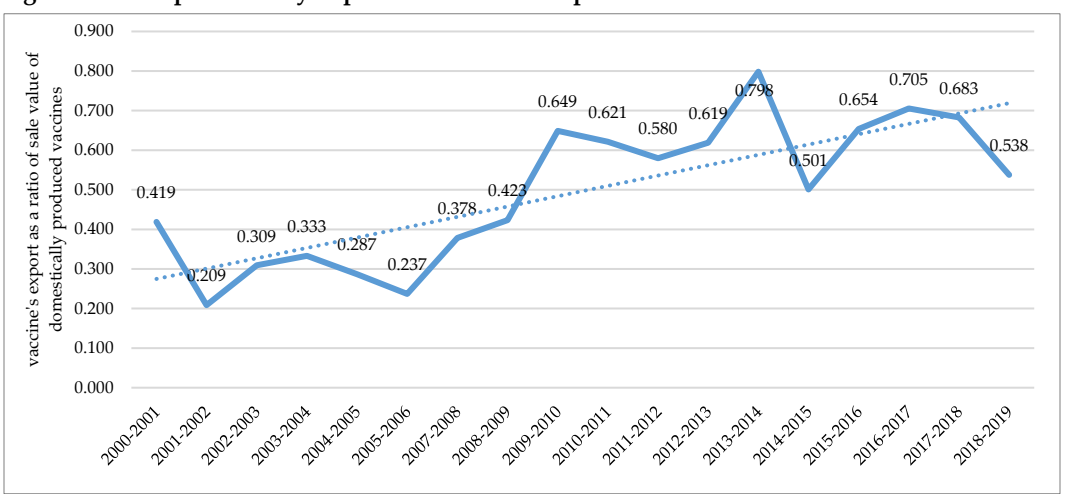
India came from exports in the recent past decade. The export efforts, in the recent two years, though, declined to 0.538 (Figure 10).

Figure 9: Trends in Vaccine Export: Comparing India and World



Source: WITS

Figure 10: The Export Intensity: Export Efforts out of total production



Source: from Table-3.

As reported in Table-3, India's export to import ratio has always been more than one, indicating that Indian vaccine export are more than the import and vaccine trade generates surplus consistently since last two decade. Revealed comparative advantage (RCA) analysis is a well-recognised measure of explaining export performance of a country with

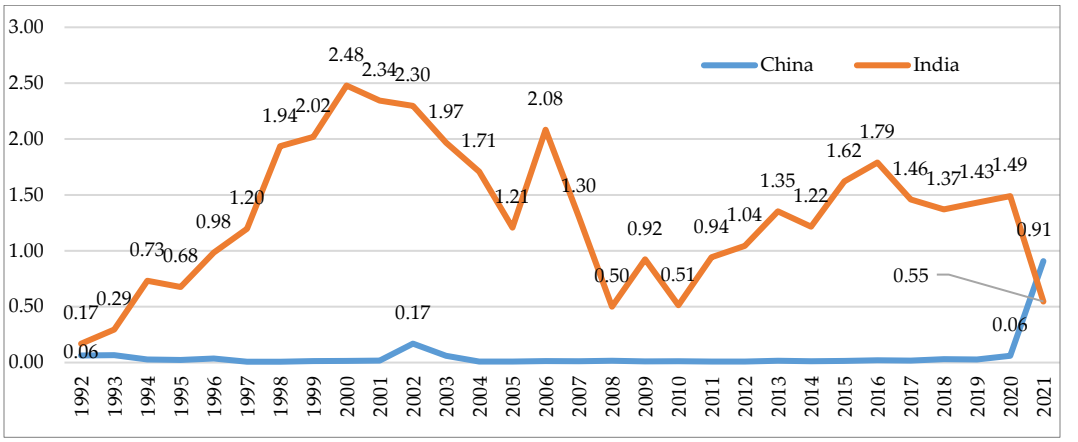
respect to a particular commodity. As per RCA estimates, a country is said to have a revealed comparative advantage in a given product when its ratio of exports of product/vaccine to its total exports of all commodities exceeds the same ratio for the world as a whole. That is, RCA>1 means country has comparative advantage. The estimates of RCA suggest that its value remained more than one for most of the period, except for few years (Figure 11). RCA value drop down to less than one in 2008, the year in which India cancelled licences of its three PSIs and suspended their vaccine production. Apparently, the manufacturing capacity that was available with the private sector at that particular time, might not have taken up the entire load of domestic and international market's requirements. Since Indian export declined, therefore, RCA value also came down to less than one and it continued to be less than one between 2008 to 2011 (Figure 11), indicating India losing out on comparative advantage. In the recent past, between 2013 to 2020, India enjoyed a comparative advantage in vaccine export.

It is interesting to note that India continued to enjoy comparative advantage in vaccines export prior to Coronavirus emergency, India's RCA value however drop down to less than one in 2021, the Covid affected year. Here it is important to note that during Covid emergency when India prioritise to vaccinate its own population over exporting, especially due to the Covid outbreak in the spring of 2021 in the country, Indian vaccine's export fell significantly. The inadequate producing capacity of indigenous manufacturing could not meet growing domestic demand and international vaccine requirement especially of developing world that India used to supply/export prior to Covid (for detail discussion see Hooda 2022). Interestingly, China has been a marginal player in vaccines export to the world with a very low share of 0.33% in recent (2011-2020) decade, before Covid years (Hooda 2022). However, in the Covid affected years, China's vaccine export to developing countries market increased significantly (see Hooda 2022). RCA value of Chine in vaccine export increased from 0.06 in 2020 to 0.91 in 2021 (Figure 11). The RCA for India has always been much higher than that of China, but, during Covid-19 years, India's RCA declined to less than one, while that of China increased and recorded close to one Based on recent fall in RCA value, does not mean that India would lose its existence. Indian export has started gaining momentum recently, due to the inefficacy of Chinese vaccine, as discussed in Hooda (2022). However, the biggest worry is the India's high import dependency on vaccine's raw material. India has a high import dependency on input used for manufacturing its indigenous vaccines. India largely depends on the USA for most of components and raw materials for manufacturing the recent Covid-19 vaccine (Mani 2021).

The compositional share of export of different type of vaccines in the recent past decade suggests that the value of export share are rising consistently for MMR and polio. India has a constant presence in export of BCG and anti-rabies vaccine in the global market. The export share of other mixed vaccines constitute a highest share since 2008, but the share shows a declining trend thereafter (Appendix 8). The share of other single vaccine segments shows increasing trends since 2012-13 to till recently, which is a healthy

indication, as this includes several newer vaccines that uses more advanced technological and manufacturing processes.

Figure 11: Revealed Comparative Advantage in Vaccine's Export: Comparing RCA of India and China



Source: Estimated using WITS data

7.3 Direction of Export

India's contribution to global vaccine market in value term is low, however, volumes supply to international market are substantial. India supply majority of its vaccines to lower-income countries (LICs) and low-middle-income countries (LMICs) markets. India's export to these markets noticed to be highest in the world with shares of about 37.43% and 24.53%, respectively (Table 5). In the '*Vaccine Initiative Decade 2010-2020*', that aimed for achieving a 90% vaccination coverage in developing countries, India made a great contribution in serving the VID needs of developing countries (Table 5). The manufacturers from developed countries, however, have shown least interest in supplying vaccine to VID requirement. They primarily serve vaccines in developed countries market. However, it is interesting to note that India's export to high-income countries has been negligible with a very low share of about 0.29% in the recent past decade (Table 5).

The compositional distribution of export across different markets also suggests that majority of Indian export goes to LICs and LMICs markets. India has been making a gradual entry in vaccines supplies to upper-middle countries (UMCs) market as well. The export share to HICs market remained very low throughout (Figure 12), largely because India has not been able get approval of its indigenously produced vaccines that are in use in the HICs market.

In terms of number of countries covered, India has explored a wide market for its vaccines. The progress towards covering different countries of the world is highly encouraging. India used to export its vaccines to around 51 countries in 1996. By 2001, Indian exports reached to almost 100 countries and 140 countries in 2011. Presently, Indian vaccines reaches to almost 178 countries (Figure 13). India used to supply 2-3 type of vaccines

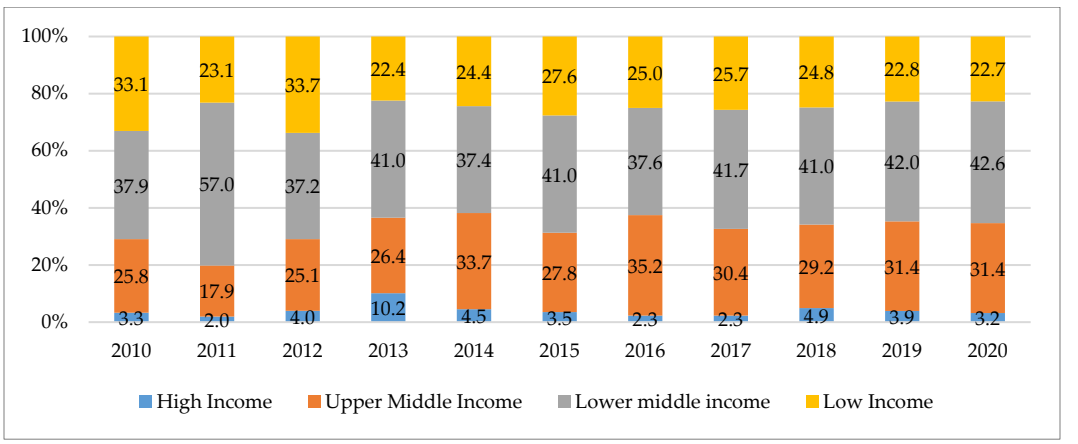
between 1996-97 to 2002-03. Between 2003-04 to 2014-15, India started exporting a large number of different types of vaccines to the world. India made tremendous progress in recent 6-7 years. Country's export reached across most of the vaccines categories to a larger number of countries. Recently, India has started exporting Japanese Encephalitis, Cholera and Typhoid, TT, DPT/DT, MMR, polio, rabies, BCG, Hepatitis and other single and mixed category to many countries as compared to the past (Figure 13). The analysis of past two decades suggests that India able to generate surplus consistently from vaccine trade, as presented in Table-3.

Table 5: Direction of Volume of Vaccines Export: Compositional Share, 2011 - 2020

Lower-Income Countries (LWICs) Market		*Low-Middle Income Countries (LMICs) market*		*High Income countries (HICs) Market*		*Overall (World Market)*	
Country	% share	Country	% share	Country	% share	Country	% share
India	37.43	India	24.53	France	29.93	France	24.96
Belgium	14.61	Belgium	18.09	United States	17.47	Belgium	15.52
United States	9.32	France	17.71	Belgium	15.28	US	14.32
Korea, Rep.	8.17	United States	10.23	Ireland	11.55	India	11.01
Brazil	5.66	Korea, Rep.	6.52	Germany	4.12	Ireland	6.90
France	5.24	United Kingdom	3.12	United Kingdom	3.85	UK	3.71
Uganda	3.32	Italy	2.77	Italy	3.26	Italy	3.19
Indonesia	3.26	Indonesia	2.35	Canada	2.80	Germany	2.84
Kenya	2.00	Netherlands	2.14	Netherlands	2.49	Korea, Rep.	2.45
Netherlands	1.43	Canada	1.33	Spain	2.33	Netherlands	2.37
Bulgaria	1.34	Brazil	1.04	India	0.29	Canada	2.14
China	0.27	China	0.98	China	0.02	China	0.37
Above all	**92.05**	**Above all**	**90.81**	**Above all**	**93.40**	**Above All**	**89.78**

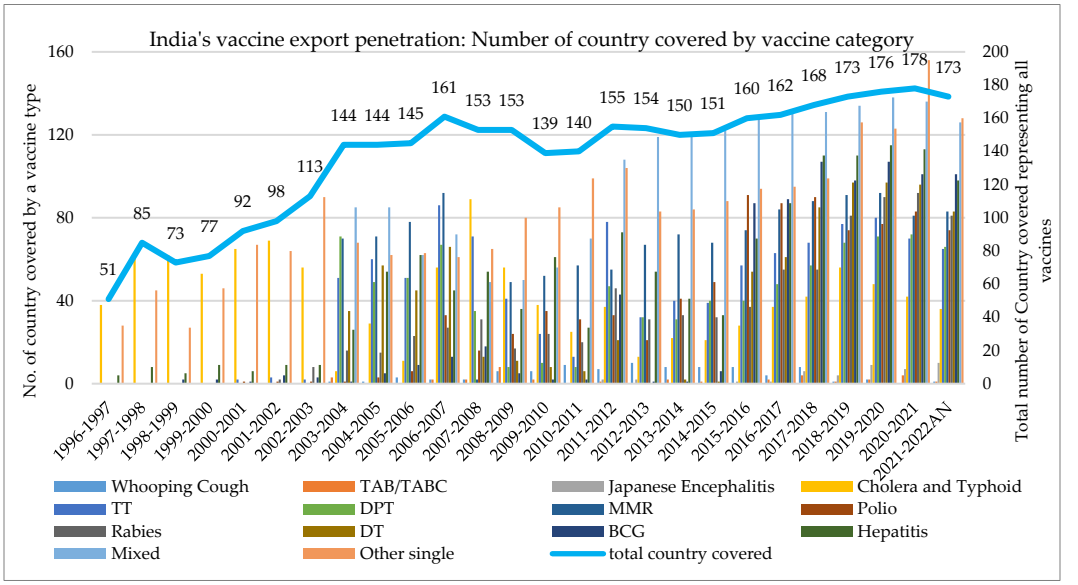
Note: Volume in KGs; in addition to top 10 countries, two extra entries are made to include either India or China in the list.
Source: WITS

Figure 12: Indian Vaccine Export to different Market: Compositional distribution of Volume of export across markets, 2010-2020



Note: unspecified country share (0.88%) not included in the figure.
Source: WITS

Figure 13: Export Orientation: Number of Countries covered by different Indian Vaccines



Note: AN-April to November; Source: designed using data from DGCI&S

8. Conclusion and Discussion

India has a century long legacy in research and development and manufacturing of vaccines. At the time when India introduced universal immunization programme (UIP) in the mid-80s, the country was self-sufficient in producing basic UIP vaccines such as BCG, DPT and Tetanus toxoid and mostly depended on public sector for vaccines supply. The public sector demonstrated their ability to innovate new processes and products. However, between the late 90s and early 2000s, a three-fourth of public sector vaccine institutions (PSIs) closed down, which further reduced to six-seven by late 2000s of the total 29 PSIs. Government of India suspended manufacturing licences of three major vaccine manufacturing PSIs in 2008, these units forced to stop production, and their entire market eliminated. They faced a consistent neglect of government in budgetary allocation even after revival of their licences, due to which public sector lost its dominance in installed capacity, production and supply of vaccines overtime and became a marginal player. The private sector overtook a major portion of UIP as well as non-UIP vaccine's market in the country. Since past one decade, most of the vaccines manufacturing is with the private sector. However, majority of the Indian manufacturers have traditional type of vaccines in their product basket hovering around UPI vaccines, the manufacturing capacity around the newer generation vaccines that are sold in retail non-UIP market has been low.

The estimated manufacturing size of sale value of locally produced vaccines increased from Rs 1.92 billion in 1999-2000 to Rs. 84.75 billion in 2018-19, while the inflation-adjusted sale increased from Rs. 2.46 billion in 1999-00 to Rs. 66.57 billion in 2018-19. Unlike the past, the nominal sale of domestically produced vaccines grew at a CAGR of nearly 20.92%, while the inflation-adjusted sale grew at a CAGR of 15.46% between 2009-10 to 2018-19. The sharp rise in sale in the recent decade is largely because of the inclusion of several other vaccines in UIP like Hepatitis B (2007-08), second dose of measles (2010) and Japanese Encephalitis (2011), yellow fewer (2015), Inactivated poliovirus vaccine (2015-2016), Rotavirus diarrhea (2016-2019) and the PCV (2017) that the indigenous manufacturers supplied at high price, except for a few. The overall manufacturing however remained less than the national requirements. The increasing uptake of high priced vaccines resulted in high DMS (final consumption) of vaccines in the country. The domestic market size increased to Rs. 60.52 billion in 2018-19 from Rs. 1.71 billion in 1999-2000. A large part of growing vaccine's needs were fulfilled through imports rather than domestic manufacturing. The country could not sustain the pace of introducing newer vaccines in the market which made the country import dependent. In 2001-02, domestically produced vaccines fulfilled almost 90.97% of final vaccine consumption demand in 2001-02 and presently, around 41% of the domestic vaccine demand are met through imported vaccines. The import penetration rate increased from 9.05% in 2001-02 to 22.4% in 2008-09, and within a year after licences suspension of three PSIs, the IPR increased to 54.2% in 2009-10. IPR recorded around 35.27% in 2018-19. India, a self-sufficient nation in meeting its vaccination requirements, started importing some basic UIP vaccines namely Hepatitis, Anti Rabies and Japanese Encephalitis from China in the following years when government neglected and suspended the licences of its public sector units. The pulse polio programme is major mass immunisation programme of the country. The country even became dependent on imported polio vaccine majorly from Indonesia after that particular time. This led to increase in government budget allocation on pulse polio programme many folds within a few years, from Rs. 659.94 crore in 2003-04 to Rs. 1341.48 crore in 2008-09. In addition, due to the uptake of DPT (triple antigen) vaccine, the IPR turned out be high (17.23%) in 2018-19 in three (DPT, BCG, TT) basic UIP vaccines category in which India was self-sufficient. India does not only import UIP vaccines where domestic supply is inadequate, the increased uptake of other newer generation vaccines like Pneumococcal conjugate vaccine, Varicella vaccine, Rotavirus vaccine, HPV and typhoid conjugate vaccine has resulted in high import and import penetration in the country.

India saw a major setback to export especially in the period when public sector was neglected. India's vaccine export share in total vaccine export of the world reduced drastically from 2.22 percent in 2007-08 to 0.60 percent in 2008-09 which took almost 4-5 years to resume to its previous level. Despite such repercussions, Indian manufacturers made a commendable progress in vaccines supply to the developing world and received WHO-prequalification for many of its vaccines. Indian export grew with a CAGR (23%) of more than the CAGR of world export (16%) in the past three decades (1991-2020). The

export efforts (export share in sale) show a consistent rise. The export efforts estimate suggest that more than half of the turnover of vaccine industry in India came from exports in recent past decade. The revealed comparative advantage measure also suggests that India has high comparative advantage in vaccine exports. In addition, India emerges as a global vaccines hub in supplying affordable vaccine to low-middle-income countries. Some of the Indian manufacturers are the most trusted supplier of vaccine to developing world. India's export to LICs and LMICs markets noticed to be highest in the world with shares of about 37.43% and 24.53%, respectively, in recent decade. Presently, India supply different type of vaccines to almost 178 countries. However, Indian vaccine export to high-income (EUs and US) countries market remains negligible, because India has not been able to get marketing approval for its vaccines in these country's markets. India has very low R&D intensity and very high dependency on imported inputs. The lack in R&D capacity and research infrastructure can hamper the future growth of the vaccine Industry.

India, in line with TRIPS agreement of WTO, re-introduced product patent protection in 2005. For bulk of existing vaccines that India manufacture (like, the DTP, TT, Pw, Pa, HepB, HiB, IPV, OPV, measles, mumps, rubella, yellow fever, etc.), the patents are not a barrier, as many of these vaccines were developed at least 20 years ago. The manufacturers based in Europe and US dominate most of the high price vaccine markets of the world. The patent barrier and technical know-how, low R&D spending and other barriers prevent companies to enter in these high price segments. However, TRIPS agreement provides some flexibilities for the countries to take appropriate action to make product more affordable and accessible which were discussed for Covid-vaccine products[25] and can be exploited for newer generation vaccines on affordability and accessibility grounds. In addition, there is *unmet needs* cutting across multiple categories of vaccines, including diseases endemic to high-income regions (such as HIV and norovirus) and those endemic to low-income regions (Zika virus, tuberculosis, malaria).India needs to work beyond Covid and look forward to play a greater role for treating the diseases and endemic of low-income setting through indigenous vaccines development including exploring the possibility of emerging market of contract manufacturing.

The first ever *National Vaccine Policy 2011* of India aimed for a self-reliant country in vaccine technology development and self-sufficient in vaccine production. Indian prime minister recently reiterated that self-reliance and self-sufficiency are the biggest lessons India

[25] At a time when there was a need for scaling up of Covid vaccine production, the countries faced intellectual property barrier relating to patents and technology transfers of key medical products. India and South Africa, along with over 120 WTO members, proposed a waiver from specific provisions of TRIPS Agreement for the prevention, containment and treatment of Covid-19 (Gallogly-Swan et. al., 2021). These specific provisions include patents, industrial designs, copyright and protection of undisclosed information such as trade secrets. The waiver, if granted, would ensure that the IPRs do not restrict rapid scaling up of manufacturing and do not hinder equitable and affordable access for vaccines and treatments throughout the globe. This proposal has faced strong opposition from a few advanced economies and big companies, however, several relaxation were given in exports of several products to make the Covid-products more accessible and affordable.

should take away from the coronavirus experience. The coronavirus pandemic exposed the world with incapability of private sector in addressing the health emergencies. This forces us to rethink on the relevance of public sector institutions. The public sector institutions earlier in India and in many other countries have not only performed basic and advanced research but also identified promising points of interventions that are expected to have disproportionally high clinical effects.

9. References

Barro R J, Ursúa JF and Weng J (2020), "The Coronavirus and the Great Influenza Pandemic: Lessons from the Spanish Flu for the Coronavirus's Potential Effects on Mortality and Economic Activity," NBER Working Paper No. 26866, March-April

Chaudhuri, Sudip (2022), "Decline of Public Sector Vaccine Manufacturing in India," March 11. Available:
SSRN: https://ssrn.com/abstract=4055411 or http://dx.doi.org/10.2139/ssrn.4055411

Cross S, Rho Y, Reddy H, et al. (2021), Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine?, BMJ Global Health, Vol.6:e007321. DOI:10.1136/ bmjgh-2021-007321

CSIS (2022), "Is China's COVID-19 Diplomacy Succeeding?" Centre for Strategic & International Studies. Available at: https://chinapower.csis.org/china-covid-medical-vaccine-diplomacy/; accessed on July 23, 2022.

DCVMN (2021), *Annual Report 2021*, Developing Countries Vaccine Manufacturers Network. Available at: http://www.dcvmn.org/IMG/pdf/annual_report_2021.pdf

Dellepiane N and Wood D. (2015), Twenty-five years of the WHO vaccines prequalification programme (1987-2012): lessons learned and future perspectives. Vaccine, Vol.33(1), pp.52-61. DOI:10.1016/j.vaccine.2013.11.066.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5355375/

Ehreth, Jenifer (2003). The global value of vaccination, Vaccine, Vol.21(7-8), pp.596-600. Available at: https://doi.org/10.1016/S0264-410X(02)00623-0

European Vaccine Manufacturers (EVM) (2008), "The vaccine industry's contribution to health and welfare in Europe, European Vaccine Manufacturers", April, available at: http://www.vaccineseurope.eu/wp-content/uploads/2012/12/The-vaccine-industrys-contribution-to-health-and-welfare-in-Europe-April-20081.pdf

Fronczek M (2017). Import penetration rate in view of a new concept of measuring foreign trade. Argumenta Oeconomica, Vol.38(1). DOI: 10.15611/aoe.2017.1.11

Gallogly-Swan K., Thrasher R., Ömer Ö. (2021), "Vaccinating the World Waiving Intellectual Property Rules on COVID-19 Products", available at https://www.bu.edu/gdp/files/2021/03/GEGI_PB_013_TRIPS.pdf

Ghosh, Prasantha K (2019), "Indian Vaccines Industry Addressing Human Health Challenges," Forum for Indian Science Diplomacy (FISD), Science Diplomacy Case Studies No. 4, Research and Information System for Developing Countries, October 2019.

GOI (2006-2022), *National Health Profile 2006 to 2022*, Central Bureau of Health Intelligence (CBHI), Ministry of Health & Family Welfare, Government of India.

GOI (2011), *National Vaccine Policy 2011*, Ministry of Health and Family Welfare, Government of India. April, Available at: https://main.mohfw.gov.in/sites/default/files/108481119000.pdf

GOI (2022), *Annual Report 2020-21*, Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers, Government of India. Available at: https://pharmaceuticals.gov.in/ sites/default/files/english%20Annual%20Report%202020-21.pdf

GOI (undated). Immunisation. Ministry of Health & Family Welfare, Government of India. Available at https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=824&lid=220 and https://main.mohfw.gov.in/sites/default/files/5628564789562315.pdf

Henderson D A (2011). The eradication of smallpox – An overview of the past, present, and future. https://doi.org/10.1016/j.vaccine.2011.06.080.

Hooda S K (2022), India in the Global Vaccine Market Prior To and During COVID-19: Some Structural Issues, ISID Working Paper 250, August, Available at: https://isid.org.in/wp-content/uploads/2022/10/WP250.pdf

Jadhav S, Gautam M, Gairola S. Role of vaccine manufacturers in developing countries towards global healthcare by providing quality vaccines at affordable prices. Clin Microbiol Infect. 2014;20 (5):37–44. doi:10.1111/1469-0691.12568

Javid Chowdhury Committee (2010), *Final Report of the Committee Set Up to Determine the Reasons for the Suspension of the Manufacturing Licenses of CRI, Kasauli, PII, Conoor and BCGVL, Guindy and To Draw the Road-map for the Revival of the Three Units*, September. Available at: http://www.mfcindia.org/main/bgpapers/bgpapers2011/am/ bgpap2011s.pdf

Khan, Mohammed Imran, Aamer Ikram, and Hasan Bin Hamza (2021), "Vaccine Manufacturing Capacity in Low- and Middle-income Countries," Editorials, *Bulletin of World Health Organisation*, Vol. 99, No. 7, pp. 479–479A. Available at: http://dx.doi.org/10.2471/BLT.20.273375

Kumraj G, Pathak S, et.al. (2022), Capacity Building for Vaccine Manufacturing Across Developing Countries: The Way Forward, Human Vaccines & Immunotherapeutics, Vol.18(1), pp.2020529(1-17), DOI: 10.1080/21645515.2021.2020529

Lahariya, Chandrakant (2014), "A Brief History of Vaccines & Vaccination in India," *Indian Journal of Medical Research*, Vol. 139, No. 4, April, pp. 491-511.

Madhavi, Yennapu (2005), "Vaccine Policy in India," *PLoS Medicine*, Vol.2, No. 5. Available at: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020127

_____ (2020), "The Public Sector is Crucial for Self-Reliance in Vaccines and Public Health," *Science: The Wire*, April 29. Available at: https://science.thewire.in/culture/books/covid-19-indian-psu-vaccines/

_____ (2022), "Wilful Neoliberal Incapacitation of India's Public Sector Vaccine Institutions," in Stuart Blume S and Baptiste Baylac-Paouly (Eds.) *Immunisation and States: The Politics of Making Vaccines*, Routledge, London, pp. 110-137.

Makenga, Geofrey *et al*. (2019), "Vaccine Production in Africa: A Feasible Business Model for Capacity Building and Sustainable New Vaccine Introduction," *Frontiers in Public Health*, March 20. Available at: https://www.frontiersin.org/articles/10.3389 /fpubh.2019.00056/full

Mani, Sunil. (2021), The role of industrial policy in market-friendly economies Case of COVID-19 vaccine R&D and its manufacturing in India and the USA, Commentary on India's Economy and Society Series – 21, Centre for Development Studies, Thiruvananthapuram, Kerala, India, July. Available at: https://cds.edu/wp-content/uploads/ 21CommentarySeriesProfMani.pdf

OECD (2011), STAN Indicators. Available at: https://www.oecd.org/sti/ind/47447210.pdf

Parliamentary Standing Committee (2009a), "Thirty-Fourth Report on the Functioning of the three Vaccine Producing PSUs, Namely, the Central Research Institute (CRI) Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL)," Chennai., Department-Related Parliamentary Standing Committee on Health and Family Welfare. Available at: https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/14/34_2016_6_14.pdf).

Parliamentary Standing Committee (2009b), "Thirty-Eighth Report on Major Issues Concerning the three Vaccine Producing PSUs, Namely, the Central Research Institute (CRI) Kasauli, The Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL)," Chennai, Department-Related Parliamentary Standing Committee on Health and Family Welfare. Available at: https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/14/38_2016_6_14.pdf.

Plotkin, S., Robinson, J. M., Cunningham, G., Iqbal, R., & Larsen, S. (2017), The complexity and cost of vaccine manufacturing - An Overview, Vaccine, 35(33), 4064–4071. DOI: https://doi.org/10.1016/j.vaccine.2017.06.003

Research and Markets (2021), *Vaccine Contract Manufacturing Market – Global Outlook and Forecast 2021-2026*. Available at: https://www.researchandmarkets.com/r/667obb

Rodrigues C.M.C and Plotkin, S.A. (2020), Impact of Vaccines, Health, Economic and Social Perspectives frontiers, July 14. https://doi.org/10.3389/fmicb.2020.01526

Stevens, A., Jonathan, et al., (2011), The Role of Public-Sector Research in the Discovery of Drugs and Vaccines, The New England Journal of Medicine, Vol.364. pp.535-541. DOI: 10.1056/NEJMsa1008268

The Economic Times (2013), "India's Vaccine Regulator National Regulatory Authority of India Meets WHO Standards," April 9. Available at: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/indias-vaccine-regulator-national-regulatory-authority-of-india-meets-who-standards/articleshow/19464003.cms; accessed on August 17, 2022.

Tull, K. (2021), Economic impact of local vaccine manufacturing, Helpdesk Report, K4D: Knowledge, evidence and learning for development, February 23. Available at: https://opendocs.ids.ac.uk/opendocs/bitstream/handle/20.500.12413/16470/974_Economic_impact_of_local_vaccine_manufacturing.pdf?sequence=1&isAllowed=y

Ulmer JB, Valley U and Rappuoli R (2006), Vaccine Manufacturing: Challenges and Solutions, Nature Biotechnology, Vol.24, pp. 1377-87. Available at: https://www.nature.com/articles/nbt1261

Vanderslott S (2018), How is the world doing in its fight against vaccine preventable diseases?, Our World in Data. Available at: https://ourworldindata.org/vaccine-preventable-diseases

Vanderslott S, Badonaite B and Roser M (2019). Vaccination, Our World in Data. Available at: https://ourworldindata.org/vaccination#:~:text=The%20WHO%20estimates%20that%202,1.5%20million%20deaths%20each%20year.

Watson O.J., Barnsley G, et. al., (2022), Global impact of the first year of COVID-19 vaccination: a mathematical modelling study, Lancet Infectious Disseases, Vol (22), pp.1293–302, June 23. DOI: https://doi.org/10.1016/ S1473-3099(22)00320-6

WHO (2022a), Poliomyelitis: Key Facts, World Health Organisation. July 4. Available at: https://www.who.int/news-room/fact-sheets/detail/poliomyelitis.

WHO (2022b), "Prequalified Vaccines," World Health Organisation. Available at: https://extranet.who.int/pqweb/vaccines/prequalified-vaccines; accessed on July 30, 2022.

WHO (undated), Vaccines and Immunization, World Health Organisation. Available at: https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1

WHO/MI4A, (2020), *Global Vaccine Market Report*, Market Information for Access to Vaccines (MI4A), World Health Organisation. Available at: https://cdn.who.int/ media/docs/default-source/immunization/mi4a/2020_global-vaccine-market-report.pdf?sfvrsn=48a58ada_1&download=true; accessed on July 24, 2022.

Xue Q.C. and Ouellette L.L. (2020), Innovation policy and the market for vaccines, Journal of Law and the Biosciences, Vol.7 (1), pp.1–41. doi:10.1093/jlb/lsaa026

Appendices

Appendix 1 Public Sector Vaccine Institutions in India established since 1800: Operational and Closed-down Status

Name of the PSVIs	*Establishment Year*	*Vaccines/sera*	*Operation Status*
Smithstrain Street Pharmaceuticals Ltd., Calcutta (established 1821 as a private company, became a PSVI1977)	1821	Vaccines/sera	Closed down 2000
Institute of Preventive Medicine, Hyderabad (formerly Plague Department)	1870	Plague, smallpox (since 1910), rabies (since 1976–1977), TT (since 1978)	Production of anti-rabies and TT stopped 2002; closed down 2005
Vaccine Lymph Department, Calcutta, 1980s	1890	Vaccine lymph	Closed down 1980s
Cholera Vaccine Lab, Calcutta, 1980s	1890	Cholera	Closed down 1980s
King Institute of Preventive Medicine, Guindy, Chennai (then Madras)	1898	Vaccine lymph, TT, typhoid, cholera	Operational , Currently produces DT and DPT, anti-snake venom, anti-rabies, anti-tetanus serum; production of TT, typhoid, cholera vaccines suspended 2005
Haffkine Institute, Mumbai (formerly Bombay Bacteriological Laboratory)	1898	DT, TT, plague, cholera, typhoid, rabies, gas gangrene anti-toxins, anti-dysentery, anti-snake venom	Operational
Pasteur Institute of India, Kasauli (Punjab province)	1900	Anti-rabies	Merged with CRI Kasauli 1939
Provincial Hygiene Institute, Lucknow	1900	Cholera	Closed down Post-2000
Public Health Laboratory, Bangalore	1900	Cholera	Closed down Post-2000
Bengal Public Health Lab, Calcutta	1900	Cholera; later conducted sterility tests on other government labs	Closed down 1980s
Vaccine Institute, Ranchi	1900	Vaccine lymph, cholera, anti-rabies	Closed down 2008
Public Health Laboratory, Patna	1900	Cholera	Closed down 2008
Bengal Chemicals and Pharmaceuticals Ltd., Calcutta (established 1901 as a private company, became a PSVI in 1980)	1901	Chemicals, synthetics, dyes, vaccines/sera	Closed down 2000; recently being revived
Vaccine Lymph Department, Patwada Nagar, near Nainital (later State Vaccine Institute)	1903	Vaccine lymph, anti-rabies	Closed down 2003
Vaccine Lymph Department, Belgaum	1904	Vaccine lymph	Production stopped and the department closed down 1980s
Central Research Institute (CRI), Kasauli	1905	Typhoid, cholera, anti-snake venom, anti-rabies	Operational*

Name of the PSVIs	*Establishment Year*	*Vaccines/sera*	*Operation Status*
Pasteur Institute of Southern India, Coonoor	1907	Anti-rabies, OPV (1967-1976), DTP, DT, TT (since 1978)	Operational*
Pasteur Institute, Calcutta	1910	Anti-rabies (unsatisfactory functioning); later a teaching institute	Closed down 1980s
Vaccine Institute, Lahore, 1910s (maintained by government of Punjab; after independence it became a part of Pakistan)	1910	Vaccine lymph	Located in Pakistan
Pasteur Institute Rangoon (currently Myanmar)	1915	Anti-rabies	Located in Myanmar
Pasteur and Medical Research Institute, Shillong, Assam	1917	Typhoid, cholera, anti-rabies treatment	Closed down 2006
Bengal Immunity Ltd., Calcutta (became a PSVI 1980s)	1919	All vaccines required for EPI, cholera, typhoid, anti-rabies, anti-snake venoms, etc.	Closed down 2003
School of Tropical Medicine, Calcutta	1922	Epidemiological and other routine diagnostic services	No vaccine production since 1980s
Public Health Laboratory, Thiruvananthapuram	1937	Anti-rabies; later functioned as immunology lab supplying yellow fever vaccine on demand	Closed down Post-2005
BCG Vaccine Lab, Guindy, Chennai	1946	BCG vaccine	Operational*
Vaccine Institute, Nagpur (established 1959, became a PSVI in 1980)	1959	Smallpox, cholera (from 1968)	Production was stopped before it was closed down post-2005
Vaccine Institute, Vadodara (became a PSVI in 1973)	1973	Anti-rabies	Closed down 2009
West Bengal Lab, Calcutta (became a PSVI 1980)	1980	Sera/vaccines, synthetics and dyes	Closed down post-2005
Indian Immunologicals Ltd., Hyderabad	1983	Main focus on veterinary vaccines; human vaccine production began 1998: tissue culture human rabies vaccine (1998), measles, MMR (2002), rDNA Hep B (2006), anti-rabies serum	Operational
Bharat Immunologicals and Biologicals Ltd. (BIBCOL), Bulandshar, Delhi	1989	OPV formulations from imported bulk	Operational
Indian Vaccines Corporation Ltd. (IVCOL), Gurgaon	1989	Intended to produce measles vaccine, but could not due to the unavailability of the technology.	Closed down 2002

Source: Madhavi, 2022: Table 5.1

Appendix 2: Licensed Vaccines with the Indigenous Public and Private Manufacturers

SN.	*Vaccine indigenous manufacturers in private sector*	*Licensed Vaccine*
1	Bharat biotech International Ltd, Genome Valley, Turka-pally (V), Shameerpet Mandal, Ranga Reddy District, Hyderabad	Hib, Rabies, bOPV, mOPV, DTP+Hib+HepB, Vi polysaccharide Typhoid, H1N1, DTP, DTP+HepB, Rotavirus vaccine, Inactivated JE vaccine, Typhoid+TT Conjugate Vaccine & DTP+Hep- B+Hib (Liquid), DTP+Hib
2	a. Biological E., 18/1 &3, Azamabad, Hyderabad, Andhra Pradesh	DTP, TT, JE bulk & DT.
	b. Biological E., 7- 4-114, Gaganpahad, Rajendranagar Mandal, Ranga Reddy District, A.P	TT Bulk
	c. Biological E., Plot No.1, S.P. Biotechnology Park Phase-II, Kolthur Village, Shameerpet Mandal, Rangareddy District, Andhra Pradesh	Diphtheria, Pertussis, DTP, DTP+Heb-B, Hib, JE, TT, Hep-B, DTP+HepB+Hib (Liquid & Lyophilized), DT & IPV.
3	Biomed Pvt. Ltd, C-96, B.S. Road, Industrial Road, Ghaziabad-201009.	Hib, Meningococcal Polysaccharide (A,C, Y,W 135), bOPV, Vi Polysaccharide Typhoid Vaccine & Meningococcal polysaccharide (A & C), Rabies
4	Cadila healthcare, Sarkhej Bavla, NH No. 8-A, Moraiya, Sanand, Ahmedabad (Guj.)	Rabies vaccine, Bulk Rabies vaccine
	Cadila Healthcare Limited, Sarkhej-Bavla N.H. No. 8A, Changodar Road, Tal. Sanand, Ahmedabad	Pandemic influenza H1N1 2009 monovalent vaccine, Typhoid Vaccine, Rabies vaccine, Tetravalent Influenza (split virion)
5	Cadila Pharmaceuticals Ltd., 1389, Trasad Road, Dholks, Ahmedabad	H1N1 VLPs Vaccine
6	Chiron Behering, GIDC, Estate, Ankleshwar, Bharuch (Guj.)	Rabies vaccine
7	Dano Vaccine & Biological Pvt. Ltd., Hyderabad	TT
8	Green signal BioPharma Ltd, 49, Pappankuppan Village, Gummidipoondi, Chennai–601201	BCG Vaccine
9	a. Panacea, Malpur, Baddi, PO Bhud, Tehsil, Nalagarh, Distt. Solan, (H.P)	DTP, HepB, DTP+Hep-B, DPT+Hep-B+Hib, IPV, Hib & H1N1, bOPV, DTP-Hib, DPT+Hep- B+Hib+IPV
	b. Panera, Ambala, Chandigarh highway, Lalru, District Mohali	Bulk DS of Hep- B, Diphtheria, TT, wP, H1N1 & Hib (Only bulk mfg facility)
10	Ranbaxy Lab, Sy. No.16, Ekarajapura, Siddlaghatta Road, Hasigila Post, Hoskote, Bangalore-562114	Typhoid polysaccharide & Hib Conjugate vaccine
11	Serum Institute of India, 212/2, Hadapsar, Pune- 411028	DTP, TT, DT, Hep-B, Hib (Vaccine & bulk), MMR, Measles, Rubella,BCG, Rabies, IPV, DTP+Hep B+Hib (Liquid +lyophilized), DTP+HepB, DTP+Hib, H1N1, Meningococcal A conjugate (Freeze dried), Mumps, MR, H1N1(whole virion inactivated), Measles +mumps, Measles+ Rubela, Influenza, Vaccine seasonal, Diphtheria Vaccine (bulk),TT bulk, Pertussis

SN.	*Vaccine indigenous manufacturers in private sector*	*Licensed Vaccine*
		bulk, Measles bulk, Mumps bulk, Rubella bulk & DT bulk & OPV vaccine, CRM 197 Bulk, DTP+ Hep B+ Hib Bulk
12	Shantha Biotechnics Ltd. Survey No. 274, Athvelli Village, medchal Mandal, Ranga Reddy District-501401	DTP, DTP+HepB+Hib (Liquid), DTP+Hib, DPT+Hep B, TT, Hib, Hep-B, DT bulk, TT Bulk, Hib Bulk, Hep B Bulk, DTP bulk, DTP+HepB+Hib bulk, DTP+HepB+Hib RTF bulk, Oral cholera vaccine, IPV RTF Bulk, IPV, Inact. B. pertussis bulk
	Shantha Biotechnics Pvt Ltd. Survey No. 354, Muppireddypalli Village, Toorpan Mandal, Medak District-502236	Oral cholera vaccine, DTP+HepB+Hib
13	GSK Asia Pvt. Ltd., Plot No. A-10/1, MIDC, Ambad-Pathardi Block, Nashik – 422 010	Pneumococcal Polysaccharide and Non-Typeable *Haemophilus influenza* vaccine (packing and labeling)
14	Sanofi Pasteur India Pvt Ltd, EL-223, TTC Industrial Area MIDC, Mahape, Navi Mumbai – 400 710. (Relabeling & Stickering)	Hib, DTP-Hib, Typhoid, Hep A, Pneumococcal, Yellow fever, Seasonal influenza, Rabies, Meningococcal, IPV, DTaP-IPV-Hib, Varicella, DTaP
S.No.	List of Vaccine indigenous Manufacturers in Public Sector Undertaking (PSU)	Licensed Vaccine
15	BIBCOL, village- Chola, Dist-Bulandshahr, U.P	bOPV
16	Haffkine, Acharya Donde Marg, Parle, Mumbai- 400012	mOPV & bOPV
17	a. Human biological institute, Rakshapuram, Gaachibowli, Hyderabad- 500032	Rabies, DTP, TT, DT & Hep- B
	b. Human biological institute, Kozhipannai, Pudumund,P.O. Udhagamandalam-	Rabies
	c. M/s Human Biologicals Institute, a Division of M/s. Indian Immunologicals Ltd., Karakapatla Village, Mulugu, Mandal, Medak Dist, Telangana State	Rabies
18	HLL Biotech Ltd., Ticel Biopark campus, CSIR Road, Taramani, Chennai	Hep B, DTwP- HepB-Hib
S.No	List of Vaccine indigenous Manufacturers in Government	Licensed Vaccine
19	BCG vaccine, Guindy, Chennai.	BCG, Tuberculine
20	CRI, Kasauli, District Solan, HP.	DTP, yellow fever, JE, TT, DT, Concentrated DTP vaccine
21	Pasteur institute of India, Coonor-643103, Nilgiris District, Tamil Nadu	DTP, TT, DT & inactivated Rabies vaccine

Source: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/facilitiesLIST.pdf; https://www.indiascienceandtechnology.gov.in/covid-19-vaccine/list-licensed-human-vaccine-manufacturing-facilities-india

Appendix 3: The Development Trajectory of Human Vaccines by Years

18th Century
Smallpox (1798)
19th Century
Rabies (1885)
Typhoid (1896)
Cholera (1896)
Plague (1897)
Early 20th Century, first half
Diphtheria toxoid (1923)
Pertussis (1926)
Tetanus toxoid (1926)
Tuberculosis (bacille Calmette–Guérin) (1927)
Yellow fever (1935)
Influenza (1936)
Rickettsia (1938)
20th Century, second half
Polio (injected) (1955)
Polio (oral) (1963)
Measles (1963)
Mumps (1967)
Rubella (1969)
Anthrax secreted proteins (1970)
Meningococcus polysaccharide (1974)
Pneumococcus polysaccharide (1977)
Rabies (cell culture) (1980)
Adenovirus (1980)
Tick-borne encephalitis (1981)
Hepatitis B (plasma derived) (1981)
Haemophilus influenzae type B polysaccharide (1985)
Hepatitis B surface antigen recombinant (1986)
H.influenzae type b conjugate (1987)
Typhoid (Salmonella TY21a) (1989)
Cholera (WC-rBS) (1991)
Japanese encephalitis (mouse brain) (1992)
Cholera (recombinant toxin B) (1993)
Typhoid (Vi) polysaccharide (1994)
Cholera (attenuated) (1994)
Varicella (1995)
Hepatitis A (1996)
Acellular pertussis (1996)
Lyme OspA (1998)
Rotavirus reassortants (1999)
Cold-adapted influenza (1999)
Meningococcal conjugate (group C) (1999)
21st Century
Pneumococcal conjugates (heptavalent) (2000)
Influenza (intranasal) (2003)
Meningococcal conjugates (quadrivalent) (2005)
Rotavirus (pentavalent; attenuated and new reassortants) (2006)
Herpes Zoster (2006)
Human papillomavirus recombinant (quadrivalent) (2006)
Rotavirus (monovalent) (2008)
Japanese encephalitis (2009) (Vero cell)
Influenza H1N1 (monovalent pandemic) (2009)
Cholera (WC only) (2009)
Human papillomavirus recombinant (bivalent) (2009)
Pneumococcal conjugates (13-valent) (2010)
Meningococcal conjugate (quadrivalent CRM197) (2010)
Influenza (cell based) (2012)
Meningococcal group B proteins (2013)
Influenza (baculovirus) (2013)
Influenza (intradermal) (2014)
Human papillomavirus (9-valent) (2014)
Meningococcal group B (bivalent fHbp) (2014)
Meningococcal group B (4-component, by means of RV) (2015)
Influenza (MF59 adjuvant) (2015)
Cholera (serogroup 01 oral (2016)

	Herpes Zoster (ASO1B adjuvant) (2017)
	Hepatitis B (CpG 1018 adjuvant (2017)
	Smallpoz and monkeypox (2019)
	Dengue (tetravalent) (2019)

	Ebola Zaire (rVSV platform) (2019)
	Covid-19 (Live attenuated) (2020)
	Covid-19 (Killed whole organisms) (2020)
	Malaria (2021)

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151719/; https://historyofvaccines.org/; https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year

Appendix 4: Compositional distribution of Sale Value across different type of vaccines

	Cholera And Typhoid	*DPT/DT*	*Hepatitis A&B*	*Japanese Enceph-alitis*	*Measles, Mumps& Rubella (MMR)*	*Mening-ococcal Meningitis*	*Polio*	*Rabies*	*T.B (BCG)*	*Tetanus*	*Whoo-ping Cough*	*Other Single vaccine (influenza, measles, yellow fever)*	*Vaccine others & other Micribial culture .N.E.C*	*Total - gross sale value*
1999-2000	0.00	22.67	34.98	0.00	0.00	0.00	14.97	0.00	0.00	0.00	0.00	0.00	27.38	100
2000-2001	0.00	34.21	41.96	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	23.83	100
2001-2002	0.00	40.36	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.94	55.69	100
2002-2003	0.00	40.99	0.09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	6.25	52.68	100
2003-2004	0.49	27.77	16.77	0.00	0.00	0.00	0.00	0.00	0.00	2.00	0.00	1.50	51.47	100
2004-2005	1.94	25.44	12.27	0.00	0.00	0.00	0.00	0.00	0.00	2.07	0.00	0.00	58.28	100
2005-2006	1.50	0.00	24.97	0.00	0.00	0.00	1.07	0.00	0.00	4.94	0.00	38.02	29.51	100
2006-2007	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	8.32	91.68	100
2007-2008	0.00	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	13.30	0.00	12.68	73.52	100
2008-2009	0.00	2.46	2.49	0.00	22.59	0.00	0.39	0.00	1.57	0.29	0.00	8.57	61.65	100
2009-2010	0.00	4.32	14.37	0.00	12.15	0.00	16.03	2.01	4.89	0.43	0.00	15.59	30.21	100
2010-2011	0.00	5.17	3.90	0.00	0.00	0.00	17.67	0.00	0.00	3.26	0.00	0.00	70.01	100
2011-2012	0.00	4.50	0.25	0.00	5.17	3.40	7.83	0.00	0.00	2.09	11.82	8.24	56.70	100
2012-2013	0.34	39.15	2.10	0.03	10.25	5.02	11.48	4.70	1.93	1.79	8.88	8.88	5.45	100
2013-2014	3.36	35.75	1.82	0.00	6.84	4.46	18.43	5.61	1.54	1.52	2.53	15.60	2.53	100
2014-2015	0.59	19.20	0.30	0.00	6.71	3.52	10.27	2.98	2.35	28.12	0.01	12.00	13.94	100
2015-2016	0.00	27.52	6.39	0.00	5.89	2.53	10.69	7.75	1.69	4.81	0.09	12.86	19.78	100
2016-2017	0.00	21.41	2.65	0.00	9.43	2.96	8.33	11.67	5.76	3.51	3.96	18.37	11.94	100
2017-2018	0.29	13.33	4.44	0.00	30.05	0.96	10.68	2.60	3.26	0.55	0.57	4.91	28.38	100
2018-2019	0.48	6.26	3.09	0.00	34.99	1.19	8.67	3.97	1.95	0.45	0.21	3.52	35.21	100

Source: Estimated using Unit level data of ASI 1999-00 to 2018-19

Appendix 5: India's Vaccine Import by type of vaccines (Rs. Lakh)

	Vaccines for cholera and typhoid	*Vaccines for hepatitis (a&b)*	*Vaccines for tetanus*	*Vaccines for polio*	*Vaccines for tuberculins (B.C.G.)*	*Anti rabies vaccine*	*Vaccine for japanese encephalitis*	*Vaccines for whooping cough (pertusis)*	*Other single vaccine*	*Mixed vaccines for DPT-TRIPLE anti gen*	*Mixed vaccines for diphtheria and tetanus*	*Mixed vaccines for M.M.R.*	*Vaccine for typhoid-paratyphoid (tab) or typhoid-paratyphoid-cholera (tabc)*	*Other mixed vaccine*	*Total*
1996-1997		539.3	138.3	1474.5						6.6					2159
1997-1998	10.8	1313.0	264.7	1609.9	3.0				4958.8	46.6	0.7		371.1	110.3	8689
1998-1999	93.9	992.6	696.1	1348.2	4903.1			0.5	1729.3					36.2	9800
1999-2000	140.8	1544.5	444.8	4707.9	1038.4				2763.1		1.0		2.3	61.3	10704
2000-2001	416.2	1117.2	358.2	8171.5	113.7				1618.6	140.6			12.6	2.5	11951
2001-2002	268.2	679.4	124.3	1757.8	19.6	24.6		0.6	5643.6	658.8	0.4			44.2	9221
2002-2003	464.5	198.7	237.9	3170.0	6.6	205.4			6367.3					188.2	10839
2003-2004	1047.6	587.7		24013.6	0.1	283.3	268.2		897.5	1.2	0.8				27100
2004-2005	98.8	87.6		8295.2		193.6	47.9		2413.5						11137
2005-2006	2028.1	379.6	1.9	5072.7		818.5		1.7	3389.3	7.9	5.3	0.1		1560.3	13265
2006-2007	1314.3	982.7	2.6	10892.3	0.1	251.4	404.7		3522.5		1.7	579.7	12.7	6265.7	24230
2007-2008	43.3	2346.6	3.5	6815.9	0.4	280.1	24.0	0.5	4341.2	4.2	32.4	681.0	16.8	3988.7	18578
2008-2009	220.5	2873.4	112.0	10549.0		669.4	65.5	26.5	10341.7	0.4		217.8		9187.6	34264
2009-2010	278.0	3160.8	220.7	20825.6		1560.5	0.2		11473.0	445.8		215.9	30.1	10332.9	48544
2010-2011	141.7	978.8	258.1	22972.5		1329.7	8.6	19.4	9544.2	853.1		72.6		14184.6	50363
2011-2012	152.5	2555.3	85.2	50315.4	0.1	2046.5	1162.8	81.0	21654.9	1447.9		293.2		22609.2	102404
2012-2013	278.9	1516.9	157.2	50538.4		1923.5	3560.3	110.0	22506.7	0.8		165.4		32536.0	113294
2013-2014	300.9	4891.3	241.8	65918.0		1713.5	6207.5	119.8	29378.2			1.4		23750.4	132523
2014-2015	378.2	8694.4	394.4	66432.4		2663.0	7555.1	539.2	33491.0		1.6	2.2		30060.5	150212
2015-2016	150.3	10806.7	1244.7	82083.8	0.1	2745.3	10898.1	1668.8	47151.8	1080.3	80.8	0.6		33664.8	191576
2016-2017	286.0	6826.0	990.2	66652.9	0.5	1805.8	16852.3	1053.5	48276.3	722.3	2.8	1199.0		42166.8	186834
2017-2018	119.3	5293.9	165.5	58870.7		793.0	8007.8	382.0	54961.2	6109.0		3089.5		25684.7	163477
2018-2019		4137.3	489.2	69061.9		2092.4	6303.6	282.5	97500.3	7999.0		688.7		24901.4	213456
2019-2020		3508.6	1017.0	91209.9		1338.2	13206.2	1585.9	109096.6	19797.1	0.5	1065.1		38524.4	280350
2020-2021	5316.1	7763.1	1185.3	92945.9	0.5	1866.7	6384.5	1696.0	85457.8	14189.5	10.7	459.7		45563.8	262840
2021-2022	1.4	6995.2	574.7	63457.3		1871.6		1200.7	149041.5	6457.5		409.3		12072.2	242081

Source: DGCIS (https://tradestat.commerce.gov.in/eidb/default.asp)

Appendix 6: India's Vaccine Import form major Countries in each Segments (Rs. Lakh)

	30022011 Cholera and Typhoid	*30022012 Hepatitis*		*30022013 Tetanus*	*30022016 Anti-rabies vaccine*		*30022017 Japanese Encephalitis*	*30022018 whooping cough (pertusis)*	*30022021 DPT*	*30022023 M.M.R.*	*30022014 vaccines for polio*		
	France	*China*	*France*	*Indonesia*	*China*	*France*	*China*	*Indonesia*	*Belgium*	*Belgium*	*Belgium*	*France*	*Indonesia*
1996-97			516.3										
1997-98			1020.5										
1998-99	29.62		724.7									132.0	
1999-00	6.91		884.3									10.5	
2000-01			642.0									210.1	
2001-02			277.2									77.0	
2002-03	13.24		190.2		17.5							2.94	
2003-04						124.7	0.34				7965.2	1981.3	958.7
2004-05											7269.5	0.20	798.2
2005-06		105.7		1.82		572.5		1.65			3772.1	0.30	17.0
2006-07	40.59	214.3		0.92		0.16					2895.0	90.4	3370.7
2007-08		377.9			60.6				0.54	677.2	1772.8	774.0	3913.7
2008-09	136.8	374.4	212.1	23.97	491.4			26.46		217.8	2774.6	584.5	3569.6
2009-10	149.4	415.6	703.5	101.1	266.0	793.2	0.15			215.6	5665.8	557.1	10030.1
2010-11	132.3	694.7	61.2		156.2	673.3					4086.1	4785.8	13753.1
2011-12	55.4	1652.3	652.3	43.8		1969.4	1159.1			292.8	5397.1	5675.4	36070.6
2012-13	231.9	377.7	1018.0	103.1	136.3	538.9	3560.2	110.0		165.4		3598.7	46939.6
2013-14	254.4	1870.5	2800.0	241.0	184.0	583.9	6094.7	119.8			391.8	613.3	64912.9
2014-15	378.0	5645.9	2835.4	391.3	439.7	475.1	706.7	539.2		2.19	0.53	1351.7	65078.7
2015-16	150.3	8265.8	1455.6	1074.9	910.9	0.48	10462.2	1668.8	1080.3			8518.2	71489.2
2016-17	286.0	6477.6	1.2	942.2	1168.6		16852.3	1051.0	711.1	950.6	0.95	9739.0	51918.3
2017-18	119.3	3197.6	1547.3	165.5	273.5	29.6	8007.8	382.0	4425.5	3082.8		7233.8	44802.4
2018-19		3028.9	859.2	489.2	1841.3		5882.4	279.6	7781.2	688.7		24473.0	40645.4
2019-20		2814.9	251.4	985.3	973.1		13204.6	1585.9	19257.5	1065.1		33475.5	48482.0
2020-21	5316.1	2011.8	1353.8	1081.7	987.4	1.07	6384.5	1696.0	12515.6	449.8		49165.7	34178.8
2021-22AN		3815.3		520.8	1129.1			1200.7	5695.9	409.3		15984.7	27258.4

Note: India's import only from major countries, excluding other single/mixed vaccine categories.

Source: DGCIS (https://tradestat.commerce.gov.in/eidb/default.asp)

Appendix 7: Public Vs Private Sector- A Case of Polio Vaccine (in lakh doses)

		2001-02	*2006-07*	*2007-08*	*2008-09*	*2009-10*	*2010-11*	*2011-12*	*2012-13*	*2013-14*	*2014-15*	*2015-16*	*2016-17*	*2017-18*	*2018-19*
Private Sector															
Bharat Biotech Int. (L). Hy.bad	Installed Capacity		10000	10000	7000	7000	7000	7000	7000	10000	10000	10000	10000	10000	10000
	Production		6.8	5.25	6550	260	6440				4000	4000	4000		
	Demand			2.32	6463	301	6058.8				2719	2719	2719		
	Supply		5.29	2.32	6463	301	6058.8				2719	2719	2719		
Bio-Med (P) Ltd. Ghaziabad	Installed Capacity	3300	80	80	80	80	80	80	80	7200	7200	7200	7200	7200	7200
	Production	5	10	16	16						1610	2176	1219	2280	2280
	Demand		10	12	12						1610	1554	1690	2090	2090
	Supply		10	12	12						1610	1554	1690	2090	2090
Panacea Bio-tech ltd. Delhi	Installed Capacity	8640	16000	16000	16000	16000	16000	16000	8000	8000	8000	8000	8000	5000	5000
	Production	4770	3167	1031	6571	4712	4712	270	3382	134	1351	1351	1351	826	187
	Demand		3514	1393	5956	5217	567	305	2950	507	1336	1336	1336	735	233
	Supply		3514	1393	5956	5217	567	305	2950	507	1336	1336	1336	735	233
SII, Pune	Installed Capacity								6000	6000	6000	6000	6000	6000	6000
	Production									4762	4293	4527	1958	4673	4673
Public Sector															
BIBCOL Bulandshahar,1989	Installed Capacity	4800	6000	6000	6000	6000	6000	0.5 vials/shift	0.5 vials/shift	0.5 vials/shift	0.5 vials/shift	0.5 vials/shift			
	Production	1631	0			0									
	Demand		126			0									
	Supply		0			0									
HBPCL Mumbai, 1899 (Haffkine)	Installed Capacity	6000	6000	6000	6000	6000	6000	6000	6000	6000	6000 (6000)	6000 (6000)	6000 (6000)		
	Production	1000.0	1156	300	250	125	72	97	127	96	123(3.8)	567(125)	567(3280)		
	Demand		1174	1350	18	100	72	114	121	84	119(2.4)	190(134)	190(3280)		
	Supply		1284	272	13	209	83	111	113	108	119(2.4)	57(125)	57(3280)		
Total	Installed Capacity	22740	38280	38080	35080	35080	35080	35080	27080	37200	37200	37200	37200	28200	28200
	Production	7406	4340	1352	13387	5097	11232	11232	11232	5375	11759	13004	9478	7778	7139
	Demand		4824	2757	12449	5619	7680	7680	7680	975	6167	6182	6318	2825	2323
	Supply		4812	1679	12443	5727	7799	7799	7799	998	6167	6049	6185	2825	2323

Note: Figure in bracket are bOPV.

Source: NHP 2001, 2006 to 2021

Appendix 8: Compositional distribution of Export across different type of vaccines

	Vaccines for cholera and typhoid	*Vaccines for hepatitis (a&b)*	*Vaccines for tetanus*	*Vaccines for polio*	*Vaccines for tuberculins (b.c.g.)*	*Anti rabies vaccine*	*Vaccine for japanese encephalitis*	*Vaccines for whooping cough (pertusis)*	*Other single vaccine*	*Mixed vaccines for dpt-triple anti gen*	*Mixed vaccines for diphtheria and tetanus*	*Mixed vaccines for m.m.r.*	*Vaccine for typhoid-paratyphoid (tab) or typhoid-paratyphoid-cholera (tabc)*	*Other mixed vaccine*	*All*	*Single Vaccines category*	*Mixed Vaccines category*
1996-1997	19.0	5.2	0.0	1.0	0.0	0.0	0.0	0.2	30.8	19.3	11.3	0.0	0.0	13.2	100.0	56.2	43.8
1997-1998	52.5	5.0	0.0	0.0	0.0	0.0	0.0	0.0	13.4	7.1	8.5	0.0	0.1	13.4	100.0	70.9	29.1
1998-1999	63.9	3.0	0.0	0.1	0.2	0.0	0.0	0.0	5.3	8.2	11.1	0.0	0.0	8.2	100.0	72.4	27.6
1999-2000	38.8	6.5	0.0	0.0	0.1	0.0	0.0	0.4	23.7	5.0	13.1	0.0	0.2	12.3	100.0	69.4	30.6
2000-2001	50.7	2.5	0.0	0.1	0.0	0.0	0.0	0.0	11.1	9.8	16.2	0.0	0.0	9.6	100.0	64.3	35.7
2001-2002	41.8	4.2	0.0	0.5	0.5	0.1	0.0	0.0	18.5	10.3	13.5	0.0	0.5	10.1	100.0	65.5	34.5
2002-2003	36.5	2.0	0.0	0.0	0.2	0.6	0.0	0.0	29.8	7.7	9.8	0.0	0.0	13.4	100.0	69.1	30.9
2003-2004	0.3	2.6	6.9	0.4	0.0	1.2	0.0	0.1	11.4	8.9	2.6	42.9	0.1	22.6	100.0	22.9	77.1
2004-2005	1.5	16.6	8.8	0.1	0.3	1.3	0.0	0.1	6.7	6.3	6.9	32.8	0.0	18.8	100.0	35.3	64.7
2005-2006	0.7	20.8	11.0	4.3	0.4	2.6	0.0	0.0	9.6	11.3	2.1	27.7	0.0	9.5	100.0	49.4	50.6
2006-2007	6.9	10.1	13.6	17.6	0.5	5.5	0.0	0.1	6.4	7.0	3.9	18.1	0.0	10.4	100.0	60.7	39.3
2007-2008	32.3	15.2	13.4	4.3	1.6		0.0 3.5	0.0	18.5	3.7	1.0	0.0	0.0	6.5	100.0	88.7	11.3
2008-2009	7.0	4.2	4.2	9.3	0.1	1.2	0.0	0.3	13.5	0.4	0.5	12.6	0.2	46.5	100.0	39.8	60.2
2009-2010	4.7	11.2	0.5	19.4	0.2	2.7	0.0	0.0	10.9	0.7	1.2	13.7	0.0	35.0	100.0	49.5	50.5
2010-2011	0.8	4.0	0.2	11.7	0.1	2.3	0.0	0.1	30.1	0.3	0.3	13.2	0.0	36.9	100.0	49.2	50.8
2011-2012	2.4	1.9	3.8	11.2	2.6	2.4	0.0	0.0	17.7	1.3	0.5	7.6	0.0	48.7	100.0	42.0	58.0
2012-2013	0.3	1.8	0.7	0.6	0.0	0.9	0.0	0.0	15.5	0.3	0.0	7.9	0.0	71.9	100.0	19.9	80.1
2013-2014	0.3	0.3	0.9	8.6	0.0	1.3	0.0	0.1	14.6	0.5	0.0	7.5	0.0	65.8	100.0	26.2	73.8
2014-2015	0.2	0.2	0.8	8.8	0.2	1.0	0.0	0.1	13.8	1.3	0.0	12.7	0.0	61.0	100.0	25.0	75.0
2015-2016	0.8	0.8	1.1	13.1	1.8	1.4	0.0	0.0	12.8	0.5	0.8	8.2	0.0	58.8	100.0	31.7	68.3
2016-2017	1.3	1.9	1.0	9.9	2.2	2.5	0.0	0.0	11.7	0.9	1.1	12.5	0.0	54.9	100.0	30.6	69.4
2017-2018	3.2	2.5	1.5	15.0	3.4	1.3	0.0	0.0	10.9	0.7	1.9	16.0	0.0	43.5	100.0	37.8	62.2
2018-2019	3.4	2.6	1.3	12.3	2.6	1.7	0.0	0.0	15.8	0.9	2.4	22.5	0.0	34.5	100.0	39.7	60.3
2019-2020	5.0	2.2	0.7	12.7	2.7	4.2	0.0	0.0	16.6	0.7	1.6	17.7	0.0	35.8	100.0	44.1	55.9
2020-2021	5.5	1.9	0.8	11.6	3.3	4.2	0.0	0.0	27.7	0.9	1.8	10.9	0.0	31.4	100.0	55.0	45.0
2021-2022	4.7	2.0	0.5	9.4	3.6	2.7	0.1	0.0	22.7	1.2	1.6	9.2	0.0	42.2	100.0	45.8	54.2

Source: DGCIS

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