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Special Issue on

Vaccine Technologies and Access to Vaccines in the Post-Pandemic (COVID-19) Era

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Editorial Introduction

Y. Madhavi* and Krishna Ravi Srinivas**

The importance of vaccines as a preventive medicine in public health was realised like never before during the Covid-19 pandemic. Pandemic experience displayed unequal global access to Covid-19 vaccines despite global COVAX-facility and compulsory license provision. Countries had to invest and make their own vaccines to meet respective domestic needs either through free or affordable technology transfers or through indigenous development during the pandemic.

Vaccine technologies and policies have evolved over a century globally and nationally in a globalised economy with its new intellectual property rights (IPR) regimes and changing regulatory norms, which has its implications on the equitable access to vaccines across the World. Vaccine development and manufacture also shifted from public to private sector as well as from a selective and evidence-driven adoption to a universal and supply-driven approach.Equitable vaccine access gaps that exist between north and south of the globe before and after the pandemic remain the same especially in developing and resource poor countries. Given this background, the role of vaccines as an important pillar of preventive health requires serious revisit to access affordable equitable technologies and vaccines for future. The articles in this special issue focuses on the issues of concern with respect to equitable affordable vaccine access that entices lessons from Indian experiences for future public health preparedness.

India played a pivotal role in global market as a key global vaccine supplier to many developing countries, despite many supply chain constraints is very well presented with evidence in S K Hooda's paper on "Access to Affordable Vaccines in Developing Countries: India's Role in Global Market, Local Production and Technology Transfer". The points out that the Indian vaccine industry is dominated increasingly by import dependence for its vaccine manufacturing and technology transfers largely driven by private manufacturers for newer formulations through an analysis of the vaccine industry. This paper argues for strengthening and revitalize public sector capacity, investing in innovative vaccine technologies, and leveraging its credibility through procurement and technology transfer platforms. He emphasizes that India has the potential to meet domestic as

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well as a major global affordable vaccine supplier to fill in the gap in meeting global vaccine inequity that is sustainable in the long run.

Irrespective of which technology is used in vaccine production, consistency of quality standards during the manufacturing process is very important is emphasized by Gaurav Pandey et al's article on "Manufacturing Excellence: Upholding Quality to Expand Vaccine Access". It highlights the importance of maintaining quality standards at all stages starting from R&D, technology transfer to robust manufacturing methods, effective regulatory checks, and global standards, such as WHO prequalification and national regulatory authority (NRA) maturity levels to gain public trust in vaccination, vaccine access and equity.

By examining quality management, global standards, and training programs, this article demonstrates how quality is maintained in various production settings. The article lays emphasis on the maintaining manufacturing excellence, through harmonised standards, transparent regulatory pathways, effective technology transfer, and mature NRAs, which forms the foundation of vaccine equity and pandemic preparedness.

K M Gopakumar and Chetali Rao in their article on "Realizing Equity in the Production and Access of Vaccines: Policy Framework for the Global South" brings out beautifully the global vaccine market structure as it exists that counterpose the volume of vaccine production versus the value of vaccine production in the market, which is embodied in north-south divide that impacts equitable access to vaccines. Global vaccine production and supply are heavily dominated by a few manufacturers concentrated in North of the globe that controls global vaccine market and its supply have become the barriers to access to vaccines. The authors recommend diversified vaccine production with a set of measures to facilitate equitable access to global south. The authors point out the gaps in ensuring the legally guaranteed framework for production diversification inthe Pandemic treaty of World Health Organization(WHO). The authors suggest that the developing countries need to implement policies to accomplish local production capacities at national or regional levels, reforms in regulatory system and international procurement mechanisms andimplementation of trade related intellectual property rights (TRIPS) flexibilities to meet future health emergency situations. The authors recommend creatingabridged vaccine pathways for non-originator manufacturing and to pursue a biopharmaceutical industrial policy with targeted interventions. The authors strongly believe that the health security and economic resilience of developing nations can be achieved through self-reliance in vaccine production and access.

The adoption of unexplored technologies shaped vaccine technology access during the pandemic. The pandemic provided a great opportunity to

innovators to explore platform technologies (e.g. DNA, mRNA platform technologies) and its application/adaptation in developing vaccines against SARS COV2 within short duration. Shweta Dubey *et al*'s article on "From Lab to Last Mile: Platform Technologies Enabling Vaccine Equity" narrates the basic understanding about platform technologies and how they facilitate vaccine innovations at faster pace bridging the gap between vaccine access and their delivery citing examples from Covid-19 pandemic times. Further, to realise the full potential of platform technologies, the study recommends innovations to improve thermostability, single-dose regimens, and needle-free delivery that may enhance access in resource-limited settings. They recommend that the adoption of digital health tools, decentralized manufacturing, and open-source licensing models that have potential to revolutionize the delivery of vaccines to the last mile to meet the goal of equitable immunization.

Critical role ofpublic sector in ensuring the national health security and equitable vaccine access is emphasised in Mahendra Shahare's article on "Reimagining Vaccine Security in the Post-COVID Era" through the analysis of two vaccine case scenarios- polio vaccine and Covid vaccine. Through these two case studies, the author points out that theimport dependence, increasing private production (or PPP), aggressive monopolisation of pharmaceutical markets, and intellectual property regimes are being the main barriers to equitable vaccine access. This paper argues that a democratic state's basic responsibility is to ensure vaccine security and public health, which can be achieved by building a strong public-sector capacity along with private innovation, in the post-pandemic era.

Ensuring Regulatory norms while safe guarding ethical concerns during the vaccine development and its clinical trialsis an important milestone to achievesafe and efficacious vaccines for the public in vaccine innovation. Sandhya Srinivasan and Veena Johari discussesissues pertaining to "The covid-19 vaccine in India: regulatory and ethical issues".The authors point out the procedural lapses, lack of transparency with respect to ethical and regulatory compliances of two vaccines (Covaxin and Covishield) manufactured by the two private companies in India that were used during the Covid-19 pandemic in India. Given this Covid-19pandemic experience, this paper expresses its concern for its future implications with respect to public health and drawsattention to the compromised vaccine efficacy, safety that are governed by regulatory system, public awareness, informed consent, and vaccine injury compensation measures.

One point that comes out very strongly from these articles is that India has the capacity to sustain its presence as a global affordable vaccine supplier through self-reliance with a strong public sector presence for future equitable vaccine access is a major consensus that emerges from this issue. Capacity

building, maintaining quality standards in vaccine manufacturing process in new innovations/adopting new technologies, and the systemic reforms in implementing regulatory norms and ethical standards to ensure public acceptance and access in vaccines comes out as another important input to work towards future public health needs.

The other two articles in this issue deal with two themes that are very important and have been discussed in the pages of ABDR. Sophy's article gives an extensive analysis of the impacts of global discussions and treaties on access to plant genetic resources (including germplasm). She also highlights how over the years the access to seeds and rights of farmers over seeds have undergone major changes on account of Intellectual Property Rights regimes at global and national levels. She points out the need for welfare measures for the benefit of farmers and accessible innovations for them. Prasanta Kumar Ghosh and Kishore M. Paknikar in 'Genetically Modified and Genome-Edited Plantsin Indian Agriculture: Time to Revisit Policy' elaborate the global trends in agricultural biotechnology and highlight the developments in India in this sector over the last twenty five years or so. They make a good case for science based and farmer oriented approach to ensure that the technology is harnessed effectively.

Thus this issue offers much food for thought on vaccines, seeds and access to seeds and harnessing agricultural biotechnology in India.

This is the final issue of ABDR which I (Krishna Ravi Srinivas), am editing ever since 2010. I thank my colleagues at RIS, the then Director Generals and the current Director General, contributors, peer reviewers and publications team at RIS for their support. I thank Scopus, and, EBSCO Host for indexing ABDR and that has been very helpful. I wish my successor all the best and assure my support and co-operation in editing and publishing ABDR.

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Access to Affordable Vaccines in Developing Countries: India's Role in Global Market, Local Production and Technology Transfer

Shailender Kumar Hooda*

Abstract: Global vaccine access has improved significantly since 2000, driven by initiatives like WHO's Expanded Programme on Immunization, Gavi, and the Developing Countries Vaccine Manufacturers Network. These programs have expanded vaccine coverage from basic childhood immunizations to include newer vaccines like hepatitis B, Hib, and rotavirus, helping to promote vaccine equity in low- and middle-income countries. Despite progress, significant disparities persist. High-income countries enjoy near-universal coverage, while LICs continue to struggle with supply constraints, inadequate funding, and limited domestic manufacturing capacity. India, a key global vaccine supplier, has played a pivotal role in supplying affordable vaccines to developing nations. However, COVID pandemic disrupted its export dominance as domestic vaccination were taken on priority, allowing competitors like China to gain market share. Indian vaccine industry is largely driven by private manufacturers with heavy reliance on traditional vaccines, while increasingly relying on expensive imports for newer formulations. To meet growing domestic demand and sustain its global leadership in newer and beyond COVID vaccines, India must revitalize public sector capacity, invest in innovative vaccine technologies, and expand its reach into high-income markets. By leveraging its credibility through procurement and technology transfer platforms, India can address global vaccine inequity and ensure a sustainable, affordable supply to developing nations.
Keywords: Vaccine Access, Affordability, Export, COVID-Doses, Local Manufacturing, Technology-Transfer, Capacity Utilisation, Developing Countries, India.

Introduction

In the past over a two decades, there have been significant changes in the global vaccine manufacturing landscape due to the rise in infectious diseases and the onset of endemics and pandemics around the world (Excler et al., 2021; Baker, 2022). Unlike the past when five big companies (Sanofi Pasteur, GlaxoSmith Kline, Merck, Pfizer, and Novartis) dominated the

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global vaccine market, the smaller biotech and emerging-market players have been aggressively intervening through technology transfer and contract manufacturing to change this order (Research and Markets, 2021). The recent outbreak of the Coronavirus (COVID-19) pandemic has altered and transformed the global vaccine market in a significant way, as many countries were keen to support the global efforts to combat it by providing safe and affordable vaccines. There were also countries who were striving to capture the global vaccine market. China launched the 'COVID-19 Vaccine Diplomacy' programme (CSIS, 2022) to capture the market. Considering the necessity of timely supply and wider access to vaccines that could be facilitated through local vaccine manufacturing effectively (Khan, Ikram, and Hamza, 2021), several countries enforced self-reliance and self-sufficiency in vaccine production, most notably South Africa (Makenga, 2019).

Considering the critical role of vaccination in preventing infectiousdiseases and saving lives, and the widespread persistent disparities in vaccine access and coverage across least-developed countries (LDCs), severalvaccine alliances have emerged to provide financial support and procurement platform to facilitate affordable vaccines to countries requiring vaccines recommended by the World Health Organisation (WHO)for national Expanded Programme on Immunisation (EPI). The EPI vaccines are procured and supplied at low cost to eligible developing countries through WHO-UNICEF procurement system since date back to 1982. In 2000, a new platform called GAVI (a public–private global vaccine alliance) emerged to further accelerate vaccine access by providing funding for vaccine procurement (for EPI, newer and more expensive vaccines like pentavalent, pneumococcal, rotavirus, HPV, etc.) and supports health system strengthening in low-income countries. Vaccine procurement under Gavi is carried using WHO-prequalified vaccines.

The Gavi platform also facilitates the transfer of technical know-how for vaccine manufacturing to developing countries, thereby reducing inadequacy of affordable vaccines (Gavi 2021). The Developing Countries Vaccine Manufacturers Network (DCVMN), of which India is a member, was established in 2000 with the goal to increase access to high-quality essential vaccines at affordable prices to safeguard people from known and emerging infectious diseases in UN agencies/countries. However, a manufacturer's vaccine must meet the 'vaccine prequalification' criteria determined and devised by WHO (known as WHO-PQ, which came into effect in 2001) for the inclusion of vaccine in the procurement tender (Dellepiane and Wood, 2015). That is, manufacturers must adhere to strict standards of quality, safety, and efficacy to ensure that the country's vaccine production lines can be relied on. Though, WHO-PQ requires compliance with GMP (good manufacturing practices) standards. These changing

regulations for ensuring vaccine quality and safety and market competitive scenarios may have influenced the overall dynamics of vaccine dependency, manufacturing and access to affordable vaccine. Given this backdrop, the paper first investigates how vaccine accessibility have evolved in developing countries since 2000 and India's comparative performance in supplying vaccines to global market relative to advanced countries. The paper then highlights structural challenges within India's vaccine industry to assess their implications on country's global position and its ability to evolve beyond a producer of traditional and Covid-19 vaccines. Finally, the paper reflects on how evolving Covid-19 pandemic dynamics may affect future vaccine technology and access to affordable vaccine access.

Data and Method

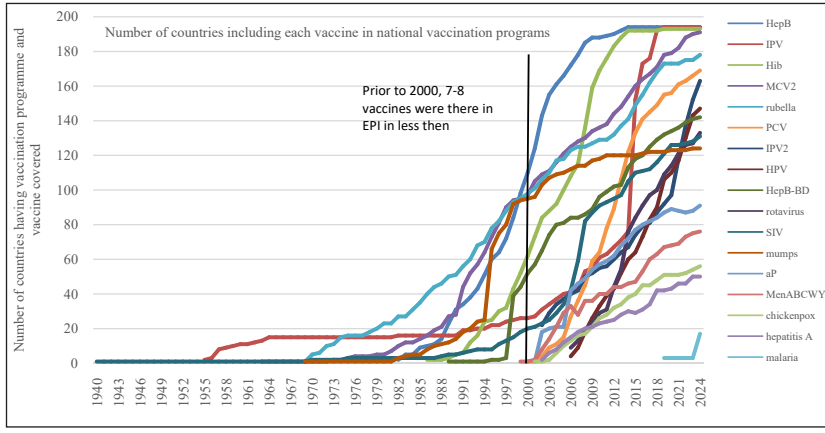
In order toanalyse the inequitable access to vaccines in the world data are taken from 'Our World in Data' platform (www.ourworldindata.org). India's position in the global vaccine market is presented through trade (export-X and import-M) statistics which has been extracted from Directorate General of Commercial Intelligence and Statistics (DGCI&S), Government of India and World Integrated Trade Solution (WITS) of World Bank at Harmonized System HS:8-digit and HS:6-digit (300220) levels respectively. A comparative analysis of technology transfer is carried out by assessing the technology transfers through the WHO, Gavi and DCVMN platforms. The structural issues and domestic manufacturing are highlighted using data from Annual National Health Profile (NHP), unit level records of Annual Survey of Industry (ASI) of Government of India (GOI), and PROWESSIQ data respectively. To examine the domestic demand size of vaccines, the X, M and country's production (S) data have been used. The S-X+M is generally referred to domestic market size (DMS) of vaccine of a country. India's changing position in the global market before and during COVID is highlighted using WITS data. Data from different vaccine trackers data are also used and cited in relevant places.

State of Vaccine Accessibility Globally

The world has witnessed significant disparities in vaccine access. Amongst the several other strategies, vaccination programme is recognised as one of the most effective public health interventions for preventing infectious diseases via making vaccines accessible to population. Vaccines have gradually been added in national programme by many countries (see Figure 1The speed of adding vaccines in national programme increased with the introduction of Expanded Programme on Immunization (EPI) since 2000, reflecting the greater role of WHO and procurement platform. If one

assesses the year-wise progress of vaccines included in EPI from Figure-1, it reflects that initial focus of many of the national vaccination programme was to protectthe child from six childhood vaccine-preventable diseases like BCG, diphtheria, pertussis, tetanus, polio and measles, however, several vaccinations for protection of older children, adolescents and adults are being added since 2000. By 2024, around 17 vaccines have been included in national vaccination programme by one or the other country, though significant disparities exist across countries. For instance, vaccines like hepatitis B (HepB), Haemophilus influenza type B (Hib), inactivated polio vaccine (IPV), measles-containing vaccine second dose (MCV2), rubella vaccine, pneumococcal conjugate vaccine (PCV), inactivated polio vaccine second dose (IPV2) are being administered through EPI of more than 160 countries. The vaccine like human papillomavirus vaccine (HPV), hepatitis B birth dose, rotavirus vaccine, mumps vaccine, seasonal influenza vaccine were included in national programme of more than 100 countries. The hepatitis A, chickenpox, meningococcal meningitis vaccine, acellular pertussis vaccines have been added by 50-100 countries, however, malaria vaccine recently added by very few countries (Figure 1). The recent Covid-19 vaccination programme was also delivered through EPI system by most of the countries. Figure-1 shows that number of countries are catching-up in administering different vaccines through their EPI overtime.

Figure 1: Year-wise Progress in Inclusion of Vaccines in EPI by Number of Countries

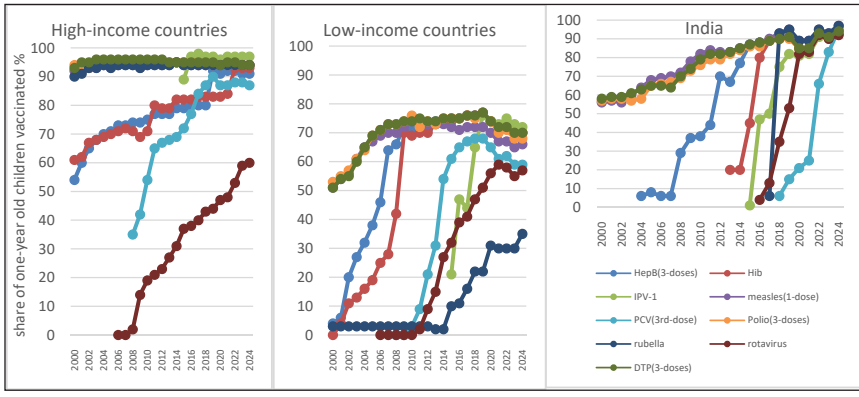


Source: https://ourworldindata.org/

One must note that inclusion of a vaccine alone cannot guaranty equitable access to vaccine. Both demand-side and supply-side factors are equally critical for promoting vaccine coverage and ensuring equity. Amongst the others, population's knowledge about vaccination and their

confidence in it (Sarce et al., 2023), vaccine hesitancy and low willingness to take traditional as well as COVID-19 vaccine, associated risk perceptionsand the accessibility of health services along with the readiness of healthcare facilities (Honata, 2025; Ekezie et al., 2022; David et al., 2017) are the one which are critical.As per a report on Global Vaccine Market Research-2024, at global level, supply constraints due to manufacturing disruptions or lack of adequate supply allocated to low and middle income countries can limit availability and reduce access to vaccines (WHO-MI4A 2025). WHO-UNICEF estimates suggest that at least 80 per cent of children globally are vaccinated with the six core vaccines under the Expanded Programme on Immunization (EPI), which protect against diphtheria, pertussis, tetanus, polio, measles, and tuberculosis (WHO 2011). Though, significant disparities were observed in access to newer vaccines like those for Haemophilus influenzae type B (Hib), rotavirus, pneumonia, and human papillomavirus (HPV), particularly between developed and developing nations. The Figure-2 reflects a wide variation in receiving vaccination, in different vaccines covered under EPI, across high and low income countries. Percentage of children vaccinated with 7-8 EPI vaccines in high income countries reported to be between 85-97 per cent while it varies between 55-70 per cent in case of low-income countries. India, being a developing country, has been able to achieve high (90-100%) status in vaccinating its one year old children in majority of the EPI vaccines listed in Figure-2.

Figure 2: Percentage of One-year-old Children Vaccinated with Vaccines Under EPI (in %)



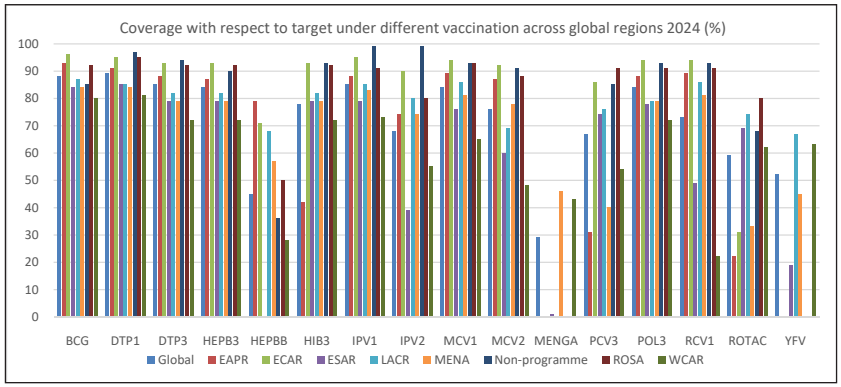
***Source*:** https://ourworldindata.org/

Note: legend is same for all, as reported in India graph.

Despite some progress in vaccination around traditional vaccines, there exist significant disparities in access to newer vaccines like the Haemophilus influenzae type B (Hib), rotavirus, pneumonia, and human papillomavirus

(HPV) across different regions of the world. Figure-3 shows the variation in coverage with respect to target under different vaccination across global regions in 2024. WHO-UNICEF provides a seven regional categories for comparing the vaccination status globally, like the East Asia and Pacific Region(EAPR), Eastern Europe and Central Asia Region (ECAR), Eastern and Southern Africa Region (ESAR), Latin America and Caribbean Region (LACR), Middle East and North Africa Region (MENA), South Asia Region (ROSA), West and Central Africa Region (WCAR) and Non-programme countries that do not include certain vaccines in their EPI. The Figure-3 reveals that significant inequality in vaccine access exists across global regions for certain vaccines, with the meningococcal-A conjugate vaccine (MenGA) showing the most pronounced disparity. Its coverage is nearly zero in several regions, particularly in non-programme areas and MENA. Similarly, rotavirus (ROTAC) and rubella-containing vaccine (RCV1) exhibit wide gaps in coverage, with regions such as WCAR, MENA, and non-programmecountries lagging far behind than others. Hepatitis B birth dose (HepBB) and measles-containing vaccine second dose (MCV2) also reflect high regional inequality, as coverage remains substantially lower in WCAR, ECAR, and non-programmeareas compared to global or high-performing regions like EAPR and ROSA. These disparities highlight systemic challenges in equitable vaccine distribution and suggest the need for targeted strategies to improve access in underserved regions. Figure-3 also reflects that many poverty-related diseases still lack vaccines. In addition to the demand side factors reported above, the insufficient research and development investment by pharmaceutical industry has been reported one of the major responsible factor in achieving equitable access to different vaccine in the world (WHO-MI4A 2025). Additionally, national stock-outs have historically remained a problem for many countries, with 68-88 countries globally reporting at least one national stock-out in 2023. Procurement and funding delays were the two most frequently reported causes of a national stock-out for each year since 2019 which are often causally related, with delays in funding creating delays in procurement (WHO-MI4A 2025). A WHO study reported that technology transfer and local vaccine production can offer a promising and sustainable way to help bridge these gaps, but such initiatives must be carefully planned and managed to ensure long-term viability and success (WHO 2011). India has entered into several technology transfer and contract manufacturing and enhanced its local vaccine production capacity, how India has fared herself in delivery vaccine to global market is discussed in the next section.

Figure 3: Coverage with Respect to Target Under Different Vaccination Across Global Regions 2024 (%)



Source: https://ourworldindata.org/

India Comparative Role in Global Vaccine Market

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

The advanced countries generally supply vaccine to high-income countries (HICs) markets. For instance, in terms of volume of export to HIC markets, France is reported to have the highest share (29.93%), followed by US (17.47%), Belgium (15.28%), and Ireland (11.55%) (Table 2). With regards to the low and middle income countries, India found to be the top supplier of vaccines to low-income countries (LICs) and to low-middle-income countries (LMICs) markets with a share of 37.43 per cent and 24.53

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

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

Source: WITS.

per cent respectively, leaving behind all dominant EU/US players. However, India's export to HIC markets was almost negligible, accounting for only 0.29 per cent share.

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

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

Source: WITS.

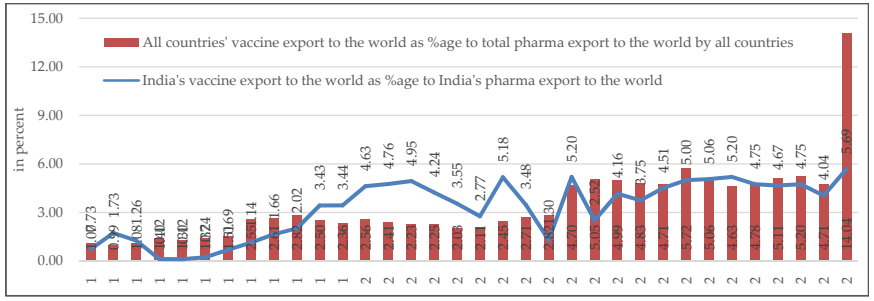
The India vs EU/US demarcation in vaccine supply to different markets explain the heterogeneity in unit prices of vaccines across suppliers/countries. MI4A-2020 study shows that, in terms of volume, HIC markets procured 0.2 billion doses annually at high price, generating US$12.3 billion in value in 2019 (WHO-MI4A 2020). Their recent report also suggests a greater proportion of volumes are being procured at higher prices in the US and other HICs (MI4A 2025). Thus, the HICs is a high price market, while LICs/LMICs are low price markets (WHO-MI4A, 2020 and 2025). That is, the price per dose of procurement of essential vaccines is much lower in LICs/LMICs market. As reported, India supplies most of its vaccines through procurement platforms, especially the GAVI platform that procures vaccines through UNICEF (United Nations International Children's Emergency Fund), to the LICs/LMICs market and such platforms tend to supply high-quality vaccines at low cost/price to low-income settings. As per WHO-MI4A (2020), in 2019, the global market accounted for 41 per cent of the volume of vaccines procured through different platforms, accounting for only 10 per cent in value, while the remaining 59 per cent of the market volume was self-procured by individual countries, accounting for 90 per cent of the market value in 2019. The advanced countries tap HIC markets where they supply vaccines at relatively high prices and receive high value in return. India has been regarded as a hub of providing low-cost affordable vaccines due to its large volume of vaccines supply at low-price to low-income countries and in fulfilling the global goal of equitable access to vaccines to all.

Changing Pattern of Global Vaccines Supply during COVID

Studies reported that innovation in blockbuster vaccines such as pneumococcus conjugate, rotavirus, human papillomavirus, and flu vaccines spurred the growth of global vaccine industry following a period of weak sales growth in the early 2000s. Due to minimal launch of newer vaccines, the growth of global vaccine sales slowed down in the later part of 2010 (WHO-MI4A, 2020). The COVID pandemic, however, rejuvenated the global trade market significantly. The global export of vaccines generally accounted for 4-5 per cent of the total global pharmaceutical exports in pre-COVID period, but reached an all-time high of 14.04 per cent in the second year of COVID (SYC), i.e. 2021-22. India's vaccine export share in the overall pharma export increased to 5.69 per cent in SYC from 4.04 per cent share in 2020 (Figure 4). From Figure-4 one can get a senses that growth in global vaccines export share was higher than India in the second year of COVID, indicating that COVID-19 brought out a significant change in export market. We observed a significant fluctuations in vaccine export

across countries. For instance, as reported in Table-1, France maintained its position as world leader in terms of volume of vaccines exported, with exports rising to 76.38 per cent in the first year of COVID (FYC) 2020-21 from 24.96 per cent in pre-COVID decade (PCD) 20211-2020, before falling back to 31.38 per cent in SYC 2021-22 (Table 1). Belgium's share in volume of vaccine export was 15.52 per cent in PCD, which declined to 7.09 per cent in FYC, but increased to 18.07 per cent in SYC. Similarly, US' share declined to 3.58 per cent in FYC, but increased to 12.75 per cent in SYC. India's share in total volume of vaccine exports decreased to 3.68 per cent in FYC from 11.01 per cent in PCD, but slightly increased to 6.18 per cent in SYC. India could not sustain its historic vaccine exports share in double digits during the COVID period. The year-on-year growth in the value (US$1000) of India's vaccine exports increased by 48.6 per cent in 2021-22 against a negative growth of -3.57 in 2020-21, while the year-on-year growth rate of global exports of vaccines increased significantly to 153.8 per cent in 2021-22 from 1.33 per cent (from original value of Figure 4) in the previous year.

Figure 4: Share of Vaccine Exports in the Total Pharma Exports: India and the World



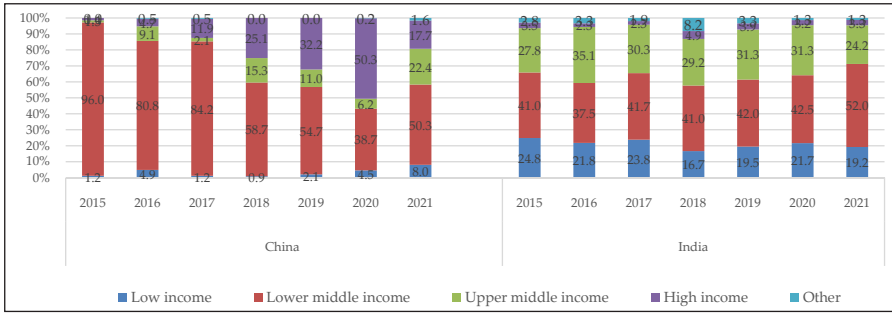
Note: For pharma export, Chapter 30 has been considered for India and the world.
Source: WITS.

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

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

We see a significant change in Chines export strategy as compared to India even prior to COVID, shifting their export from LICs market to LMIC and recently to the HICs markets (Figure 5). However, hardly any change was observed in India's approach to entering the HICs markets – the high price vaccine market. Indian manufactures continuously relaying on exploring LICs/LMICs markets. We closely monitored that, in recent past, China's exports were around 5-7 per cent of India vaccines exports. China's vaccine exports reached to 179.09 per cent of India's vaccine exports in SYC. An exclusive analysis of the supply of COVID vaccine doses offers a much better insight, especially where India is headed as compared to China.

Figure 5: India and China in Vaccine Supply: Compositional Share of Vaccines Export (Doses in Kg) to Different Markets



Source: WITS.

Comparing Covid Dose Supply in Global Market

Recent studies highlighted that outbreak of COVID was an opportunity for countries to establish themselves as global leaders in the vaccine market. The global market size of the total COVID doses as of May 31, 2022 is reported

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

The reason of China going ahead of other countries in total supply of COVID vaccine doses could be its manufacturing capacity and also Chinese companies were ahead in receiving WHO's approval in the first year of COVID 2020 itself where around 4-5 China-manufactured COVID vaccines received approval for usage in international market. By June 2022, China has the highest number of vaccine approvals (nine) for use in international market, followed by US (six), Russian Federation (six), India (five), Iran (four), and Cuba (three). For some advanced countries like Germany, France, UK, Canada, and Australia, only one vaccine was approved. China was ahead of the US and the EU in vaccine approval for use. However, if one takes into consideration the different stages (discovery to preclinical to clinical trial Phase III) of vaccine development in the pipeline, the US is far ahead (126 vaccine pipelines) of China (53 vaccine pipelines) and other advanced economies. In addition to five approved vaccines, India had (in June 2022) 27 vaccines in pipeline at different stages of development (Figure 6, Part-1).

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

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

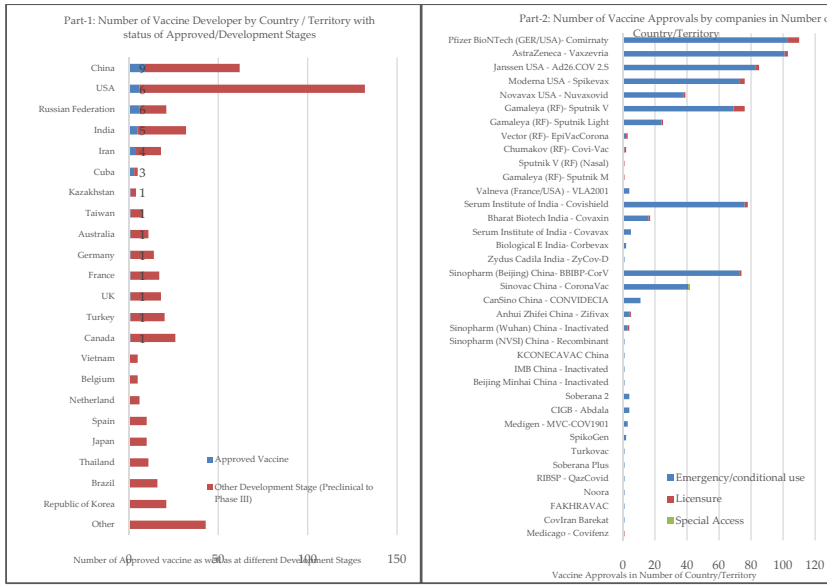
Note: *Total supply contains both exported and domestically delivered doses.
Source: https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm

If one considers all parameters of vaccine use such as emergency/conditional use, the Pfizer-BioNTech (Germany-US) vaccine has been approved for use in many (110) countries. The UK's AstraZeneca COVID-19 vaccine is sold in 103 countries, the US' Novavax/Moderna/Janssen vaccines taken together in 102 countries, India's SII/BE/BBIL/Zydus vaccines in 100 countries, China's Sinopharm/other vaccines in 110/85 countries respectively, and Russian Federation vaccines in 75 countries (Figure 6, Part-2). Of the total supply of Indian COVID vaccine doses, around 90 per cent doses went to only 20 countries in 2022. The Netherlands has the highest percentage share (around 35.64%), followed by Bangladesh (10.39%), and Myanmar (9.75%). Nigeria, Nepal, Australia, and Indonesia each have a share of around 4 per cent (Hooda, 2022). In 2021, the top importers of Chinese vaccines were Indonesia, Brazil, Pakistan, Turkey, Iran, the Philippines, Morocco, Thailand, Argentina, Venezuela, Cambodia, Sri Lanka, Chile, Mexico, Bangladesh, Myanmar, and Afghanistan (Hooda, 2022). As of March 31, 2022, China delivered the maximum number of COVID vaccine doses across the globe through its 'COVID-19 Vaccine Diplomacy' programme (https://chinapower.csis.org).

It is important to note that India has a long history of producing vaccines for LICs/LMICs markets. No doubt, India enhanced its capacity

of producing COVID vaccines, but when a devastating COVID wave hit in the spring of 2021, India prioritised immunizing its own population over exporting vaccines. The combined vaccine production of two Indian manufacturers, namely Bharat Biotech and Serum Institute of India – the world's leading COVID vaccine manufacturer, was insufficient to meet the growing international demand as well as vaccine supply for domestic vaccination drive. China seized the chance when India suspended its vaccine exports in mid-April after having delivered 66 million doses to various developing countries, especially to neighbouring countries (Zeeshan, 2021). China pursued it aggressively. Of the eight leading vaccines (CoronaVac, Pfizer–BioNTech, Sinopharm, Oxford–AstraZeneca encompassing SII, Moderna, Sputnik V, Johnson & Johnson and Bharat Biotech) that account for majority of COVID-19 vaccine doses delivered globally, China's CoronaVac and Sinopharm vaccines accounted for nearly half of all doses by middle of 2021 (Mallapaty, 2021). Of the total vaccine doses produced in China, over two billion doses were administered within China and nearly one billion doses were exported to 110 countries (Mallapaty, 2021). Thus, China, from its non-existent presence in the international vaccine market, emerged as a leading vaccine exporter to many developing, neighbouring, and Asia Pacific regions.

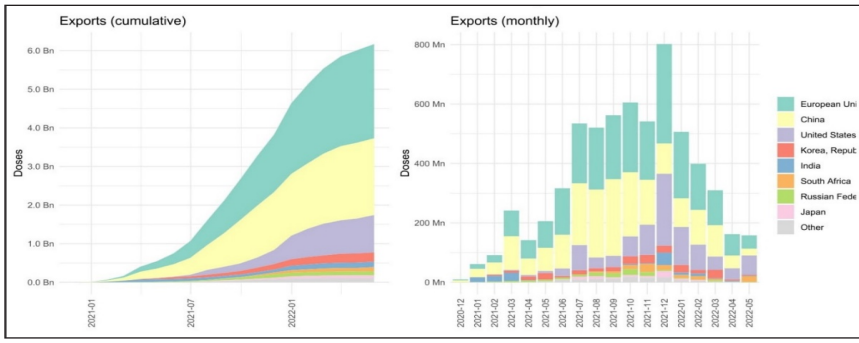
Figure 6: Number of Vaccine Developers and Vaccine Approvals by Country/Territory



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

However, of late, countries that relied heavily on Chinese vaccines voiced concerns about efficacy and safety of their vaccines. Chinese vaccines have come under increasing scrutiny in developing, Asian, and neighbouring countries and many countries either suspended or taken other measures to turn away from the use of Chinese vaccines (Lin, 2021; Wong, 2021). Therefore, China's vaccine exports decreased significantly between October 2021 and May 202, as illustrated by the monthly vaccine supply shown in Figure 7. No doubt, China-manufactured vaccines appear to be losing favour, but their supply of COVID vaccine doses to world remains the second highest (Figure 7).

Figure 7: Cumulative and Monthly Export of COVID Vaccine Doses as of May 31, 2022



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

Source: Taken directly from https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm; accessed on June 30, 2022.

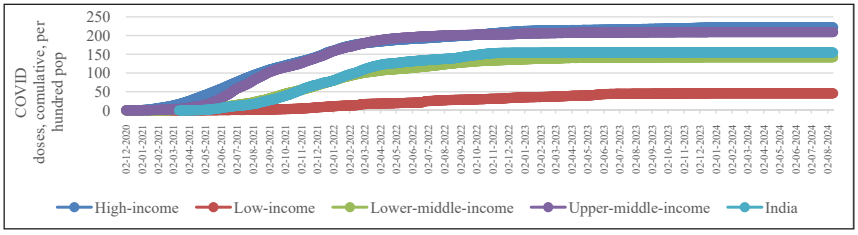
Since manufacturers from the US and the EU tend to serve only the HIC markets and China's vaccine came under scrutiny, India, as a highly trusted and tested country, has a chance to reclaim its position in LICs/LMICs markets and would have helped address the vaccine inequity between advanced and developed countries. As per WHO vaccine trackers, as on May 31, 2022, in LICs, only 14.1% population were fully vaccinated and 17.3% received at least one dose. In LMICs, around 48% population still needs to be vaccinated to achieve the 'fully-vaccinated' status as against the over 74% population received vaccination in HICs (Table 4). The Figure-8 shows a long-term trends in access to COVID doses. It shows a significant variation in vaccination across developed and low-income countries. In HICs dose received per hundred population cumulatively was 222 person in high-income countries as against the only 45 persons in low-income countries in middle of 2024 (Figure 8).

Table 4: Vaccination Status by Level of Development of Countries

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

Note: * A course is defined as a series of vaccine doses required to be fully vaccinated.
***Source*:** https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm

Figure 8: Trends in Access to COVID-19 Vaccine doses (cumulative, per hundred)



***Source*:** ourworldindata.com

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

Vaccine Prequalification and India Role at Procurement Platforms

WHO vaccine Prequalification (WHO-PQ) programme has been ascertained crucial for setting quality, safety, and efficacy standards for a vaccine to be used in country's national immunisationprogramme and requires the manufacturer to adhere to good manufacturing practices (GMP). A vaccine can enter in international market only after receiving the WHO-PQ status. In India, there are about 25 local manufacturers in the private sector along with a few multinational companies (MNCs) such as GlaxoSmithKline and Sanofi that primarily import vaccines and repackage them for sale in the Indian retail market (Ghosh, 2019). The local manufacturers have made commendable progress on international (WHO-PQ) platform. Of the total 52 vaccine manufacturers (as on July 2025) listed on the WHO-PQ list, seven or eight are from India namely Serum Institute of India Pvt. Ltd., Biological E. Limited, Bharat Biotech International Limited, Panacea Biotec Ltd., Haffkine Bio Pharmaceutical, Sanofi Healthcare India Private Limited, Zydus Lifesciences Limited, and GreenSignal Bio Pharma Pvt Limited. Around 277 doses of around 58 different vaccines received WHO-PQ with different commercial names in July 2025. Of the total 277 prequalified vaccines (in doses form) around 124 prequalified vaccines (45%) are being produced by these Indian manufacturers (Table 5). However, in 2012, only 67 prequalified vaccines in doses forms were being produced by seven Indian manufacturers (The Economic Times, 2013).

Amongst the top global 5 manufacturers having WHO-PQ for their vaccines, three manufactures are from India in July 2025. The Serum Institute of India (SII) has the most (72) PQ vaccines, Biological E obtained WHO-PQ for 29 different doses and Bharat Biotech International Limited for 10 PQ. India dominates in getting WHO-PQ for Measles and Rubella, Rubella, Diphtheria-Tetanus-Pertussis, Typhoid (Conjugate), Rotavirus, Malaria, Measles, Rabies, Japanese Encephalitis Vaccine, Measles, Mumps and Rubella, Tetanus Toxoid, Hepatitis B, and Menigococcal vaccines. The Serum Institute of India received WHO-PQ on large number of vaccines namely BCG, Covid-19, Diphtheria-Tetanus, Diphtheria-Tetanus, Diphtheria-Tetanus-Pertussis, Haemophilus influenzae type b, Hepatitis B, Influenza, Pandemic (H1N1), Influenza, seasonal (Trivalent), Malaria, Measles, Measles and Rubella, Measles Mumps and Rubella, Menigococcal, Pneumococcal, Inactivated Polio Vaccine, Oral Polio Vaccine, Rabies, Rotavirus, and Rubella-Tetanus-Toxoid. The Biological-E received on TT, DTP, JE, DT, measles and rubella, and typhoid conjugate vaccines. Bharat Biotech received for polio, typhoid, and rotavirus. Sanofi Healthcare, an MNC, received WHO-PQ for three vaccines. Cadila Healthcare and Chiron Behring both received WHO-PQ for rabies vaccine in 2021, but they were not there in July 2025. However, within the listed WHO prequalified

vaccines, India has not been able to receive prequalification for vaccines for Dengue, Ebola, Hepatitis A, Human Papillomavirus, Respiratory Syncytical Virus vaccine, Smallpox and Mpox vaccine, Varicella, and Yellow Fever vaccines.

Table 5: List of WHO Prequalified Vaccines: Number of Vaccines in Different Doses Form

Sl.No.	Vaccine Type	Total	India	India as % to Total
1	Measles and Rubella	7	7	100
2	Rubella	4	4	100
3	Diphtheria-Tetanus-Pertussis	30	28	93
4	Typhoid (Conjugate)	6	5	83
5	Rotavirus	15	11	73
6	Malaria	3	2	67
7	Measles	6	4	67
8	Rabies	3	2	67
9	Japanese Encephalitis Vaccine	7	4	57
10	Measles, Mumps and Rubella	7	4	57
11	Tetanus Toxoid	11	6	55
12	Hepatitis B	16	8	50
13	Menigococcal	8	4	50
14	Polio Vaccine	47	21	45
15	Pneumococcal (conjugate)	8	3	38
16	Haemophilus influenzae type b	3	1	33
17	BCG	7	2	29
18	Covid-19	4	1	25
19	Cholera	5	1	20
20	Diphtheria-Tetanus	15	3	20
21	Influenza, Pandemic	11	2	18
22	Influenza, seasonal	23	1	4
23	Dengue	2		
24	Ebola	3		
25	Hepatitis A	4		
26	Human Papillomavirus	6		

Continued...

Continued...

27	Respiratory Syncytical Virus vaccine	1		
28	Smallpox and Mpox vaccine	1		
29	Varicella	4		
30	Yellow Fever	10		
	Total	277	124	45

***Source*:** https://extranet.who.int/prequal/vaccines/prequalified-vaccines

The Developing Countries Vaccine Manufacturers Network (DCVMN) – a voluntary coalition of vaccine manufacturersfrom low and middle-income countries established in 2000 – aims to protect population against known and emerging infectious disease through providing high quality vaccines at affordable prices and to achieve vaccine equity. It plays a vital role in strengthening vaccine production capabilities and fostering local manufacturing among member countries through technology transfer, capacity building and knowledge sharing. With the strategic partnerships with international organisation like WHO, Gavi, CEPI, UNICEF and PAHO, DCVMN leverage resources, expand manufacturing capacity and shape global vaccine market. As on July 2025, around 47 manufacturers from 17 countries ranging from Africa, Asia, Europe, the Middle East and Latin America regions were listed with DCVMN (https://dcvmn.org/members). In a 2019 internal survey, DCVMN members reported that they have the capability to supply over 400 distinct vaccine products to 170 countries with more than 100 of them having WHO-prequalification, totaling over 6 billion doses annually (Hayman and Dennehy 2021). During COVID pandemic, DCVMN members supplied over 60 per cent of global COVID vaccine doses through 8 different vaccine technology platform, demonstrating their potential and resilience. According to DCVMN Annual Report-2022, of the 12.8 billion COVID doses produced over the preceding 20 months, 60 per cent were manufactured primarily by India (in a leading role), China, Brazil, Indonesia and South Korea. They could make this significant contribution with the meagre ($5.6 billion) funding received for product development, as against the $51 billion investment received by developed countries (DCVMN, 2023).The member countries are now developing and producing novel vaccines for neglected tropical diseases illnesses that include rotavirus, Japanese encephalitis, pertussis, heamophilus influenzae, hepatitis B, hepatitis E, meningitis A, cholera, poliovirus, human papillomavirus infection, dengue fever, chikungunya virus and COVID-19 and also proceeding towards advancing new platforms such as mRNA and DNA vaccine.

Indiahas been the most trusted vaccine manufacturer at this platform. Out of the total listed vaccine manufacturers at DCVMN, nine are from India and they contribute a substantial share in total vaccine doses supplied by DCVMN members collectively to 170 countries annually (DCVMN, 2023).The Indian company Panacea Biotech developed, produced, and introduced the first fully liquid Pentavalent (DTwP-HepB-Hib) and the first fully liquid Hexavalent vaccine in 2008 and 2017 respectively. The first conjugated typhoid vaccine was developed and manufactured by Bharat Biotech; it was launched in 2013 and received WHO-PQ in 2017. The first thermostable rotavirus vaccine, developed by SII, became available in 2017. First Meningitis-A vaccine developed for use in Africa was manufactured by SII and prequalified by WHO in 2010 (Chaudhuri, 2022). However, most of the vaccines they manufacture are traditional/conventional in nature, unlike those produced by the India's public sector. A few of them produce (with a very low base) newer and recombination vaccines such as typhoid, meningococcal, meningitis, haemophilus influenzae (Hib), quadruple (DTwp-HepB), tetravalent (DTwp+Hib), pentavalent (DTwp-HepB-Hib), and MMR and a couple of conjugate vaccines (Hooda, 2022) whose intellectual property right protection period has already expired. The private sector has been unable to bring indigenous vaccines for seasonal influenza vaccine and inactivated polio vaccine (IPV) so far (GoI, 2006–2022). The conventional centric vaccine manufacturing, no doubt, made India a global leader in the supply of three conventional vaccines, namely DPT, BCG, and measles. India accounts for 60 per cent of the global production of these vaccines, meeting 40 to 70 per cent of WHO's demand for DPT and BCG vaccines, and 90 per cent of WHO's demand for measles vaccine in 2020 (GoI, 2022).

India's Evolving Trajectory in Technology Transfer and Contract Manufacturing

India's entry into vaccine technology transfer (TT) and contract manufacturing (CM) was rooted in its early public health infrastructure and institutional capacity, developed during the colonial and early post-independence periods. Phase-wise India's indigenous vaccines development and its entry in various TT and CM are presented in Table-6. The Table-6 suggests that the process of vaccine development began with public-sector institutions such as the Haffkine Institute, which developed one of the first indigenous plague vaccines in 1897, followed by the establishment of the Pasteur Institute of India (1907) and the Central Research Institute, Kasauli. These institutions played a key role in adapting and scaling vaccine technologies, often received through international collaborations, into large-scale production for domestic use. By mid-20th century, India had

developed the technical and manufacturing capabilities to produce vaccines such as BCG, DPT, rabies, and yellow fever through partnerships with WHO and UNICEF, marking its early participation in technology transfer arrangements.

India's role in TT and CM was further institutionalized in the context of the Expanded Programme on Immunization (EPI), where public-sector units like BIBCOL (1989) and the BCG Vaccine Lab (1948) contributed to the production of oral polio and other essential vaccines. These collaborations often involved receiving bulk antigens, production know-how, or seed strains from global agencies, which were then indigenized, scaled, and distributed for mass immunization. This model of absorbing external technology while developing local manufacturing infrastructure laid the groundwork for India's later expansion into international contract manufacturing and vaccine export.

By the late 1990s and early 2000s, India's growing technical expertise and favourable policy environment enabled a transition from passive technology recipient to an active player in global vaccine TT and CM. The launch of India's first recombinant hepatitis B vaccine by ShanthaBiotechnics in 1997 demonstrated the country's capability to innovate and produce vaccines at scale and at lower costs. This period also saw the rise of private-sector manufacturers like the Serum Institute of India (SII), Bharat Biotech, and Biological E., which began entering formal TT and CM agreements with multinational pharmaceutical companies, public health organizations, and global consortia such as WHO, PATH, GAVI and UNICEF and produced critical vaccinesincluding those for meningitis, rotavirus, and pentavalent formulations. These partnerships not only enhanced India's visibility in global health but also established it as a low-cost supplier capable of producing high-quality vaccines that met WHO prequalification standards.

India's role in TT and CM was significantly amplified during the COVID-19 pandemic, which served as a turning point in its global vaccine leadership. The Serum Institute of India (SII) entered a landmark technology transfer agreement with AstraZeneca to manufacture Covishield – the Indian version of the Oxford–AstraZeneca vaccine. Through this partnership and the COVAX facility, SII delivered billions of doses globally, reinforcing India's centrality in pandemic response. Simultaneously, Bharat Biotech, in collaboration with the Indian Council of Medical Research (ICMR), developed Covaxin, a fully indigenous inactivated vaccine. These developments showcased India's dual strength in absorbing complex technologies and independently developing vaccines under accelerated timelines. Several other manufacturers, including Biological E. and Zydus Cadila, also entered into TT and CM arrangements for COVID-19 vaccines, further diversifying India's production capacity.

In the post-pandemic period, India has strategically shifted toward next-generation vaccine platforms, positioning itself not only as a manufacturing hub but also as an innovation partner. Biological-E's collaboration with the WHO mRNA Technology Transfer Hub to develop mRNA-based vaccines marks a major leap in India's technological capabilities. Likewise, SII's engagement with Coda Biotherapeutics to explore mRNA vaccines and Indian Immunologicals Ltd partnership with Griffith University for intranasal COVID-19 vaccines signal a broader commitment to platform diversification. India has also advanced its role in CM through malaria vaccine production, notably SII's manufacturing of the R21/Matrix-M vaccine (WHO-prequalified in 2023), and Bharat Biotech and ICMR's work on AdFalciVax, with an Expression of Interest (EoI) issued in 2025. These initiatives reflect India's growing ability to participate in TT not just as a recipient or contract manufacturer, but as a co-developer and strategic contributor to global health innovation. The rest of India's vaccine development and manufacturing capacity is discussed in the next section.

Table 6: India in Vaccine Development, Technology Transfer and Contract Manufacturing

Indian Institution / Company / status	Vaccine / Platform	Collaboration Type	Partner(s)	Time line	Remarks, supplied vaccine to and support received from
Prior to 2000					
Haffkine Institute (PSU)	Plague	Indigenous TT	None	1897	First vaccine developed in India; Institute founded 1899
Pasteur Institute of India (PSU)	Rabies, DPT, DT, TT	Licensed TT	Govt. of India, WHO	1907-1990s	First anti-rabies vaccine; DPT licensed for public programs
BCG Vaccine Lab, Chennai (PSU)	BCG	Licensed TT, Scale-up	WHO, UNICEF	1948-1990s	National BCG campaigns from 1951
Central Research Institute (CRI), Kasauliv (PSU)	Yellow Fever	In-house TT	Govt. of India, WHO	1960-1990s	Expanded antigen/sera production; Founded 1905
Central Research Institute (CRI), Kasauli (PSU)	JE, DTP, TT, Rabies	Licensed TT	Govt. of India, WHO	1970s-1990s	Major public-sector vaccine producer

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Haffkine Institute (PSU)	Cholera, BCG, DTP, OPV	Licensed TT	Govt. of Maharashtra	1970s-1980s	Major early 20th-century vaccine institution
Indian Immunologicals Ltd (IIL) (PSU)	DTP, TT, Rabies, Hep A, MR	Indigenous TT	National Dairy Board India	1982-1990s	Multi-platform vaccine production; Founded 1982
BIBCOL (PSU)	Oral Polio Vaccine (OPV)	TT	USSR	1989-1990s	Established for OPV production
IVCOL (PSU)	Measles	Attempted TT	Govt. of India	1990s	Failed measles TT program
Shantha Biotechnics	Recombinant Hepatitis B	TT	N.A	1997	India's first recombinant vaccine
2000 to Pre-COVID (2000–2019)					
Serum Institute of India (SII)	Meningitis A, Pentavalent, MR, Polio, Rotavirus, BCG, DTP, Pneumococcal, HPV	TT, CM	WHO, UNICEF, GAVI, IVI, GoI, DBT	2000-2019	Supplies GAVI/ UNICEF; Low-cost global vaccine infrastructure; Founded 1966
HLL Biotech Ltd (PSU)	Hep-B, DTwP-HepB-Hib	CM, TT-based	Govt. of India	2000s-2019	Supports UIP vaccines
Bharat Serums and Vaccines Ltd	Traditional Vaccines	TT, CM	N.A	2000s-2019	Historical TT and CM contracts
Maharashtra State Vaccine Institute (MSVI) (PSU)	Traditional Vaccines	TT, CM	Various	2000s-2019	State PSU vaccine production and TT
Panacea Biotec	Pentavalent	TT	WHO	2008	WHO PQ
Serum Institute of India (SII)	H1N1 Influenza	TT	None	2009	Indigenous development in <6 months
Bharat Biotech	Typhoid Conjugate	TT	WHO	2013-2018	WHO PQ 2018
Panacea Biotec	Hexavalent	TT	WHO	2017	WHO PQ
Bharat Biotech	Chikungunya, Rabies	TT	None	2000s-2019	Indigenous development
Zydus Cadila	Recombinant Vaccines	TT	Novavax, Others	2000s-2019	Recombinant vaccine development

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Biotech Consortium India Ltd (BCIL) (public)	Multiple Vaccines	TT Facilitation	Various, DBT	2000-2019	Supports DBT TT pipeline; Ongoing into later periods
Covid-19 Period					
Serum Institute of India (SII)	Covishield (ChAdOx1-COVID-19)	Licensing, CM	AstraZeneca, Oxford, GAVI, COVAX (WHO, UNICEF, CEPI)	2020-2021	Produced >1B doses for India & LMICs via COVAX
Serum Institute of India (SII)	Covovax (NVX-CoV2373-COVID-19)	TT, CM	Novavax	2021	WHO PQ; Supplied globally via GAVI
Serum Institute of India (SII)	Sputnik V (COVID-19)	CM	Gamaleya Institute	2021	Targeted 300M doses/year; Abandoned due to delays
Bharat Biotech	Covaxin (Inactivated COVID-19)	Co-develop., Adjuvant TT	ICMR, NIV, NIH (ViroVax), DBT	2020-2021	Licensed nationally and regionally
Biological E. Ltd	Corbevax (COVID-19 Subunit)	Component TT	Baylor College, Dynavax, PATH	2021	Licensed in India and globally
Indian Immunologicals Ltd (IIL) (PSU)	Intranasal COVID-19	Codon-deoptimized TT	Griffith University	2020-2021	Needle-free, live-attenuated vaccine in development
Indian Immunologicals Ltd (IIL) (PSU)	Covaxin Adjuvant	TT (Component)	Bharat Biotech, Govt. of India	2021	Joint public-private COVID-19 effort
BIBCOL (PSU)	Covaxin Adjuvant	TT (Component)	Bharat Biotech	2021	Fill-finish support during COVID-19
Zydus Cadila	ZyCoV-D (DNA COVID-19)	Licensing, TT	None	2021	India's first DNA vaccine
Post-COVID (2022–2025)					
Serum Institute of India (SII)	R21/Matrix-M (Malaria)	Co-development, TT, CM	PATH, Oxford University, Novavax, GAVI	2022-2024	WHO PQ 2023; India rollout 2024
Serum Institute of India (SII)	mRNA Platform	Early-stage TT	Coda Biotherapeutics	2022-2025	Exploring mRNA vaccine capacity
Bharat Biotech	RTS,S (Malaria Antigen)	Antigen TT	GSK, PATH	2022–2025	Sole antigen supplier by 2029
Bharat Biotech	Shigella (altSonflex1-2-3, GMMA)	In-licensing, TT	GSK	2025	Phase III trials

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Bharat Biotech	TAK-003 (Dengue)	Full TT	Takeda	2022–2025	50M doses/ year goal by 2030
Biological E. Ltd	Qdenga (Dengue)	TT, CM	Takeda, GAVI, PAHO	2022–2024	50M doses/ year goal
Biological E. Ltd	Oral Cholera (OCV-S)	TT, Licensing	IVI	2022–2025	WHO PQ expected 2025
Biological E. Ltd	mRNA Platform	Platform TT	WHO mRNA Hub	2022–2025	Expanding mRNA manufacturing
ICMR-RMRC Bhubaneswar (public R&D)	AdFalciVax (Recombinant Malaria)	Non-exclusive Recombinant,TT	Indian Industry (via EoI)	2025	EoI issued July 2025; 7-year development with royalties
IIT Guwahati (academic)	Swine Fever Vaccine (Veterinary)	Reverse-genetics TT	BioMed Pvt Ltd, AAU	2024	First recombinant pig vaccine; Clinical/ regulatory underway

Note: This is only a selected list of TT and CM

***Source*:** various platform like the GAVI, WHO, UNICEF, PAHO, PATH, PubMed, and individual company/unit web page.

India's Vaccine Manufacturing: Some Structural Issues

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

15 in early 2000s, leaving only six units functional, namely BCG Vaccine Lab (BCGVL) Chennai, Central Research Institute (CRI), Kasauli; Pasteur Institute of India (PII), Coonoor; Bharat Immunologicals and Biologicals Corporation Ltd (BIBCOL), Bulandshahr; Haffkine Bio-Pharmaceutical Corporation Limited (HBPCL), Mumbai; and, Human Biological Institute (HBI), a division of Indian Immunological Ltd, Gujarat (Hooda 2023).

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

This had serious repercussion on country's installed capacity for vaccine manufacturing. For instance, installed capacity increased to 1,19,093 lakh doses in 2014-15 from 89,888 lakh doses in 2006-07, which declined to 80,816 lakh doses in 2018-19 (Table 7). The public sector's share in installed capacity declined to 10.2 per cent in 2018-19 from 22.7 per cent

in 2006-07. Its share in vaccine production also declined significantly to a meagre 1.7 per cent in 2018-19 from 29.4 per cent in 2006-07. Capacity utilisation (measured as the share of production in installed capacity) of the public sector fell to an all-time low of 4.5 per cent in 2018-19 from 20.7 per cent in 2006-07. The public sector was primarily focused on meeting UIP requirements, but the demand for UIP vaccines from the public sector dropped significantly to a negligible 0.8 per cent in 2018-19 from 32.2 per cent in 2006-07 (Table 7). Over time, the government started redirecting UIP vaccine demand to private sector. Currently, private firms supply over 95-99 per cent of the UIP vaccine demand. This suggests that the country has stopped utilising the full manufacturing potential of its public sector. In India, the public sector, which provided commendable services to the nation during epidemic emergencies ranging from plague to cholera, has lost its dominance and become a marginal player. Except for tissue culture based anti-rabies (78.32%), DPT (29.20%), and TT (1.42%) vaccines, almost the entire market for the public sector was eliminated, and the country relied heavily on the private sector for vaccine supply (Hooda, 2022).

Table 7: Public and Private Sector Installed Capacity, Production, Demand, and Capacity Utilisation Status for All Types of Vaccines

(Quantity in lakh doses)

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

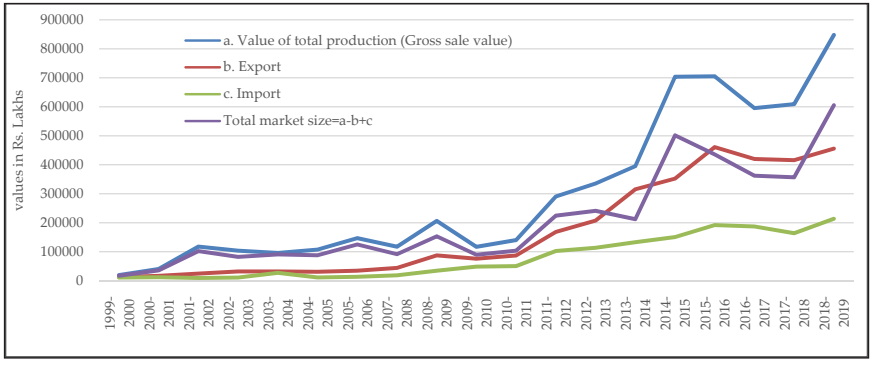
***Source*:** National Health Profile (2008, 2012, 2016, and 2021), GoI.

However, due to inadequate production of UIP and non-UIP vaccines, India, which had previously been self-sufficient, could not meet the growing domestic requirements and was forced to rely on imported vaccines to fill in such gaps. India's domestic vaccine market size [DMS=S+M-X] grew at a CAGR of 18.7 per cent in the past one decade from 2009-10 to 2018-19, reaching INR 60.52 billion in 2018-19 from a low of INR 1.71 billion in 2000 (Figure 9). In 2001, around 90.95 per cent of the domestic market

requirements were met by domestically produced vaccines and the remaining 9.05 per cent by imported vaccines, while the share of imported vaccines meeting the domestic requirements increased to 35.26 per cent in 2018-19 (estimated from Figure 9). This suggest that India became a significant market for imported vaccines. The imported (generally high priced) vaccines resulted in high budget allocation for Pulse Polio programme to nearly double in just five years to Rs 1341.48 crore in 2008-09 from Rs 659.94 crore in 2003-04 (Hooda, 2022). Several states also faced vaccine shortages, the gap to an extent was filled by private sector, but the cost of procuring vaccines from the private sector increased manifold (Madhavi, 2022), pushing India's routine immunisation budget significantly up within a year to Rs 615 crore in 2008-09 from Rs 317 crore in 2007-08 (Hooda, 2022). The increased uptake of newer generation vaccines such as pneumococcal conjugate vaccine, varicella vaccine, rotavirus vaccine, HPV, and typhoid conjugate vaccine contributed in high import (Hooda, 2022). They are mainly high-priced vaccines, the production and sales of which are dominated by a few MNCs (GSK, Pfizer and Merck) worldwide and which are generally sold in the retail market (Chaudhuri, 2022). It is observed that private companies supplied in vaccine gap through imports rather than domestic production.

Figure 9: Domestic Market Size of Vaccines in India and Import Dependency

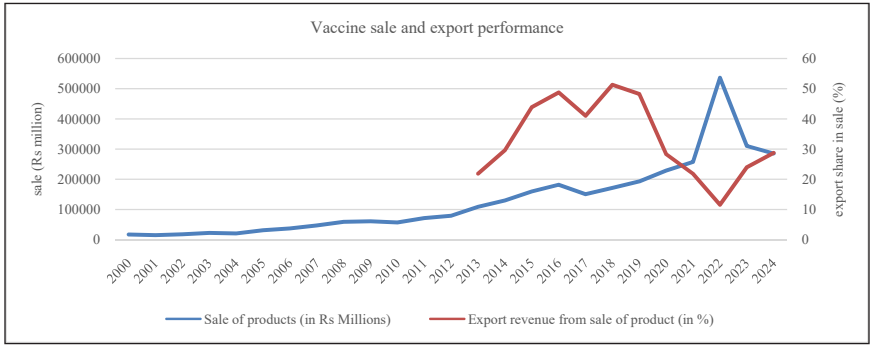
(Rs in lakhs)



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

Indian vaccine export showed an upward trend untill 2015-16, after which growth remained stagnant through 2018-19 (Figure 9). Export surged again during the COVID period, but returned pre-COVID levels by 2024 (Figure 10). The export performance of several vaccine manufacturing companies reveals a disruption in exports due to the pandemic.

Figure 10: India's Vaccine Sale and Export Performance Prior, During and After COVID Pandemic



***Source*:** ProwessIQ, data of only prowess data 16 companies reported in Table-8.

Data from 16 leading vaccine companies (Table-8) shows that the share of vaccine export revenue in total vaccine sales declined significantly, from 45 per cent during the pre-COVID period (2014-2019) to just 21 per cent in the CVOID and post-Covid period (2020-2024). The Serum Institute of India (SII), which accounted for roughly one-third of total vaccine exports from these companies, saw its export share fall from 83 per cent to 49 per cent between the two periods. Similarly, Zydus, contributing about one-fourth of total vaccine exports, experienced a drop in export share from 65 per cent to zero during the same timeframe.In contrast, companies like GlaxoSmithKline Asia, Panacea Biotec, and Haffkine Bio-Pharmaceutical reported significant increases in export share. Their export contributions rose from 5.3 per cent to 32.9 per cent, 18.17 per cent to 80.76 per cent, and 0 per cent to 25.39 per cent, respectively, between the pre-COVID and COVID/post-COVID periods.

Table 8: Export and Revenue Performance of Selected Vaccine Manufacturing Companies

	Revenue from vaccine export in total sale of the product of respective company		**Composition distribution of sale by companies**	
	2014-2019	2020-2024	2014-2019	2020-2024
Serum Institute Of India Pvt. Ltd.	83.43	48.53	23.76	33.73
Zydus Lifesciences Ltd.	65.28	0.00	29.69	24.56
Glaxosmithkline Pharmaceuticals Ltd.	0.05	0.01	17.76	9.78

Bharat Biotech Intl. Ltd.	38.97	18.48	2.97	8.64
Biological E. Ltd.	29.16	5.02	5.45	5.45
H L L Lifecare Ltd.	5.51	0.00	5.06	3.93
M S D Pharmaceuticals Pvt. Ltd.	0.00	3.87	2.25	3.42
Sanofi Healthcare India Pvt. Ltd.	60.47	18.61	1.73	3.06
Indian Immunologicals Ltd.	12.91	15.48	2.79	2.90
Glaxosmithkline Asia Pvt. Ltd.	5.30	32.91	3.90	2.66
Panacea Biotec Ltd.	18.17	80.76	2.34	0.74
Chiron Behring Vaccines Pvt. Ltd.	39.21	6.89	0.61	0.62
Haffkine Bio-Pharmaceutical Corpn. Ltd.	0.00	25.39	0.26	0.25
Bharat Immunologicals& Biologicals Corpn. Ltd.	0.00	0.00	0.73	0.14
Hester Biosciences Ltd.	9.96	0.00	0.61	0.08
Greensignal Bio Pharma Pvt. Ltd.	60.52	27.34	0.12	0.03
All above 16 companies	44.64	20.98	100	100

***Source*:** ProwessIQa

Summary and Conclusion

Since 2000, global vaccine access has improved significantly, propelled by initiatives like the WHO's Expanded Programme on Immunization (EPI), Gavi, and the Developing Countries Vaccine Manufacturers Network (DCVMN). Originally covering six childhood vaccines (BCG, diphtheria, pertussis, tetanus, polio, measles), the EPI now includes 17 vaccines by 2024, such as hepatitis B, Hib, pneumococcal conjugate vaccine (PCV), and rotavirus, adopted widely. Gavi has been instrumental in supplying low-cost vaccines and enabling technology transfers to low- and middle-income countries (LMICs), while DCVMN bolsters local production for

vaccine equity. Yet, disparities remain stark. High-income countries (HICs) achieve 85-97 per cent EPI vaccine coverage, compared to 55-70 per cent in low-income countries (LICs). Newer vaccines like Hib, rotavirus, and HPV see lower uptake in LICs/LMICs due to supply shortages, funding delays, and limited manufacturing capacity. In 2023, 68-88 countries faced national stock-outs, mainly due to procurement and funding issues, while inadequate R&D investment hampers vaccines for poverty-linked diseases, highlighting the need for sustainable local production.

India has emerged as a major global vaccine supplier, particularly for affordable, traditional vaccines to LICs and LMICs. From 2014-2020, India ranked eighth in vaccine export value (2.58% share) but fourth in volume (11.01%), providing 37.43 per cent of vaccines to LICs and 24.53 per cent to LMICs, surpassing HIC leaders like the EU and US, who hold 80 per cent of export value. India's vaccines, primarily distributed via Gavi and UNICEF, ensure high-quality, low-cost supply to low-income regions. The COVID-19 pandemic disrupted this, with global vaccine exports peaking at 14.04 per cent of pharmaceutical exports in 2021-22. India's export volume share fell to 6.18 per cent from 11.01 per cent as it prioritized domestic vaccination (94.3 per cent of production) during a severe 2021 wave. Meanwhile, China captured 10.97 per cent of global vaccine export volume in 2021-22, leveraging "COVID-19 Vaccine Diplomacy" and early WHO approvals for nine vaccines by June 2022, compared to India's five. Of 15.2 billion global COVID vaccine doses by May 2022, the EU supplied 39.7 per cent, China 32.6 per cent, the US 15 per cent, and India just 2.3 per cent, underscoring India's reduced global role during the crisis.

India's vaccine industry faces structural hurdles that threaten its global leadership. The public sector, once self-sufficient for Universal Immunization Programme (UIP) vaccines in 1985, has dwindled, with functional units dropping from 29 to six by the 2000s. Public sector capacity utilization fell from 20.7 per cent in 2006-07 to 4.5 per cent in 2018-19, and its production share declined from 29.4 per cent to 1.7 per cent, with private firms now supplying 95-99 per cent of UIP vaccines. Private manufacturers like Serum Institute of India (SII), Biological E, and Bharat Biotech lead WHO-prequalified vaccines, producing 45 per cent of the 277 global prequalified doses, with SII holding 72 prequalification for vaccines like measles, rubella, and COVID-19. However, India's private sector focuses on traditional vaccines (e.g., 60 per cent of global DPT, BCG, and 90 per cent of measles vaccines) and lags in newer vaccines like HPV, dengue, and Ebola due to reliance on outdated technologies and limited innovation in platforms like mRNA, restricting access to high-value HIC markets dominated by EU/US suppliers.

India's increasing dependence on imported vaccines adds complexity. The domestic vaccine market grew at an 18.7 per cent CAGR from 2009-19, reaching INR 60.52 billion, but imported vaccines' share rose from 9.05 per cent in 2001 to 35.26 per cent in 2018-19, driven by costly newer vaccines from multinationals like GSK, Pfizer, and Merck. This raised costs for programs like Pulse Polio, with budgets nearly doubling from Rs 659.94 crore in 2003-04 to Rs 1341.48 crore in 2008-09. India's vaccine exports surged during COVID but reverted to pre-COVID levels by 2024, with export revenue share for major firms dropping from 45 per cent (2014-19) to 21 per cent (2020-24). For example, SII's export share fell from 83 per cent to 49 per cent, and Zydus' exports dropped to zero, though firms like Panacea Biotec and Haffkine Bio-Pharmaceutical saw export gains.

Despite challenges, India's trusted WHO-prequalified manufacturing base (7-8 firms, including SII, Biological E, and Bharat Biotech) positions it to tackle global vaccine inequity, where LICs have 14.1 per cent full vaccination coverage and LMICs 48 per cent compared to HICs' 74 per cent. China's declining vaccine credibility due to efficacy concerns provides India an opportunity to regain dominance in LICs/LMICs through DCVMN-supported technology transfer and capacity building. To ensure sustainable growth, India must revitalize its public sector, invest in innovative platforms like mRNA, and penetrate HIC markets while maintaining affordable vaccine supply. DCVMN's success in supplying 60 per cent of global COVID vaccine doses with limited funding underscores the potential of collaborative efforts to bolster India's global vaccine leadership.

Vaccine production has been India's strength for over a century. The public sector once ensured self-reliance for basic UIP vaccines, but post-liberalization dismantling reduced domestic capacity, increasing reliance on imports. Private firms filled the gap through imports rather than local production. Globally, India ranks fourth in vaccine supply volume but eighth in export value, cementing its role as a hub for affordable vaccines to LICs/LMICs. However, during the COVID-19 crisis, India nearly lost its leadership, as it halted COVID vaccine exports in spring 2021 to meet domestic needs, relying on two private firms for supply, with only Bharat Biotech developing an indigenous vaccine (Covaxin) with public sector support from ICMR and NIV. This highlights the need to revive the public sector to ensure self-sufficiency in vaccine technology and production.

Most Indian manufacturers focus on conventional vaccines, limiting their presence in HIC markets, which require investment and innovation in diverse vaccines. Indian firms have promising R&D pipelines that are to be materialized. Technology transfer and contract manufacturing for vaccines like HPV, rotavirus, and pneumococcal conjugate could open HIC markets, but barriers like patents, technical complexity, and insufficient R&D infrastructure pose challenges. Beyond COVID-19, vaccines must address both preventive and therapeutic roles for diseases like HIV, norovirus, Zika,

tuberculosis, and malaria. As a trusted WHO-prequalified player, India can capitalize on these opportunities by investing in novel vaccine platforms and expanding its global footprint to drive industry growth.

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Manufacturing Excellence: Upholding Quality to Expand Vaccine Access

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Abstract: Fair access to safe and effective vaccines depends not only on new scientific discoveries but also on being able to produce large quantities of vaccines of consistently high quality. This chapter explores the intricate frameworks that uphold vaccine quality throughout the entire product life cycle. It examines the importance of robust manufacturing methods, effective regulatory checks, and global standards, such as WHO prequalification and NRA maturity levels. Particular emphasis is placed on technology transfer, both from research and development to manufacturing and across global production sites, as a strategic enabler of quality continuity and equitable access. By examining quality management, global standards, and training programs, the chapter demonstrates how quality is maintained in various production settings. Ultimately, it asserts that maintaining manufacturing excellence, through harmonised standards, transparent regulatory pathways, effective technology transfer, and mature NRAs, forms the foundation of vaccine equity and pandemic preparedness.

Keywords: Vaccine, NRA, ISO, Equity, Covid-19

Introduction

Vaccines represent a highly effective strategy for safeguarding public health, preventing an estimated 3.5 to 5 million deaths annually (Montero, 2024). The COVID-19 pandemic highlighted both the strengths and weaknesses of global vaccine development and distribution processes. The rapid development of novel vaccine platforms, such as mRNA and viral-vectored technologies, was unprecedented; however, challenges in scaling up production and ensuring equitable distribution revealed systemic gaps (Sharma, 2021). Manufacturing excellence in vaccines is defined as the ability to consistently produce high-quality products that meet stringent regulatory and safety standards, while optimising efficiency and access (Riley et al., 2022; Robinson et al., 2023). This requires integrating advanced manufacturing technologies, robust quality management systems, and international cooperation. Quality assurance is not a single checkpoint, but a continuum that spans raw materials, process control, regulatory oversight, and post-market surveillance. Equally critical is the establishment of strong regulatory systems.

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This chapter provides a comprehensive analysis of the frameworks that uphold vaccine quality and manufacturing excellence, focusing on:

1 Regulatory systems and global benchmarks (NRA maturity, WHO prequalification)
2 Ensuring Quality in manufacturing vaccine material at different stages of the vaccine lifecycle, which include steps from basic research to development, to testing in preclinical study, to different phases of clinical trials, and post-licensure monitoring.
3 Technology transfer as a tool for ensuring continuity and equity
4 Policy, workforce, and future directions for sustaining access

Regulatory Systems, Global Benchmarks, and Prequalification

The regulatory systems of different countries, commonly referred to as National Regulatory Agencies (NRA), global benchmarks, and prequalification play a crucial role in ensuring manufacturing excellence for vaccines. Strong regulatory frameworks safeguard quality, safety, and efficacy, while alignment with global benchmarks fosters harmonisation and comparability across markets. Prequalification by international agencies, such as the WHO, further establishes credibility and facilitates global access by assuring that vaccines meet stringent international standards.

Role of National Regulatory Authorities (NRAs)

NRAs are national regulatory agencies responsible for ensuring that products released for public distribution (typically pharmaceuticals and biological products, such as vaccines and medical devices, including test kits) are properly evaluated and meet international standards of quality, safety, and efficacy (Milstien et al., 2004). All countries need an NRA. Countries manufacturing medical products must exercise at least six critical control functions, as discussed later, and do so in a competent and independent manner, backed by enforcement power (Saidu et al., 2013). Market Authorisation and post-marketing surveillance, as well as adverse events following immunisation (AEFI) monitoring, are functions that all NRAs must establish, regardless of their production capacity and procurement policy, i.e., whether the vaccine is locally manufactured, directly imported, or imported through UN procurement agencies (Milstien et al., 2004).

NRAs are the cornerstone of vaccine oversight. They ensure that vaccines are manufactured, tested, and distributed according to global standards of safety, efficacy, and quality (WHO, 2021a). Core functions include

a **Vaccine Regulatory Framework:** A statutory and enforceable system is required to regulate vaccines effectively. This framework must define lines of authority, establish independence of the regulatory authority from manufacturers, and include mechanisms for product recall and confirmed destruction of lots. Adequately trained staff and institutional development plans are necessary to sustain operations (Gupta et al., 2015).

b **Licensing Process:** Licensing of a product for the market involves a thorough evaluation of both manufacturing facilities and vaccine products. A single, uniform standard must apply to both domestic and imported vaccines. Clear written guidelines are required for submissions, GMP assessments, and license applications. Procedures for expert committee involvement, consultations with manufacturers, and publication of licensed product lists enhance transparency and accountability (Giaquinto & Rocchi, 2017).

c **Post-Market Surveillance:** Continuous monitoring of vaccine performance is vital. Written procedures should define adverse events following immunization (AEFI) and guide their investigation. Epidemiological data must be integrated into performance assessments, while regular safety and efficacy reviews provide a basis for regulatory action. Post-marketing (Phase IV) monitoring must be a licensing requirement (Cheng & Buttery, 2022).

d **Lot Release System:** Lot release is critical to maintaining vaccine quality. It relies on protocol reviews, control laboratory data, and inspection records. Written criteria, consistent documentation, and ongoing dialogue with manufacturers ensure reliability and highlight deviations. Exemptions from lot release are strictly controlled (Kato et al., 2019).

e **Testing Laboratory Oversight:** Laboratories must follow comprehensive quality systems, supported by a Quality Manual, SOPs, equipment validation, and maintenance records. Staff training, audit systems, safety programs, and participation in collaborative studies ensure technical competence. Data trends must be analyzed routinely, with corrective measures applied as needed (Patel et al., 2024).

f **GMP Inspections and Clinical Evaluation:** Regular GMP inspections, based on WHO standards, must be conducted by qualified and independent inspectors. Inspections should follow written plans and result in defined actions. Clinical evaluation requires adherence to GMP, GLP, GCP, and ethical oversight. Guidelines for local trial requirements,

> access to epidemiological expertise, and product-specific experts are essential to ensure credible evaluation. (Regulation of vaccines: building on existing drug regulatory authorities WHO/V&B/99.10 Annexure 3 1999), (Sardella, 2021).

To all NRAs, WHO offers technical assistance for the development and implementation of plans to strengthen their system. Ongoing support is provided to countries for assessing NRA functions. Additionally, the Global Training Network on Vaccine Quality (GTN/VQ) delivers support based on identified gaps and national plans.

WHO Global Benchmarking Tool (GBT) and NRA Maturity Levels

The benchmarking of regulatory systems, as outlined in resolution WHA 67.20, is a structured process enabling Member States to identify and address gaps in order to establish robust, integrated regulatory oversight. The WHO Global Benchmarking Tool (GBT) is the primary mechanism for evaluating medical product regulatory systems. It helps identify strengths and weaknesses, supports the creation of institutional development plans (IDPs), guides investment priorities, and monitors progress. The WHO began assessing vaccine regulatory systems in 1997, using specific indicators, and later expanded and refined these tools for broader application. To date, over 150 countries have undergone benchmarking assessments. In 2013, WHO initiated the development of a unified GBT covering both medicines and vaccines, ensuring coherence across policies, improving regulatory outcomes, and minimizing the burden on national authorities. This unified approach strengthens global health systems by aligning evaluation standards and facilitating consistent, effective regulation of medical products, primarily vaccines worldwide. This unified system proved highly effective during the COVID-19 pandemic, when WHO centrally coordinated vaccine development and facilitated cross-border vaccine supply, ensuring clarity and avoiding ambiguities or questions on vaccine quality among national regulatory authorities (NRAs).(Ostad Ali et al. 2025).

WHO's most evolved version of Global Benchmarking Tool (GBT) based on two international consultations with Member States in 2015, a public consultation in early 2018 and a series of meetings involving experts from regulatory authorities from different parts of the world, assesses National Regulatory Agencies with concept of 'maturity level' or ML (adapted from ISO 9004) on a scale from 1 to 4, which is graded representation of 'overall maturity' of the regulatory system in terms of scale as mentioned below complying to ISO 9004:2018 (benchmarking_ manual_v2_09mar2021, WHO 2021b)

ML1: regulatory systems in which some elements of regulatory systems exist; corresponds to "no formal approach"

ML2: evolving national regulatory systems that partially perform essential regulatory functions; corresponds to "reactive approach"

ML3: stable, well-functioning and integrated regulatory systems; corresponds to "stable formal system approach", and

ML4: regulatory systems operating at an advanced level of performance and continuous improvement; corresponds to "continual improvement emphasized"

Achieving a maturity level of 3 (signifying a stable and effective regulatory environment) or higher is essential for a country to be recognised as a reliable manufacturer and exporter of vaccines. Countries at Level 3 or higher can support local manufacturers in achieving WHO prequalification, a prerequisite for UNICEF and Gavi procurement, as described in Table 1 (WHO, 2024).

Table 1: NRA Maturity Levels for Vaccine Manufacturing

Country/Region	NRA Body	WHO Maturity Level (ML)
India	Central Drugs Standard Control Org (CDSCO)	ML3
Nigeria	National Agency for Food & Drug Admin (NAFDAC)	ML3
United Republic of Tanzania	Tanzania Medicines and Medical Devices Authority (TMDA)	ML3
Ghana	Food and Drugs Authority (FDA)	ML3
USA	Food and Drug Administration (FDA)	ML3
China	National Medical Products Administration (NMPA)	ML3
Egypt	Egyptian Drug Authority (EDA)	ML3
Indonesia	National Agency of Drug and Food Control (BADAN POM)	ML3
Republic of Korea	Ministry of Food and Drug Safety (MFDS)	ML4
Rwanda	Food and Drugs Authority (Rwanda FDA)	ML3

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Sénégal	Agence sénégalaise de Réglementation Pharmaceutique	ML3
Saudi Arabia	Saudi Food and Drug Authority (SFDA)	ML4
Serbia	Medicines and Medical Devices Agency (ALIMS)	ML3
Singapore	Health Sciences Authority (HSA)	ML4
South Africa	South African Health Products Regulatory Authority (SAHPRA)	ML3
Thailand	Food and Drug Administration (FDA)	ML3
Turkiye	Turkish Medicines and Medical Devices Agency (TİTCK)	ML3
Vietnam	Vaccine regulatory system in Vietnam represented by: a) The Drug Administration of Viet Nam (DAV), b) Administration of Science, Technology and Training (ASTT), c) National Institute for the Control of Vaccines and Biologicals (NICVB), and d) General Department of Preventive Medicine (GDPM)	ML3
Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ)	ML3

Source: WHO (2024).

WHO Prequalification as a Benchmark for Global Acceptance: History, Mission and Vision

The World Health Organization (WHO) launched the Expanded Programme on Immunization (EPI) in the late 1970s to ensure global access to life-saving vaccines. As an increasing number of vaccines were procured and distributed by UN agencies, there was a need to guarantee consistent safety and effectiveness. In 1987, WHO introduced vaccine prequalification requirements, including reviews of production consistency, evaluation, and inspections of GMP manufacturing sites. The procedure was formally published in 1989, and by 1992, the World Health Assembly mandated that all vaccines used in national immunisation programmes must meet WHO standards. Later, it also included continuous post-market monitoring. It has become the gold standard for global acceptance, especially for manufacturers in LMICs (Dellepiane & Wood, 2015).

As vaccine demand and complexity expanded after 2000, WHO revised its prequalification process. From 2002, only vaccines from manufacturers in countries with a WHO-assessed "functional" national regulatory authority (NRA) could be submitted. This strengthened regulatory capacity in low-income nations. Further revisions in 2010 emphasized collaboration with NRAs, clearer vaccine specifications, and improved efficiency, reducing timelines without compromising quality. (Dellepiane & Wood, 2015).

In 2012, WHO introduced a streamlined process to address growing volumes and costs of newer vaccines. This approach recognized regulatory assessments from select stringent authorities, incorporated manufacturer annual reports, and applied risk-based reassessment, allowing resources to focus where most needed. (Dellepiane & Wood, 2015).

The vision of the WHO's prequalification programme is universal access to quality vaccines, enabling healthier and more productive lives. Its mission is to support UN agencies, national programmes, NRAs, control laboratories, and manufacturers in ensuring that all Member States can obtain safe, effective, and reliable vaccines tailored to their immunisation needs ('t Hoen et al., 2014).

As of now, around 277 vaccine formulations against various diseases has been Prequalified, out of which 4 has been of Covid19. It may be noted that during the COVID-19 pandemic, various vaccines were EUL-approved, and the WHO played a central role in coordinating global efforts, particularly through mechanisms such as the Emergency Use Listing (EUL), Collaborative Registration Procedures (CRP), and reliance on WHO-Listed Authorities (WLAs). These tools enabled national regulatory authorities (NRAs) to expedite decision-making by drawing upon trusted assessments, reducing duplication of effort, and promoting convergence in regulatory standards. At the same time, the WHO facilitated cross-border vaccine supply through platforms such as COVAX, ensuring that vaccines could move rapidly and equitably across countries. This reduced potential ambiguities regarding vaccine quality, safety, and efficacy, providing NRAs with a common reference point and reinforcing confidence in authorized products ("WHO Lists 9th COVID-19 Vaccine for Emergency Use with Aim to Increase Access to Vaccination in Lower-Income Countries," 2022).

Importance of Regulatory Convergence

Different national regulations shape the vaccine supply chain, often resulting in a fragmented system with inefficiencies, higher costs, and quality concerns. These differences come from varying risk tolerance, benefit-risk approaches, approval standards, and the resources available to each country's regulatory authorities. Although many agree that better

alignment would help, progress toward global regulatory harmonisation is still inconsistent. Three related ideas guide these efforts: convergence, reliance, and harmonisation(Zerhouni & Hamburg, 2016).

Regulatory convergence is a voluntary process in which regulatory requirements across countries gradually align as authorities adopt internationally recognized standards, technical guidance, and scientific principles(Tominaga, 2020). Convergence improves efficiency, accelerates access to medical products, and strengthens regulatory capacity. Regulatory reliance occurs when one regulator gives significant weight to the decisions or assessments of another trusted authority while retaining accountability for its own decision. Reliance does not require harmonization but is facilitated by aligned standards. Regulatory harmonization is the formal development of uniform guidelines, processes, or standards across multiple authorities. While harmonization offers predictability and consistency, it can be more challenging to achieve due to differing legal and health system frameworks (Sheets & Knezevic, 2017).

Work in these areas brings important benefits. It makes regulatory processes more efficient and predictable, supports fair access to safe medicines, and helps regulators with fewer resources. These efforts also make the supply chain stronger, help focus resources where they are needed most, and lower the risk of poor-quality or fake products, which is especially important during health emergencies. Still, it is difficult to align priorities between countries and to measure progress in a consistent way.

To address such gaps, the World Health Organization (WHO) introduced the Global Benchmarking Tool (GBT). The GBT standardizes evaluation of regulatory systems worldwide, offering a uniform frame of reference and reducing inconsistencies in interpreting regulatory strengthening. (Guzman, 2020) It also allows countries to track incremental progress, fostering cooperation and accountability while encouraging shared advancement toward stronger public health systems.

The COVID-19 pandemic showed both the progress made and the ongoing challenges in bringing regulations closer together. Fast teamwork helped develop and distribute vaccines, but different rules in each country slowed things down and made the global response harder. The European Medicines Agency's OPEN pilot program was one creative solution, involving regulators from outside the EU in reviewing COVID-19 vaccines and treatments. («EMA COVID-19 assessments 'OPEN' to non-EU regulators», 2020) This program improved communication, allowed several regulators to review data at the same time, cut down on repeated work, and sped up reviews outside the EU. (Reggi, 2017) Even with these achievements, there is still a need for clearer guidelines and more transparency.

Also, regulatory harmonization through initiatives like the International Council for Harmonisation (ICH) and African Medicines Agency (AMA) reduces duplication, accelerates vaccine availability, and strengthens global

trust in supply chains (Ndomondo-Sigonda & Ambali, 2011; Abdulwahab, 2024).

In summary, convergence, harmonization, and reliance are key to creating a stronger and more flexible global regulatory system. Tools like the WHO's GBT and programs like EMA's OPEN have helped, but ongoing work is needed to fix the remaining gaps. A more unified approach would make it easier to get important medicines to people and better prepare the world for future health emergencies.

Quality Assurance Across the Vaccine Lifecycle

Vaccines are different from small-molecule drugs because their identity, safety, and effectiveness depend closely on how they are made (Fuchs, 2002). This is why people often say, "the process is the product." Vaccines are complex and made in living systems, so even small changes in how they are grown, purified, or formulated can affect important features like stability or how the immune system responds. Because testing cannot catch every detail, regulators focus on making sure the manufacturing process stays consistent (Robinson et al., 2023). This focus continues throughout the entire life of the vaccine, not just at the start.

Vaccine Research and Development during product development: During research and development, process understanding guides the design of candidate vaccines, where critical quality attributes (CQAs) are initially defined. As the vaccine progresses into clinical development and scale-up, the process is refined, and manufacturing knowledge enhances confidence that the product will remain consistent when produced at larger scales. In commercial manufacturing, robust control of upstream and downstream parameters ensures that each batch meets quality standards. When changes occur, such as facility upgrades or technology transfer to other sites, comparability studies are required to demonstrate that the vaccine remains essentially the same (Ramin et al., 2024).

Quality by Design (QbD) works alongside the idea that the process defines the product by building quality into every stage of the vaccine's life. QbD starts with a Quality Target Product Profile (QTPP), which describes the needed safety, effectiveness, and stability. This helps identify critical quality attributes (CQAs) and the process parameters that affect them. By setting a design space, which is a scientifically supported range of process conditions, manufacturers can achieve reliable results during development, scaling up, regular production, and ongoing management (Taticek & Liu, 2015).

Applying QbD throughout the lifecycle offers multiple advantages: it reduces batch failures, enables regulatory flexibility for adjustments within the design space, and supports continuous improvement (Taticek & Liu, 2015). Importantly, it extends quality assurance beyond manufacturing into

storage, distribution, and post-market surveillance, where maintaining cold chain and monitoring safety are vital for protecting product integrity and public trust (Krummen, 2015).

Thus, for vaccines, quality is not confined to the product itself but resides in the entire lifecycle of the development process. Together, the principles of "the process is the product" and QbD ensure that from early development to delivery at the point of care, vaccines remain consistently safe, effective, and reliable.

Let's review some of the key components during vaccine production steps. In practice, vaccine production relies on biologic antigens, cell culture inputs, buffers and stabilisers, single-use consumables, and adjuvants such as aluminium salts, squalene emulsions, saponins, and Toll-like receptor (TLR) agonists. Thus, the quality of materials, regulatory quality control, and reliance on single-source supplies significantly constrain manufacturing capacity. In contrast, diversification of suppliers, process scale-up, thermostabilization, and advanced analytics enhance supply chain resilience.

Primary raw materials and manufacturing steps:

Vaccine production depends not only on the active immunogen but also on a wide range of materials required throughout manufacturing and formulation processes. Any shortage or compromise in quality at these stages can decrease yield, impact final product performance, and disrupt the supply chain. We observed such a strong interdependency during the pandemic as well.

The manufacturing process begins with antigens and platform components, such as live or attenuated pathogens, inactivated viruses, recombinant proteins, viral vectors, or nucleic acids (mRNA/saRNA). These define the upstream process requirements and critical analytical needs. Upstream processing and reagents include cell culture media, supplements, amino acids, sera or substitutes, antibiotics for contamination control, bacterial strains, and host-cell substrates, some of which may remain as trace excipients in the final product. The upstream process ensures that the desired amount and quality of immunogen are produced through cultivation (Genzel et al., 2014; Robinson, 2016).

In downstream processing, essential materials include chromatography resins, filters, buffers, solvents, and process enzymes used for purification and formulation. Increasingly, single-use biocontainers and tubing facilitate scale-up and quicker turnaround between production campaigns. For most vaccines, during downstream processing, the active product formed during upstream processing is in contact with the material used; utmost precaution is taken to ensure the absence of leachable from the material used, to ensure safety. For formulation and packaging, stabilisers (e.g., sugars, polysorbates), preservatives, buffers, lipids for LNPs, excipients

including adjuvants, as well as container-closure systems such as stoppers, vials, and syringes, ensure stability and proper delivery (Schlegl & Hahn, 2012; Lopez Cardoso et al., 2017).

Key adjuvants used in commercial vaccines: Adjuvants amplify, shape or prolong immune responses and are chosen according to antigen type, desired immune phenotype and regulatory precedent; established classes include aluminum salts, oil in water emulsions, saponin based compounds (QS 21) and pattern recognition receptor agonists such as TLR ligands (Laera, D et al., 2023; Phan T et al., 2020; Lopes J M et al., 2022). Typical role of each adjuvant available along with its typical immunological role and its advantages during manufacturing and supply risk is tabulated in Table 2. Adjuvant composition and particulate structure significantly impact formulation stability and processability, with implications for cold-chain needs and manufacturability (Golan M S et al., 2021).

Table 2: Functional and Supply Chain Characteristics of Major Vaccine Adjuvants

Adjuvant class	Typical role	Advantages	Supply risk
Aluminum salts (alum)	Antigen adsorption, Th2 biased enhancement	Long regulatory history, low cost, broad availability (Laera, D et al., 2023)	Low
Oil in water emulsions (e.g., MF59, AS03; squalene based)	Potent antibody responses and dose sparing	Enable antigen dose sparing and liquid presentations; scalable with process innovation (Firdaus F Z et al., 2022)	Medium (natural squalene sourcing historically constrained) (Firdaus F Z et al., 2022)
Saponin derivatives (QS 21)	Strong cellular and humoral enhancement, used in combination systems	High potency in licensed formulations	High if natural bark sourcing required; alternative plant cell production can mitigate bottlenecks (Lykins W R et al., 2023)

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Synthetic PRR agonists (TLR ligands, lipid A mimetics)	Direct innate activation to tune Th1/Th2/Th17 profiles	Precisely engineered, scalable chemistry possible (X. Lv et al., 2024)	Variable depending on synthetic route and raw inputs (Golan M S et al., 2021)

Source: WHO (2024).

Development of new vaccine adjuvants requires careful consideration of multiple interdependent factors. A primary determinant is mechanistic selection, wherein the choice of adjuvant is dictated by the nature of the immune response to be elicited, such as Th1, Th2, or Th17-mediated pathways, while ensuring compatibility with the antigen platform and an acceptable reactogenicity profile. In parallel, formulation constraints represent a significant challenge, as particulate and emulsion-based adjuvants frequently complicate processes such as lyophilization and thermo stabilization, thereby heightening dependence on cold chain infrastructure unless addressed proactively during product design and development. Furthermore, sourcing innovations are increasingly pivotal in overcoming supply limitations of naturally derived adjuvant components. For instance, the plant cell culture-based synthesis of QS-21 exemplifies a sustainable strategy to reduce reliance on scarce botanical sources, thereby strengthening supply chain resilience and enabling broader accessibility of advanced adjuvant systems.

Fill-finish and cold-chain supplies: Finally, fill-finish and cold-chain supplies, including vials, stopper assemblies, primary packaging, and distribution logistics, often become bottlenecks during rapid scale-up and global deployment. The use of isolator technology, sterile filtration, and tamper-proof packaging ensures integrity (Elmadhoun, 2025). This final stage is also susceptible to contamination risks. Therefore, every lot must pass safety, potency, and sterility testing before release. Regulatory submissions document compliance with pharmacopeial and NRA standards (Shim, 2023).

Since vaccines must remain within specified temperature ranges (2–8 °C for most, –70 °C for mRNA), a slight temperature excursion may affect vaccine potency; therefore, a monitoring programme should be established for stability testing and real-time tracking to safeguard potency (Gavi, 2021).

In all the above-mentioned stages, either one or more components, their desired availability may be affected by the production capacity of the supplier or constraints arising from IPR.

Quality control requirements for materials during manufacturing

Quality control (QC) procedures are required to verify the identity, purity, potency, and safety of antigens, excipients, and adjuvants. The use of specific assays and process analytics is essential for product release and for preventing downstream failures. Early QC planning reduces supply risks during scale-up. Material release testing is a crucial step in ensuring the quality of biologic inputs. The identity and purity of these materials are verified using spectroscopy, colorimetric, chromatographic techniques and Immunoassays. In addition, quality control measures for testing residual or no impurities include testing for endotoxin levels, bioburden or sterility, residual host-cell proteins and DNA, and screening for adventitious agents. It is recommended to use animal component-free materials for manufacturing to meet Transmissible Spongiform Encephalopathy (TSE) free requirements. Otherwise, it is mandatory to test raw materials, such as sera, for TSE. These comprehensive tests are essential to confirm that raw materials meet the necessary standards for use in production (Domachowske, J. 2021; Harrak M. El et al., 2021).

For adjuvants, quality control involves a detailed analysis of multiple parameters beyond those previously mentioned. The measurement of particulate or particle size is performed using dynamic light scattering (DLS) or laser diffraction. There is also an evaluation of emulsion droplet size and stability, as well as an analysis of viscosity and composition through HPLC or charged-aerosol detection, which is especially important for oil-in-water adjuvants. Additionally, chemical structure and specific assays are utilised to assess saponins or synthetic ligands (Phan T et al., 2020; Harrak M. El et al., 2021).

Under evolving regulations, process and product analytics are increasingly sophisticated, employing process analytical technologies (PAT), potency assays with both in-vitro and in-vivo correlates, next-generation sequencing, and single-particle characterization. These advanced tools help define critical quality attributes and facilitate quality-by-design release strategies (Buckland et al., 2024)

Formulation and thermostability testing are also vital components of quality control. These tests include evaluating stability under intended storage conditions, such as comparing liquid versus lyophilized forms, controlling water activity, conducting accelerated degradation studies and temperature excursion studies. The insights gained help guide decisions related to cold-chain requirements and market accessibility (Lykins W R et al., 2023).

A detailed vaccine stability plan is necessary to extract insights across development phases. Stability planning in vaccines begins early, during formulation selection and process development. At this stage, stabilizers and presentation formats—liquid or dried—are chosen to support antigen

integrity. Planning continues across preclinical and clinical phases, through to post-licensure monitoring, always with attention to cold-chain resilience and lifecycle management.

Manufacturing development focuses on selecting formulations and excipients that balance antigen stability with manufacturability. Stabilizers, buffers, and adjuvant compatibility are assessed for both liquid and dried formats. Quality-by-design and process analytical technologies help define critical quality attributes and in-process controls. Stress testing and accelerated degradation studies identify degradation pathways early, while technologies such as lyophilization and spray-drying are explored to improve thermostability.

In preclinical studies, stability testing verifies that formulations perform as intended under both normal storage and stressed conditions. Stability-indicating assays and in vitro potency tests guide final composition choices. Real-time and accelerated studies establish provisional shelf life and permissible excursions, while animal immunogenicity studies after stressed storage confirm that potency is retained.

At the clinical stage, stability protocols are integrated with bridging studies whenever formulations or processes change. Comparability of clinical batches, container-closure integrity, and expiry dating are documented. Thermostable or lyophilized presentations may be advanced into trials to simplify distribution and reduce cold-chain dependency.

Following approval, post-licensing activities shift to lifecycle management. Ongoing real-time stability testing, trending, and lot release commitments accompany tech transfer. Surveillance data drive label updates and cold-chain resilience measures. Where feasible, further optimization toward dried or thermostable formats enhances global access. Effective communication and training ensure smooth implementation across stakeholders.

In summary, from a regulatory perspective, documentation and the use of validated methods manuals and assays are required to ensure raw material quality and traceability. The quality control of excipients and adjuvants plays a significant role in Chemistry, Manufacturing and Controls (CMC) submissions (Harrak M. El et al 2021; Buckland et al., 2024.

All the detailed knowledge described above regarding the complete vaccine life cycle aids in effective vaccine manufacturing and commercilaization, not only at the site but also across multiple sites if needed, through the technology transfer discussed in the following section.

Technology Transfer for Quality Continuity

As per WHO, Technology transfer in the biopharmaceutical sector is defined as a logical, systematic procedure that governs the movement of any bioprocess with production strains or constructs or with precise knowledge

of creating the construct, along with its supporting documentation and professional expertise, from development to manufacturing, or between manufacturing sites. It ensures that the knowledge and experience gained during product development or commercialization are passed on to a responsible and authorized party. Crucially, it includes the transfer of documentation, starting material and the demonstrated ability of the receiving unit (RU) to reproduce the critical aspects of the process to the satisfaction of the sending unit (SU), regulatory authorities, and other stakeholders.

The objective of technology transfer is to enable consistent, efficient, and compliant production of medicines and vaccines, regardless of where or by whom they are manufactured. It ensures that the RU can reproduce the product or process reliably, meeting predefined specifications, while preserving product quality, safety, and efficacy. This process also facilitates business strategies such as capacity expansion, relocation, mergers, or contract manufacturing.

Types of technology transfer commonly include:

a Intercompany transfers: Between sites, such as between different organizations, often driven by mergers, partnerships, or licensing agreements.

b Intracompany transfers, within the same organization, usually from R&D to manufacturing for development, or between sites to expand production capacity or streamline operations.

Objectives for both above include reproducibility, compliance with regulatory expectations, and safeguarding patient safety (Simões, 2024).

Best Practices for Quality-Centric Technology Transfer

The quality aspects of technology transfer are paramount. Best practices during transfer require a detailed documentation, risk assessment, validation of critical process parameters, and use of quality-by-design (QbD) frameworks (Duarte, 2025), along with planned approach supported by trained personnel and an established quality system. Key principles include quality risk management, similarity of facilities and equipment, thorough gap analysis, regulatory alignment, and comprehensive product and process knowledge transfer. Ultimately, quality in technology transfer is demonstrated when the RU consistently reproduces the product according to agreed specifications, backed by transparent communication and regulatory compliance.

Case Studies: Successful and Challenging Transfers

The significance of quality-focused technology transfers is demonstrated through case studies from the COVID-19 pandemic period. Finally, Table 3 provides a comparison and summary of the main features of various technology transfers, including goals, key challenges, different Quality Assurance strategies, and results.

Case Study 1: Oxford–AstraZeneca and the Serum Institute of India

The technology transfer between Oxford–AstraZeneca and the Serum Institute of India (SII) during the COVID-19 pandemic stands as a benchmark for rapid, large-scale manufacturing. AstraZeneca provided the core cell line, process know-how, and regulatory dossiers, while SII leveraged its massive production capacity and prior experience with WHO-prequalified vaccines. Despite initial challenges in raw material supply and alignment of regulatory filings, the partnership enabled the production of over a billion doses of Covishield within a year, which were distributed both domestically and through the COVAX facility. The success lay in harmonizing quality standards across sites, frequent technical exchanges, and joint quality reviews by AstraZeneca and SII teams. This collaboration illustrated that effective technology transfer, when backed by transparent knowledge sharing and aligned quality systems, can drive vaccine equity in low- and middle-income countries (LMICs) (Somasundaram, 2021; Choi, 2021).

Case Study 2: Bharat Biotech–Indian Immunologicals Technology Transfer Supported by BIRAC

In India, a public–private technology transfer initiative between Bharat Biotech and Indian Immunologicals Limited (IIL), facilitated by the Biotechnology Industry Research Assistance Council (BIRAC), demonstrated the critical role of government-backed partnerships in ensuring manufacturing scalability. Bharat Biotech developed a COVID-19 vaccine candidate based on inactivated virus technology, and to meet urgent demand, BIRAC sponsored the transfer of this technology to IIL. This required adaptation of the production process to IIL's infrastructure while maintaining stringent quality standards, including biosafety compliance, batch consistency, and process validation. The collaboration not only expanded manufacturing capacity but also strengthened India's ecosystem for pandemic preparedness by diversifying vaccine production sites. Despite technical hurdles in scaling the inactivation step and aligning fill-finish operations, continuous technical assistance ensured quality continuity. This case underlined how structured partnerships, supported by national funding and oversight, can accelerate vaccine availability while upholding regulatory compliance (BIRAC, 2021; DBT, 2021).

Case Study 3: mRNA Vaccine Technology Transfer Hubs in Africa

The World Health Organization's initiative to establish mRNA vaccine technology transfer hubs in South Africa marked a pioneering step toward regional self-reliance. The hub, coordinated by WHO and Medicines Patent Pool, aimed to replicate Moderna's vaccine platform without direct company involvement, using publicly available data and reverse-engineering approaches. Challenges included limited availability of specialized raw materials, lack of trained workforce for lipid nanoparticle formulation, and stringent cold-chain requirements. Nonetheless, the hub successfully produced lab-scale mRNA vaccines for early training and proof of concept. This effort represented not just a transfer of manufacturing know-how, but also an investment in capacity building, regulatory strengthening, and long-term vaccine equity. The hub model, if scaled, could empower LMICs to reduce dependency on external suppliers while fostering South–South cooperation in quality-assured vaccine production (WHO, 2022; Oladipo, 2023).

Table 3: Comparison of Case Studies on Technology Transfer for Vaccine Manufacturing

Case Study	Objective of Technology Transfer	Key Challenges	Quality Assurance Strategies	Outcome / Impact
Oxford–AstraZeneca and Serum Institute of India (SII)	Rapid large-scale production of ChAdOx1 nCoV-19 to ensure timely access in LMICs	Scaling from pilot to billions of doses; maintaining consistency across sites	Joint quality teams; tech-assisted knowledge transfer; harmonized QC testing under WHO prequalification	Over 2 billion doses supplied globally; strong trust in SII as a global supplier (Somasundaram et al., 2021)
Bharat Biotech – Indian Immunologicals Ltd. (BIRAC-sponsored)	Expand domestic capacity for Covaxin via inter-company transfer	Facility adaptation for a novel inactivated platform; regulatory coordination	Structured documentation; BIRAC oversight; shared QA/QC protocols	Boosted Indian vaccine output during crisis; showcased public–private collaboration (BIRAC, 2021; DBT, 2021)

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mRNA Technology Transfer Hub, South Africa (WHO-sponsored)	Establish mRNA production capability in Africa for pandemic resilience	Lack of prior mRNA expertise; IP and know-how access barriers	Modular tech packages; open-access training; iterative validation with WHO support	Successful replication of mRNA prototype; groundwork for future local autonomy (WHO, 2022; Oladipo et al., 2023)

Source: Author own compilation.

Note. LMICs = low- and middle-income countries; BIRAC = Biotechnology Industry Research Assistance Council; QA/QC = quality assurance/quality control.

Role of Public–Private Partnerships and Global Consortia and knowledge transfer

COVID-19 vaccines constitute the most effective medical countermeasures for mitigating and ultimately ending the COVID-19 pandemic. As the global context shifts toward endemicity, persistent inequitable access to vaccines, especially in low- and middle-income countries (LMICs), continues to present significant risks, including widespread disruptions and the emergence of viral mutations that could result in vaccine-resistant variants. Strategies informed by previous responses to human immunodeficiency virus (HIV) and influenza outbreaks have guided efforts to prevent barriers to vaccine accessibility in LMICs. The intended societal benefit of SARS-CoV-2 vaccines was to address and reduce the racial, ethnic, and geographic inequities that COVID-19 has exposed and intensified.

Vaccine nationalism was a prominent feature during the COVID-19 crisis. Many high-income countries secured substantial advance orders for vaccines, resulting in restricted access for resource-limited countries. This disparity persisted despite international initiatives aimed at facilitating the development and equitable distribution of vaccines, such as the COVID-19 Vaccines Global Access (COVAX) pillar.

Significant supply shortages and national procurement strategies that circumvented the vaccine pillar hindered the effective operation of COVAX in delivering timely and adequate vaccine doses to participating countries. In response, COVAX promoted fundraising, coordinated vaccine donations from countries with surplus doses, expedited the review of vaccine candidates, and facilitated the expansion of manufacturing capacity. Technology transfer initiatives further reduced operational silos, enhanced

manufacturing standardization, and increased transparency in production data.

Two successful examples from India, among many, are the transfer of Covaxin® technology by Bharat Biotech to Indian Immunologicals Limited through a BIRAC-supported public partnership, which expanded domestic capacity while maintaining quality (Press Information Bureau [PIB], 2021). Another example is the adoption of vaccine technology from Oxford/AstraZeneca for large-scale production by Serum Institute of India. Ultracold storage requirements for leading mRNA vaccines, compounded by intellectual property restrictions, posed significant challenges to global immunisation efforts, particularly in LMICs with limited resources to support advanced cold-chain systems. Manufacturers sought to relax cold-chain restrictions based on stability data submitted to national regulatory authorities. The development of single-dose vaccines provided promising solutions to simplify the administrative and logistical complexities of COVID-19 vaccination programmes. Consequently, ultracold storage requirements were eased and concerns regarding booster doses were addressed. Additionally, to expand coverage, the dosing intervals for Oxford/AstraZeneca vaccines were extended in accordance with data from Phase III clinical trials on effectiveness.

Policy, Workforce Development, and Future Directions

Sustaining manufacturing excellence requires enabling policies, investment in a skilled workforce, and continuous innovation (Mehta, 2024). Global regulatory convergence, expansion of WHO PQ, and strengthening NRAs in LMICs will be critical. Technology transfer hubs, such as the WHO mRNA hub in South Africa, exemplify forward-looking strategies for vaccine equity (WHO, 2021; Mahoney, 2023). Efforts from intergovernmental organisations like the International Vaccine Institute in creating the workforce for the complete vaccine lifecycle with both theoretical and hands-on training programmes such as GTHB at site and offsite have created the required manpower for the globe, particularly supporting Africa and the ASEAN region.

Conclusion

Manufacturing excellence in vaccines is a multidimensional pursuit that integrates quality systems, regulatory maturity, and technology transfer. NRAs and WHO PQ frameworks provide the scaffolding for trust in vaccines, while quality assurance ensures consistency across the lifecycle. Effective technology transfer bridges global disparities in production capacity. Together, these mechanisms uphold vaccine quality and expand access-cornerstones of global health security.

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Realizing Equity in the Production and Access of Vaccines: Policy Framework for the Global South

K M Gopa kumar* and Chetali Rao**

Introduction

The COVID-19 outbreak exposed the world to the consequences of concentrated production and supply of medical products. Excessive dependence on producers from a limited number of countries not only delayed an effective pandemic response but also led to vaccine hoarding and stockpiling by the wealthier nations. Furthermore, this concentration of production emboldened vaccine manufacturers to impose immunity clauses, forcing countries to pledge foreign and military assets against future liabilities. These troubling experiences led to calls for equitable access to medical products required during health emergencies, particularly during epidemics. There has been a movement to designate all health products required for pandemic prevention, preparedness, and response as global public goods or global common goods (Katiuska King Mantilla et all (2022)). An important step toward realizing these goals is diversifying the production of health products, including vaccines.

In contrast to other medical products, particularlysmall molecule therapeutics, vaccines do not have an abridged. To obtain a marketing approval, a non-originator vaccine manufacturer must conduct both safety and efficacy studies. Lack of a streamlined regulatory pathway, coupledwith substantial high manufacturing facilities, constitutes significant and results in a highly concentrated vaccine production. Paradoxically, initiatives designed to facilitate vaccine access, led by the Global Alliance for Vaccines and Immunization (GAVI) and United Nations Children's Fund (UNICEF), furtherreinforce this concentration. Thusto promote a geographically, a range of structural and regulatory reforms are needed to reduce the entry barriers, without compromising vaccine safety and efficacy. Such diversification willensure reliable supply at affordable prices, especially during epidemic.

Against this background, this article proposes a set of measures for the Global South to facilitate equitable access through diversified vaccine production. The second section discusses the current global vaccine structure and its impact on vaccine access, including current global arrangements such as GAVI and UNICEF and their unintended consequences on

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diversified production. The third section examines relevant provisions of the International Health Regulations (IHR) and the Pandemic Treaty and their role in facilitating diversified vaccine production. The fourth section suggests measures for developing countries to realize diversified production and facilitate equitable vaccine access. The fifth section contains conclusions and recommendations.

Vaccine Market Structure

The vaccine market is a procurement-driven market dominated by governments and international agencies like UNICEF, PAHO, and UNICEF procurement financed by organizations like GAVI. WHO's South East Asia and Africa regions together account for 46 per cent of vaccine procurement by volume (WHO 2019). Self-procurement by middle-income countries accounts for 53 per cent of global vaccine procurement by volume, followed by UNICEF (including GAVI-funded procurement) at 47 per cent. Self-procurement by high-income countries represents only 9 per cent by volume. However, in value terms, high-income countries dominate the market. In 2018, high-income countries in WHO's American and European regions accounted for 68 per cent of the global vaccine market, valued at USD 26 billion. By 2023, this rose to 72 per cent of the global vaccine market, valued at USD 77 billion (WHO 2019).

Global vaccine production and supply are heavily dominatedby afew manufacturers. In 2023, just ten companies accounted for 73 per cent of the total volumes and 85 per cent of the market value. Conversely, only 90 other manufacturers collectively contributed only 27 per cent of volume and 15 per cent of value. A pronounced north-south divide exists in global vaccine manufacturing as highlighted by WHO in2025 (WHO, 2025). Manufacturers indeveloping countries produce half of the global vaccine volume but capture a mere 11 per cent of the market value. In contrast, companies from developed nationshold a commanding 85 per cent of market value while supplying only 34 per cent of volume.

The Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, produces 22 per cent of global volume but captures mere 2 per cent in terms of market value. In contrast, the second-largest vaccine producer, Pfizer, with 11 per cent of volume, accounts for 25 per cent of market value – making it the number one in terms of market value. Similarly, Merck and GlaxoSmithKline (GSK) rank second (18%) and third (16%) respectively in terms of value. GSK accounts for 7 per cent of volume, while Merck does not appear among the top ten manufacturers by volume (WHO 2025). Among the top 10 vaccine manufacturers by volume, six are from developing countries. Apart from SII, three more vaccine companies from developing countries appear among the top ten by value, each with a 1 per cent share.

While Developing Countries Vaccine Manufacturing Network (DCVMN)includes 48 vaccine manufacturers from 17 countries, bulk of high-volume productionis concentrated in India and China. The situation for African region remains extremely grim, despite representing the largest procuring regions by volume - the continent contributesonly 0.1 per cent of the global vaccine supply (GAVI 2022). Justfive countries - Algeria, South Africa, Ethiopia, Senegal, and Tunisia-have the capacity to produce at least one vaccine on the continent (Joachim Doua et al. 2025). Notably, the drug substance production facilities in Algeria, Senegal, and Tunisia are all operated byInstitut Pasteur. Currently, there are 158 prequalified vaccines from 44 manufacturers, comprising nearly 65 per cent of the global vaccine procurement volume (WHO 2025). Among these 44 prequalified manufacturers, only one producer from Africa is prequalified (WHO 2025).

International vaccine procurement has unintended consequences for local production. Since procurement by international organizations like UNICEF is limited to WHO-prequalified manufacturers, these agencies do not procure from local producers. This promotes economies of scale by prioritizing low-value, high-volume production, which leads to further market concentration. Non-WHO-prequalified local manufacturerscannot access procurement markets unless governments use their own resources for procurement (Connor Fuchs 2019).

Concentrated production and supply can disrupt access for those in need. A striking example is the refusal of US, Canada and Switzerland to provide Mpox vaccines from their strategic stockpiles in 2024 after Mpox was declared a public health emergency of international concern (Chetali Rao et al. 2024). Data also shows that UNICEF paid up to $65 per dose for Bavarian Nordic mpox vaccine (MVN-BN), which is over $10 per dose higher than the price paid by US government for the same vaccine (Public Citizen 2024). UNICEFs purchase price made MVN-BN one of its most expensive vaccines costing 26 times more than the other vaccines it procured in 2024. This clearly underlines the consequences of single-supplier dependence and raises issues about equitable access, since generic vaccines for the same can be supplied for a fraction of this cost.

The business model of large companies focuses primarily on clinical studies and product launches (Felix Lobo 2021). Most upstream research and product development occurs in small and mid-size companies. Vaccine development, especially for infectious diseases, relies heavily on public sector funding (Felix Lobo 2021).COVID-19 exemplifies this pattern, where most vaccines were developed with public funding through R&D support or advance market commitments.

COVID-19 experiences resulted in several initiatives to diversify vaccine production. WHO initiated the mRNA vaccine hub project to transfer mRNA vaccine technology to partners. However, the project design

and participation of actors from developing countries make the technological outcomes uncertain (Matthew Herder 2025). Another initiative is GAVI's Africa Vaccine Manufacturing Accelerator (AVMA), launched in 2024 to provide USD 1 billion over the next 10 years to promote local manufacturing. However, WHO prequalification is an important criterion for accessing this facility. According to the AVMA webpage, «Manufacturers may submit an application to GAVIfor an AVMA eligibility assessment during the WHO prequalification process but only after the vaccine manufacturing site visit by WHO Inspection Services is completed.» This criterion limits the number of African manufacturers eligible for AVMA financing.

Another initiative is CEPI's 100-day mission to develop vaccines within 100 days of a pandemic outbreak by «creating libraries of vaccine constructs against representative pathogens from virus families with greatest pandemic potential.» While it promises diversification, the plan delivers this through establishing a network of vaccine manufacturers without providing a clear roadmap for geographically diversified production. Interestingly, WHO's role in all these initiatives is minimal, despite its effective role in facilitating technology transfer of vaccines and other medical products (Melissa Barber 2024). These initiatives are insufficient to transform the existing vaccine market framework and foster geographically diversified production.

Despite vaccine hoarding and vaccine nationalism witnessed in the early COVID-19 pandemic, vaccines did slowly reach many developing countries, particularly low-and middle-income countries (LMICs), offering several lessons for the future. Firstly, while vaccine development typically takes 10-12 years, COVID-19 vaccines were introduced at a breakneck speed for human use within 8-11 months, demonstrating the possibility of reducing development timelines (Felix Lobo 2024). Secondly, mRNA vaccines, which can be produced through chemical synthesis, offer opportunities to revamp regulatory pathways, especially for non-originator production. Thirdly, massive contract manufacturing demonstrated that technology transfer and production can occur within 4-6 months, dispelling myths about complications in technology transfer and barriers for for diversified production. Lastly, public funding via R&D or advance market commitments (AMC) has reduced the financial risks for vaccine manufacturers, however, no robust mechanisms have been implemented to ensure equitable access, thereby enabling privatisation of profits.

Drawing learnings from the COVID-19 pandemic, legal reforms now are focused on crafting robust frameworks to address Public Health Emergencies of International Concern (PHEIC) and pandemics. Two initiatives launched in 2021 – the amendment of the IHR and the creation of a new legal instrument called the pandemic treaty, place equitable access as a main objective of these international law-making efforts. Rather than remaining reactive – these reforms increasingly seek to embed equity,

transparency and accountability into both PHEIC and pandemic prevention and response. Further, it also translated the idea of geographically diversified production from a policy objective into a normative goal.

Amendments to IHR and Pandemic Treaty

The current system fails to recognize developing countries' contributions to vaccine research while rewarding only the vaccine developers, most of whom belong to the Global North. Developing countries contribute to vaccine research, especially for infectious diseases, by timely sharing of pathogen samples and facilitating clinical trials. However, there is no legal assurancethat developing countries will be able to secure these vaccines at affordable prices. Vaccines are often protected by various forms of intellectual property rights, particularly patents and trade secrets. This creates an inequitable system that perpetuates inequity in both production and affordable access, contradicting the provisions of the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit Sharing. These legal instruments establish national sovereignty over genetic resources and obligate parties to link genetic resource sharing for R&D with benefit-sharing conditions. Many international pathogen-sharing arrangements contradict CBD and Nagoya Protocol provisions because they impose no clear obligations on parties accessing pathogen samples to share benefits with sample-providing countries.

Disturbed by lack of access and patenting of influenza pathogens, Indonesia ceasedsharing virus samples in 2007. This bold move sparked international negotiations which culminated in the establishment of a framework ensuring uninterrupted influenza pathogen sharing balanced by commitments to equitable vaccine access during influenza pandemics (Martin Khor 2007). The framework, known as the Pandemic Influenza Preparedness (PIP) Framework, adopted in 2010, obligates vaccine manufacturers to provide monetary contributions for system functioning and share 10 per cent of real-time production as donations to WHO. Additionally, vaccine manufacturers must reserve another 10 per cent of real-time production at affordable prices for WHO purchase. Monetary contributions from vaccine manufacturers have generated USD 270 million for the PIP Framework, supporting global pandemic preparedness and efforts. However, the PIP Framework's scope is limited to only influenza pandemics, consequently the same framework was not applicable to COVID-19 vaccine. Thus, COVID-19 manufacturers had no obligation to comply with these requirements (WHO 2021).

Widespread inequity in access to health products, especially vaccines, fundamentally reshaped global health diplomacy, pushing for the creation of a more equitable, transparent and fair system during the pandemic

preparedness. It triggered the launch of two negotiations among WHO member states aimed at creatingstrongerlegal frameworks to enhance preparedness for future disease outbreaks: negotiations to amend the International Health Regulations (IHR) and negotiations on the pandemic treaty. IHR amendment negotiations have, for the first time, incorporated access-related provisions, obligating WHO to take measures facilitating access and requiring IHR State Parties to cooperate with WHO in fulfilling these obligations (WHO 2024). However, these amendments do not spell out details of measures required to establish local production.

None of the Pandemic Treaty provisions, except Article 12, guarantee predictable access to vaccines and other health products. Article 12 establishes the Pathogen Access and Benefit Sharing (PABS) System (WHO 2025). Paragraph 1 states: «Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the rapid and timely sharing of 'materials and sequence information on pathogens with pandemic potential' (hereinafter 'PABS Materials and Sequence Information') and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes...» The details of the PABS system are currently under the negotiation.

Paragraph 6 of the Pandemic Agreement states: «each participating manufacturer shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20 per cent of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10 per cent of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization.» Careful reading reveals that Paragraph 6 creates clear obligations only for sharing 10 per cent of real-time production, while reserving additional percentages for sale at affordable prices varies by manufacturer capacity. Whether there will be obligations to share vaccine doses during PHEIC or maintain stockpiles remains unclear. Upcoming negotiations on the PABS System are expected to provide clarity.At this stage it remains unclear whether mandatory technology transfer to diversify and scale up production during a pandemic will be included as a part of the benefit sharing mechanism. Greater clarity is expected only after the conclusion of negotiations on the PABS System.

Although Articles 10 and 11 of the Pandemic Agreement recognize the need for production diversification and technology transfer, there is no guarantee these objectives can be achieved. Article 10 states: «The Parties

shall take measures, as appropriate, to achieve more equitable geographical distribution and rapid scale-up of the global production of pandemic-related health products and increase sustainable, timely and equitable access to such products, as well as reduce the potential gap between supply and demand during pandemic emergencies...» Paragraph 2 of Article 10 obligates parties to take certain measures for equitable geographical distribution, but these measures are qualified as «appropriate.» Paragraph 2 reads: «The Parties, in collaboration with the World Health Organization and other relevant organizations, shall, as appropriate and subject to national and/or domestic law...» Therefore, actual implementation may not achieve expected outcomes.

One listed measure reads: «take measures, to provide support for, and/or strengthen, existing or newly created production facilities of relevant health products, at national and regional levels, particularly in developing countries, with a view to promoting the sustainability of such geographically diversified production facilities, including through supporting and/or facilitating skills development, capacity-building and other initiatives for production facilities.» However, there is no guaranteed access to technologies for these facilities.

Technology transfer provisions under Article 11 limit the scope of technology transfer activities under the Pandemic Treaty. Paragraph 1 states: «Each Party shall, in order to enable the sustainable and geographically diversified production of pandemic-related health products for the attainment of the objective of the WHO Pandemic Agreement, as appropriate:» It then lists six measures. The first measure states: «promote and otherwise facilitate or incentivize, transfer of technology as mutually agreed.» The footnote to «mutually agreed» states: «For the purposes of the WHO Pandemic Agreement, 'as mutually agreed' means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.» Thus, technology transfer scope is limited to activities dependent on technology holders' willingness and does not guarantee transfer. One important demand during negotiations was mandatory technology transfer of publicly funded pandemic technologies, including vaccines. However, the pandemic treaty provides no guaranteed access to publicly funded R&D.

In the absence of a legally guaranteed framework for production diversification, developing countries must implement policies to achieve local production capacities at national or regional levels.

Towards a Policy Framework for Local Production

While numerous barriers hinder vaccine production diversification, four primary challenges stand out: the cost of manufacturing facilities, restrictive

intellectual property rights, complex regulatory frameworks, and the prevailing market structure.

Role of State: R&D and Production: As mentioned above, most vaccine R&D is government-funded. However, governments often fail to take concrete measures to facilitate access to affordable vaccines, especially in developing countries. Without conditions ensuring equitable access, vaccine funding primarily functions as a mechanism to de-risk R&D while ultimately enhancing private sector profitability rather than guaranteeing broader public access. Governments must balance public funding for vaccine R&D withensuring affordable access. A successfulexample of the above is the development of a cervical cancer vaccine in India by the Serum Institute of India with funding fromthe Department of Biotechnology, Government of India. This non-originator vaccine costs USD 3.4 to 4.5 as compared to the originator's price of USD 45-102 (Sarah Johnson 2024). The COVID-19 vaccine research and development clearly show the role of public fund in the vaccine development. Public sector accounts nearly 98.15 per cent of the COVID-19 vaccine R&D while the share of private sector is only 0.29 per cent (Katiuska King Mantilla et all 2022). Additionally, beyond R&D funding, governments should maintain a control over the production capacities by directly or indirectly owning production facilities, as the private sector often lacks interest in establishing local production that may not provide direct financial returns. Sole dependency on private sector could pose a danger to secured supply (Sudip Chaudhuri 2022). Further, vaccine is also closely linked to health security where the public sector productioncould play an important role in facilitating production of commercially non-attractive vaccines. Realizing the importance of health security many new investments are made to establish publicly owned vaccine manufacturing facilities (Peter J Hotez 2021).

Cost of Manufacturing Facilities: Vaccine production costs vary significantly based on technology platforms used with factors such as capital investment and manufacturing complexity influencing expenses. Furthermore, no single manufacturing facility is equipped to produce all vaccine types, as different platforms require different equipment's, processes and expertise . Manufacturing facility establishment costs therefore constitute an important barrier. Traditional technology platform facilities cost approximately USD 105-225 million to establishhowever, a modular facility could be established for as low as USD 30-65 million (UNIDO 2017). This offers Global South an opportunity to invest in such plants for the local production.

Intellectual Property (IP) Barriers: Like other pharmaceutical products, vaccines are protected through various IP forms, including patents and trade

secrets. Unlike small chemical molecules, single patents cannot protect vaccines. Generally, patents are sought on various vaccine aspects: vaccine materials, adjuvants, lipid particles used in production, delivery devices, or production processes. Proper implementation of TRIPS flexibilities can eliminate patent protection on certain vaccine materials, such as inactivated or partially activated pathogens or pathogen particles. The implementation of TRIPS flexibilities could restrict multiple patents around a vaccine and bring down the patent barriers. Patent examination guidelines focusing on vaccines could provide clear gaudiness to the patent examiners to avoid patent thickets.

The most significant IP barrier in vaccine production is trade secret protection.Vaccine production is often protected as trade secrets, requiring non-originator vaccine producers to demonstrate evidence of following originator production methods. Without such evidence, non-originators are typically treated like originators and must prove the safety and efficacyof the vaccine (K M Gopakumar et. al. 2021). In this context, providing exceptions to trade secret protection is important. Regulatory authorities often protect manufacturer-submitted dossiers as trade secrets and do not share information with non-originator vaccine manufacturers. There should be exceptions to this general rule, and dossiers or contained information should be shared in the following circumstances (Chetali Rao et. al. 2023) :

- Public health emergencies
- Facilitating production under compulsory or government use licenses
- Speeding up originator production to address high prices
- Addressing unmet needs

Article 39.3 of the TRIPS Agreement allows such limited exceptions to trade secret protection. According to Article 39.3, TRIPS members can allow test data disclosure when necessary to protect the public or after ensuring «data are protected against unfair commercial use.» However, strict reading of Article 39.3 reveals it addresses only new chemical entities, not biologics. Since vaccines are generally treated as biologics, Article 39.3's scope may not cover them.It is important that the medicine regulatory authorities make exceptions to the trade secret rule to protect the public health. Doha Declaration on the TRIPS Agreement and Public Health reiterates the right to provide such exception. It states: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

Regulatory Reform: Unlike biotherapeutics, there is no abbreviated regulatory pathway for most vaccines, except for diseases that are eradicated (like smallpox) or those with immune correlate of protection (ICP) (WHO 2017). According to WHO, efficacy trials are not required when: «it is established that clinical immunological data can be used to predict protection against disease. For example, if there is an established ICP against a specific disease (for example, antitoxin levels against diphtheria and tetanus toxins, or antibody against hepatitis B surface antigen) the candidate vaccine should be shown to elicit satisfactory responses based on the relevant correlate(s).» This means in all other circumstances the non-originator companies also needs to prove the efficacy of the vaccine. Clinical trials to establish the safety and efficacy are both costly and time consuming, representing a significant barrierthat is more pronounced as compared to small molecule drugs. The absence of an abbreviated pathway for non-originator vaccine is emanating from the assumption that any deviation from the originator's pathway would have implications on safety and efficacy. The scientific basis of this assumption warrants a re-evaluation in the light of recent advancements in science and technology. Notably, similar assumptions regarding biotherapeutics have faced scrutiny, leading to bodies like the WHO, the UK regulatory agency to eliminate the requirement of comparative efficacy study in the marketing approval of biosimilars.

The WHO has formally revised its 2009 influenza focused regulatory guidelines to adopt a broader risk-based frameworks for all pandemic vaccines and continues to leverage mechanisms like Emergency Use Listing (EUL) for health emergencies (WHO). However, scientific and technological developments offer possibilities for abbreviated regulatory pathways for non-originator vaccine and not just pandemic vaccines. Advances in recombinant DNA technology have transformed vaccine development offering precise characterization. Since recombinant DNA methods allows precise characterization at molecular level. This creates opportunities for applying the biosimilar pathways to vaccines (Michael J Corbel (2009). Similarly, mRNA vaccines can be characterized more as chemical vaccines than biological vaccines, offering possibilities for developing generic vaccine pathways.

Technology Transfer: Most discussion surrounding vaccine technology transfer operate on the assumption that a successful technology transfer is nearly impossible without the cooperation of the originator vaccine manufacturer. This largely stems from the current regulatory frameworks that do not accommodate non-originator pathways for most vaccine, thereby reinforcing originator control over manufacturing and approval process. However, science and technology now offer clear possibilities on vaccine reverse engineering challenging the current paradigms. The

regulatory assumption that any deviation from originator manufacturing processes affects vaccine safety and efficacy makes reverse engineering efforts ineffective due to huge clinical trial costs required to prove safety and efficacy (K M Gopakumar et. al. 2021). In other words, the absence of abbreviated pathway does not offer much advantage especially the time and cost required to bring non-originator vaccine in the market. As mentioned above, regulatory system reforms to create abbreviated vaccine pathways for non-originator manufacturing can reduce technology transfer barriers. This would pave the way for parallel technology transfer routes for vaccines, which can be implemented without the cooperation of the originator within a short span of time.

Reform the International Procurement Market: International procurement under various agencies often requires WHO prequalification as a precondition. This excludes all local manufacturers from international procurement markets and disincentivizes local production. Reforming current international procurement rules is important for facilitating local production. As shown above the current international procurement mechanisms leads to more concentration and undermines the local production. There should be efforts to reform the procurement from domestic manufactures, who satisfies the quality standards of national regulatory authorities. The WHO prequalification process for vaccines, while essential for safety and efficacy, is both costly and time consuming. Furthermore, it only permitsthe inclusion of only those manufacturers operating under maturity level of 3 and 4 (Sanjana Mukherjee et al 2023). This maturity threshold acts as a significant barrier for new or less resourced manufactures from entering the market. The list of regulatory authorities with Maturity Level 3 and 4 contains 14 developing countries excluding Singapore and South Korea. Out of these 14 regulatory agencies eight belongs to Africa however vaccine production is happening only within the jurisdiction of two regulatory authorities. Consequently, the prequalification process, inadvertently limits the diversity of vaccine suppliers available for international procurements and limits access and affordability of vaccines.

Conclusion

The COVID-19 pandemic exposed to the world the vulnerabilities of a highly concentrated global vaccine production controlled by a handful of manufacturers predominantly based in the Global North. Though developing countries contribute to the vaccine research through pathogen sharing and clinical trial facilitation, the benefits of vaccine R&D is not shared in a fair and equitable way. Initiatives to promote access at the international level through international procurement leads to further concentration and

undermines local production. The current situation calls for fundamental restructuring of the global vaccine ecosystem through geographically diversified production capacities, particularly in the Global South. This is critical in the light of the R&D pipeline which contain nearly 68 per cent vaccines for prophylactic and 25 per cent for oncology. Further, vaccines are now projected to address the antimicrobial resistance.

In order to realize objective of geographically diversified production of vaccines, developing countries need to pursue a biopharmaceutical industrial policy with targeted interventions. These interventions include strategic government investment in R&D and manufacturing facilities, implementation of TRIPS flexibilities to address intellectual property barriers, regulatory reforms to create abbreviated pathways for non-originator vaccines, and reformation of international procurement mechanisms that currently exclude most of local manufacturers from developing countries. Only through such comprehensive reforms can Global South achieve vaccine sovereignty and ensure that the future of health emergencies do not replicate the inequities witnessed during COVID-19. The health security and economic resilience of developing nations depend on this transformation from dependence to self-reliance in vaccine production and access.

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From Lab to Last Mile: Platform Technologies Enabling Vaccine Equity

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Abstract: Achieving vaccine equity is one of the most critical global health challenges. This is especially true in low and middle-income countries, where access barriers persist despite scientific advances. This chapter examines how platform technologies, such as mRNA, viral vectors, virus-like particles (VLPs), and nanoparticle-based delivery systems can revolutionize vaccine development and distribution. These platforms offer modular, rapidly adaptable, and scalable approaches. As a result, they enable swift responses to emerging infectious diseases and reduce time-to-market for vaccines targeting neglected diseases. The chapter also highlights how innovations such as improved thermostability, single-dose regimens, and needle-free delivery enhance access in resource-limited settings. Additionally, digital health tools, decentralized manufacturing, and open-source licensing models are revolutionizing the delivery of vaccines to the last mile. By bridging the gap from laboratory breakthroughs to equitable immunization, platform technologies offer a sustainable path toward global vaccine justice.

Introduction

The vaccine equity gap: from innovation to immunization

Despite major advances in vaccine science and biotechnology, a significant equity gap persists. Innovative vaccines are not delivered equitably to all populations. This gap is most visible in low and middle-income countries (LMICs), where life-saving vaccines arrive years after their launch in high-income places, or sometimes not at all (Duan et al., 2021, Subsittipong et al., 2022). Many interlinked challenges drive this gap. These include limited local manufacturing, regulatory delays, high costs, poor cold-chain infrastructure, and fragmented health systems (Wouters et al., 2021). Intellectual property restrictions, a lack of technology transfer (Storeng et al., 2021), and insufficient investment in local disease burdens also hinder access (Sharma et al., 2025). The COVID-19 pandemic exacerbated these problems. Vaccine nationalism and supply chain issues left vulnerable populations behind. Even when vaccines are available, other barriers, such as, vaccine hesitancy (WHO, 2015) and low community engagement (Etowa et al., 2024) can hinder uptake. Solving this equity gap requires much more

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than just developing new products. Approaches must include platform-based manufacturing, regulatory harmonization, open licensing, and global financing tools. Local innovation, strong public–private partnerships, and better health infrastructure are all essential to share scientific advances equitably (Kana et al., 2023), from the lab to the last mile. This paper focuses on how platform technologies can be utilised to enable faster innovations and how self-reliance can be achieved in times of health crisis to facilitate equitable access to vaccines/medicines. This manuscript describes various platform technologies available and how they were handy in managing the covid-19 pandemic and their future potential in meeting epidemics/pandemics.

[Give a brief introduction on what are platform technologies before proceeding to next section would give a clarity/idea to readers who have no knowledge of it and on- Are different platform technologies are different from other vaccine technologies (how and why they are called so) that ultimately gets translated into innovations of pharmaceutical products, and various stages of processes starting from platform technologies to final product (vaccines ortherapeutics etc.). Who owns platform technologies and how to access them, etc.]

Platform technologies in vaccinology are adaptable frameworks for developing vaccines. Instead of designing everything from scratch for each pathogen, a platform provides a common backbone (vector, delivery system, or manufacturing process) that can be quickly adapted by inserting or encoding pathogen-specific components (e.g., antigen sequences). The development process typically moves from establishing the platform to antigen integration, preclinical studies, clinical trials, and final product manufacturing, with much of the safety and process data reused across different vaccines. This accelerates development timelines, reduces cost and streamlines regulatory evaluation. We can segregate platform technologies in two parts: i) core component ((the vector, nucleic acid, or delivery system) and (ii) the variable component which is pathogen specific antigen sequence. Platform vaccines differ from conventional ones in that they use a standardized backbone—such as a viral vector, nucleic acid construct, or delivery system—into which different antigens can be inserted, rather than relying on pathogen culture or attenuation. Major vaccine platforms include mRNA and DNA vaccines, which encode antigens for in vivo expression; viral vectors, which deliver genes using modified viruses; protein subunits, which use purified recombinant proteins with adjuvants; and microneedle patches, which provide innovative delivery directly to the skin. Each platform has distinct advantages and limitations in terms of speed, stability, immunogenicity, and ease of distribution. Platform technologies are largely owned by biotech companies, pharmaceutical firms, and academic institutions. Access is typically through licensing, collaborations, public–private partnerships, or global initiatives like the

WHO mRNA tech transfer hub, which aim to expand equitable availability in low- and middle-income countries. However, intellectual property protections, restrictive licensing, and high development costs remain major challenges, often limiting technology transfer and widespread availability. To understand the implications of IPR on platform technology, let's consider an example from the most trusted and advanced platform during the COVID-19 pandemic, namely, mRNA vaccine technology. The earliest work on mRNA modification and stabilization was done in academia. Prof Katalin Karikó and Drew Weissman (University of Pennsylvania) discovered in the mid-2000s that modified nucleosides (like pseudouridine) could reduce immune responses to synthetic mRNA. Their patents are considered foundational (background IP) and are licensed to companies like BioNTech and Moderna. Moderna further developed and owns a large patent portfolio on mRNA design, lipid nanoparticle (LNP) delivery systems, and therapeutic applications. Similarly, BioNTech developed and holds patents on modified mRNA constructs, vaccines, and therapeutic uses. Another company, CureVac, which is again an early pioneer in mRNA vaccines, succeeded in getting patents on mRNA structure and expression optimization. Another company, not a vaccine company, Arbutus Biopharma & Genevant Sciences, owns critical patents related to lipid nanoparticles (LNPs) used to deliver mRNA into cells.

Platform Technologies as Accelerators of Scalable, Adaptable Solutions

Platform technologies are crucial to achieving vaccine equity, as they enable scalable, rapid, adaptable, and cost-effective vaccine development and distribution, particularly in resource-limited settings (Charlton et al., 2017). These span manufacturing, formulation, delivery, and data technologies. By addressing key barriers throughout the vaccine lifecycle, from development to immunization, platform technologies can bridge the persistent equity gap more effectively than traditional approaches. Crucially, unlike disease-specific pipelines, platforms such as mRNA, viral vectors, DNA, protein subunits, and microneedle patches offer modular, reusable frameworks, vastly reducing the time, cost, and complexity involved in delivering vaccines for both emerging and neglected diseases (Yang et al., 2025). This is particularly important for low- and middle-income countries (LMICs), which have historically been underserved. Decentralized manufacturing is a pivotal advantage, as standardized, scalable platform processes enable technology transfer to regional hubs, empowering LMICs to produce vaccines locally and building resilience against global supply chain disruptions (Kumraj., 2022). Open licensing and partnerships further support this shift, ensuring even resource-limited countries can access vaccine innovations.

mRNA vaccine platforms enable the rapid design and synthesis of vaccines once a pathogen's genetic sequence is known. The success of mRNA vaccines against SARS-CoV-2 showed their ability to respond quickly to health emergencies, with high potency, low contamination risk, and scalable manufacturing (Szabo et al., 2022). Similarly, viral vector platforms (e.g., adenovirus-based) offer robust cellular immunity and have been adapted for use in the treatment of Ebola, COVID-19, and HIV (Syyam et al., 2022). These platforms can be quickly modified for new variants or emerging threats without requiring the reengineering of the entire infrastructure (Okuyama et al., 2023).

Virus-like particles (VLPs) and nanoparticle platforms mimic the structure of viruses without containing infectious material, eliciting strong immune responses while remaining safe (Dhawan et al., 2023). VLPs are used in hepatitis B and HPV vaccines, and their modular design is well-suited for multi-valent or combination vaccines (Kheirvari et al., 2023). DNA-based and protein subunit platforms offer thermostability, cost-effectiveness, and potential for microbial or plant-based production (Cid et al., 2021), making them accessible for decentralized or resource-limited manufacturing.

Platform technologies offer scalable manufacturing: once established, platforms can be scaled rapidly to meet demand. Standardization streamlines regulatory review, enabling faster clinical trials and approvals during emergencies. Modular biomanufacturing units deployed regionally enhance local production and reduce dependence on the supply chain (Vicardo, 2024). Formulation innovations such as thermostabilization, lyophilization, and needle-free delivery—improve shelf life, reduce cold-chain dependency, and enable easier deployment in remote areas, thereby addressing last-mile delivery challenges in immunization (D'Amico et al., 2021).

Ultimately, the defining contribution of platform technologies is enabling true vaccine equity on a global scale. Their modularity and speed support pan-pathogen preparedness, enabling health agencies and governments to proactively develop vaccine candidates and respond quickly to new threats. When coupled with open models, data sharing, and partnerships, these technologies make vaccine development accessible and scalable for all, empowering broader participation and benefiting a wider audience. In essence, platform technologies represent a paradigm shift—moving from faster vaccine delivery alone to fundamentally supporting equity, sustainability, and preparedness across global public health.

Rationale for a Dual Focus: Manufacturing Platforms and Delivery Platforms

To close the vaccine equity gap, both manufacturing and delivery platforms must advance in tandem. Manufacturing ensures rapid, scalable vaccine production, while delivery platforms enable effective immunization, especially in low-resource and remote settings.

Manufacturing Platforms: Accelerating and Decentralizing Vaccine Production

Modern manufacturing platforms—such as mRNA, viral vectors, DNA, protein subunits, and virus-like particles (VLPs)—offer flexible, scalable solutions that can be rapidly adapted to different pathogens (Vicardo, 2024). These platforms significantly reduce the time from pathogen identification to vaccine readiness by enabling a modular «plug-and-play» design, where only the antigenic sequence changes, but the production and purification workflows remain the same. This allows for faster regulatory approval and the establishment of stockpiles for emerging infectious threats (Yang et al., 2025). [is regulatory approvals same for platform technologies and other biologicals/ pharmaceutical products? It's not clear. Please elaborate on thsi] Platform technologies undergo the same approval pathway but benefit from regulatory flexibilities that allow partial reuse of established data, reducing duplication and speeding up authorization. For platform technologies, the backbone (e.g., viral vector, mRNA–LNP, DNA plasmid) is treated as a reusable component, therefore,once validated, much of its CMC, toxicology, and delivery safety data can be reused across products. Only the "variable component" (new antigen sequence or protein) requires fresh evaluation in preclinical and clinical studies. This data-bridging approach shortens development timelines and facilitates faster approvals, as seen with COVID-19 vaccines where existing mRNA and adenoviral vector platforms accelerated regulatory review.

Moreover, the emphasis on platform-based manufacturing supports decentralized and regional production, critical for improving access in LMICs. Modular biomanufacturing facilities equipped with standardized platform technology can be established closer to where vaccines are needed, reducing reliance on global supply chains, avoiding export restrictions, and enhancing regional self-sufficiency. This also creates opportunities for local workforce development and technology transfer.

Delivery Platforms: Enabling Reach, Coverage, and Impact

Even the most advanced vaccines are ineffective if they cannot reach the people who need them. Delivery platforms—which encompass not only the physical method of administration but also formulation, packaging, and distribution systems—are crucial for ensuring equitable immunization. These include innovations such as:

i) Thermostable formulations that remove cold chain dependence,
ii) Microneedle patches, inhalable vaccines, and oral delivery platforms that eliminate the need for trained healthcare workers or cold storage,
iii) Single-dose regimens that improve compliance and logistics,

Digital tracking and mobile health platforms to manage inventory, monitor coverage, and engage communities. These delivery innovations become indispensable in contexts such as fragile health systems, conflict zones, or rural regions, where conventional solutions encounter substantial barriers. By emphasizing both manufacturing and delivery platforms together, stakeholders can rapidly respond to outbreaks, strengthen health system resilience, and extend equitable access to immunization—fully addressing both upstream and downstream challenges in vaccine equity. [at what stage the above mentioned innovations are in India compared to the other parts of the World?] In India digital platforms like eVIN digitizes vaccine supply chains nationwide, while CoWIN successfully managed COVID-19 vaccination and is being extended to routine immunization. U-WIN, launched in 2024, aims to provide a real-time digital registry for children and pregnant women and is currently in phased rollout. Broader systems like Integrated Health Information Platform (IHIP) support disease surveillance, and Ayushman Bharat Digital Mission / Health Account (ABDM/ABHA) provide the backbone for digital health IDs and interoperability. Together, these platforms demonstrate India's advanced capacity for large-scale digital health implementation, though challenges remain in full national coverage, data integration, digital access, and privacy safeguards.

iv) In summary, simultaneously advancing manufacturing and delivery platforms not only drives scientific innovation but turns it into real-world impact—ensuring that vaccines are produced at scale, reach all communities efficiently and equitably, and close the vaccine equity gap for good.

Platform Technologies for Ensuring Vaccine Equity

mRNA Vaccine Platforms: mRNA vaccines represent a paradigm shift in vaccinology, using synthetic messenger RNA encoding the target antigen, encapsulated in lipid nanoparticles (LNPs). Originally developed through research into in vitro transcription systems in the 1980s (Weissman & Karikó, 2005), key advances include nucleoside modification to reduce innate immune activation and increasing the stability of mRNA. [provide some examples during the covid times, if there are any successful cases from the other countries. Are there examples of potential successful examples but certain barriers could not enable them?]

Modular Adaptations: The BioNTech "BioNTainer" model, a containerized, modular manufacturing system, allows for rapid deployment in regions with limited biomanufacturing capacity. Nucleotide sequence changes for new targeted antigens require minimal process redesign, making it a true "plug-and-play" system for new

pathogens.[what kind of infrastructure and capacity building is required to do so in India or in LMICS? What is the status in the rest of the World?] Making mRNA vaccines in LMICs is possible, but it needs strong investment in modern manufacturing (GMP facilities), lipid nanoparticle (LNP) formulation, quality testing, cold-chain systems, skilled staff for all these areas, and clear regulatory pathways. Access to the core technology also has to be negotiated. Global efforts like the WHO mRNA hub and CEPI partnerships are working to close these gaps, but large-scale commercial production is still underway

Equity Relevance: Rapid design (weeks), adaptability, and potential for local deployment improve pandemic responsiveness. However, ultra-cold storage needs remain a barrier for low-resource settings. [what kind of capacity building is needed to overcome such barriers?] THis has been answered above

Case Study: BioNTech's BioNTainer and mRNA Vaccine Capacity in Africa

In 2022, BioNTech [give details about if BioNTech is a company, based in which country etc. for the benefit of readers] BioNTech SE is a biotechnology company from Mainz, Germany, founded in 2008. It focuses on mRNA-based therapies for cancer and infectious diseases and co-developed the first approved COVID-19 mRNA vaccine (Comirnaty) with Pfizer (USA). BioNTech is a global leader in mRNA design, LNP delivery, and manufacturing . These companies launched the BioNTainer initiative, a modular system housed in shipping containers designed to bring end-to-end mRNA vaccine manufacturing to Africa. The concept emerged from lessons during the COVID-19 pandemic, when African countries relied almost entirely on imports, with over 80 per cent of doses shipped from Europe or Asia. BioNTainer units integrate drug substance (DS) production, including mRNA synthesis, purification, and lipid nanoparticle encapsulation, within a compact, GMP-compliant environment. Installed in Rwanda and Senegal, these facilities were paired with workforce development programs that trained local scientists and engineers in advanced biomanufacturing. By decentralizing production, BioNTainers reduces dependency on transcontinental supply chains, which were vulnerable to export bans during the pandemic. Importantly, the modular design allows reconfiguration to produce vaccines beyond COVID-19, such as those targeting malaria, tuberculosis, or future emerging pathogens.

For equity, the model embodies a paradigm shift: instead of donor-driven dose provision, LMICs gain ownership of vaccine production capacity. Challenges remain, such as ensuring stable fill-finish capacity and integrating regulatory oversight, but the initiative represents a critical step toward closing the North–South vaccine gap. If scaled, BioNTainers could

serve as replicable hubs across regions, offering standardized, transportable mRNA capacity that is both adaptable and sustainable. The approach demonstrates how platform modularity + localized training can structurally reshape global vaccine equity.

Viral Vector Platforms: These use replication-deficient viruses (e.g., adenoviruses) as carriers for antigen genes. Technology matured in the 1990s through gene therapy trials (Dull et al., 1998). [give some examples, also their relevance with examples during covid time]. During COVID-19, this platform proved to be very crucial: the Oxford/AstraZeneca vaccine (ChAdOx1 nCoV-19, Covishield in India) used a chimpanzee adenovirus vector and enabled rapid, large-scale vaccination globally, especially in LMICs. The Johnson & Johnson/Janssen vaccine (Ad26 vector) provided a single-dose option, improving access in resource-limited settings. Russia's Sputnik V used a heterologous prime-boost adenovirus vector system (Ad26 + Ad5). These examples show how viral vector platforms offered scalable, affordable, and adaptable solutions, particularly valuable where ultra-cold storage (needed for mRNA vaccines) was a challenge.

Modular Adaptations: Adenovirus backbones have been engineered for multiple antigens and reused for different pathogens. Manufacturing leverages mammalian cell culture facilities, often already present in LMICs, including India. During the COVID-19 pandemic, SSI adopted this technology from Oxford University via AstraZeneca. By the end of November 2021, SSI produced 1.25 billion doses, with a monthly capacity of about 120 million doses.[give some examples, also their relevance with examples during covid time].

Equity Relevance: Unlike the mRNA vaccine, which requires temperatures below 80 °C for storage, this vaccine can be stored at 2 °C to 8 °C; thus, it needs simple refrigeration and can be stored at room temperature for up to 6 hours. This feature supports immunization programs through multidose presentation. . [give some examples from Covid pandemic times] [give examples for all the platform technologies described in this manuscript with respect to Covid pandemic and their status and how any hinderances experienced can be overcome in future through appropriate measures]

Case Study: Oxford–AstraZeneca Viral Vector Vaccine and Licensing to the Global South

The Oxford–AstraZeneca ChAdOx1 nCoV-19 vaccine, based on a chimpanzee adenoviral vector, became a cornerstone of equitable vaccine distribution during the COVID-19 pandemic. Unlike mRNA vaccines, which required ultra-cold storage, ChAdOx1 was stable at 2–8°C, making

it suitable for use in LMICs with limited cold-chain infrastructure. From the outset, Oxford University pursued a nonprofit strategy during the pandemic, licensing AstraZeneca to distribute the vaccine at cost. AstraZeneca, in turn, established over 20 technology transfer agreements, most notably with the Serum Institute of India (SII), the world's largest vaccine producer. SII scaled production to billions of doses, becoming the primary supplier for COVAX. By mid-2022, over 1.5 billion doses had been distributed globally, reaching more than 170 countries.

Despite these issues, the Oxford–AstraZeneca case set a benchmark for equitable vaccine deployment. It showed that viral vector platforms, combined with global partnerships and LMIC-based manufacturing, can enable affordable access during pandemics. The experience highlights the importance of early IP sharing, South–South collaboration, and transparent governance in sustaining equity beyond emergencies.

Virus-Like Particle (VLP) Platforms: VLPs mimic virus structure without genetic material, inducing strong immune responses. First successful use was the HPV vaccine (Schiller & Lowy, 2006).

Modular Adaptations: Expression in yeast, insect, or plant systems enables adaptation for many antigens and production in distributed facilities.

Equity Relevance: Thermostability and use of low-cost host systems improve feasibility in LMICs.

Case Study: Medicago's Plant-Based VLP Vaccine in Canada

Medicago's COVID-19 vaccine, authorized in Canada in 2022, was the world's first approved plant-based VLP vaccine. [how many were vaccinated with this plant vaccine and how many or percentage population were protected from Covid-19 injection?] This vaccine was tested in 24,000+ adults across six countries. It showed ~71 per cent protection against symptomatic COVID-19 (ages 18–64)., ~75 per cent against Delta, ~89 per cent against Gamma and 100 per cent efficacy against severe disease (though few cases). This vaccine is authorized for two-dose schedule for adults 18–64. This vaccine was rolled out in Canada only; there is no clear data on how many people actually received it beyond clinical trials (https://www.gsk.com/en-gb/media/press-releases/medicago-and-gsk-announce-positive-phase-3-efficacy-and-safety-results/). The technology used Nicotiana benthamiana, a relative of tobacco, as a biofactory to produce self-assembling virus-like particles displaying the SARS-CoV-2 spike protein. The process involved transient expression via Agrobacterium tumefaciens infiltration, with VLPs harvested within days-much faster than traditional egg- or cell-based systems. This approach offered rapid scalability, reduced

reliance on mammalian cell cultures, and lower infrastructure costs. In principle, VLP production in greenhouses or vertical farms could be adapted for LMIC settings, offering a low-barrier vaccine platform with fewer biosafety requirements.

FMedicago's case highlights both the promise and vulnerability of alternative platforms: even sound, equity-enabling technologies can fail without sustained funding, policy support, and secure procurement. Nevertheless, plant-based VLP platforms offer modular, distributable manufacturing models that could help LMICs build regional vaccine capacity using agricultural infrastructure. The key lesson: future efforts must leverage global consortia and demand guarantees to turn innovation into equitable health impact.

Protein Subunit Platforms: These platforms represent purified antigenic proteins produced in microbial or eukaryotic expression systems. Protein subunit vaccines have been used for decades (e.g., Hepatitis B, 1986).

Modular Adaptations: Expression vectors and adjuvant formulations can be readily adapted for different antigens.

Equity Relevance: Low-cost manufacturing, minimal cold chain requirements, and compatibility with existing fill-finish lines make these particularly LMIC-friendly.

Case Study: Novavax Protein Subunit Vaccine and Global Partnerships
Novavax developed NVX-CoV2373, a recombinant protein subunit vaccine produced using a baculovirus–Spodoptera frugiperda insect cell system. Unlike mRNA vaccines, NVX-CoV2373 was stable at standard refrigerator temperatures, making it compatible with LMIC health systems. The vaccine contained full-length spike proteins formulated with Matrix-M, a saponin-based adjuvant that enhanced immunogenicity at lower antigen doses. To scale access, Novavax partnered with the Serum Institute of India (SII), ensuring high-volume production for global markets. SII's involvement was crucial for supplying doses through COVAX, particularly to Asia, Africa, and Latin America.

Initially, Novavax faced delays in regulatory filings and production, which limited early rollout. However, once approved, the vaccine became an affordable alternative for countries unable to store or distribute ultra-cold-chain products. Equity benefits were significant: by leveraging existing protein production expertise in LMICs, Novavax reduced costs and diversified the vaccine landscape beyond mRNA. Importantly, protein subunit vaccines are familiar to regulators and health systems, facilitating uptake where newer platforms faced skepticism.

The case highlights the strategic role of protein-based vaccines in achieving equity: they bridge cutting-edge immunology with established infrastructure, ensuring that LMICs are not excluded from innovation cycles. In the long term, the Novavax model highlights the importance of platform-agnostic preparedness, where investments in multiple vaccine modalities foster resilience against supply bottlenecks and ensure broader geographic participation in production.

DNA Vaccine Platforms: DNA vaccines deliver plasmid DNA encoding the target antigen, which is transcribed in vivo. Developed in the early 1990s (Wolff et al., 1990), improvements include optimized promoters, CpG motifs, and delivery via electroporation or needle-free injectors.

Modular Adaptations: The same fermentation and purification processes can be used for different plasmids, enabling multi-pathogen manufacturing in a single facility.

Equity Relevance: Ambient-temperature stability and low production costs make DNA vaccines especially suited for resource-limited areas.

Case Study: ZyCoV-D – The World's First Approved Human DNA Vaccine ZyCoV-D, developed by Zydus Cadila, represents a milestone in vaccine innovation as the first DNA vaccine approved for human use. Granted Emergency Use Authorization by India's Drugs Controller General (DCGI) in August 2021, ZyCoV-D was designed to combat SARS-CoV-2 during the COVID-19 pandemic. Unlike traditional needle-based vaccines, ZyCoV-D employs a needle-free intradermal delivery system (PharmaJet's Tropis® injector), which not only improves compliance but also reduces needle-associated risks and hesitancy.The vaccine is based on a plasmid DNA platform, encoding the spike protein of SARS-CoV-2. Once administered, the plasmid enters host cells, leading to antigen expression and subsequent immune activation. Zydus optimized plasmid design and expression cassettes to ensure stable production at scale. Importantly, the platform is modular, meaning future plasmid swaps could rapidly generate vaccines for emerging pathogens.

From an equity perspective, ZyCoV-D is a strong example of innovation from the Global South. Developed entirely in India, with clinical trials involving over 28,000 participants across the country, it demonstrates the feasibility of indigenous vaccine R&D and manufacturing. The vaccine also avoids cold-chain dependency of mRNA vaccines, making it suitable for distribution in resource-limited regions. [what is the percentage of population vaccinated with this vaccine in India or elsewhere?] As of a report, ZyCoV-D had not been administered outside of clinical trials as

per the CoWIN portal, meaning no public vaccination numbers beyond trials were recorded. (https://www.thehindu.com/sci-tech/health/indias-other-covid-vaccines-status-of-under-trial-approved-but-unused-jabs/article65410283.ece)

Scalability was ensured by Zydus' in-house DNA manufacturing facilities, which were expanded to produce up to 10–12 million doses per month at peak capacity. Beyond COVID-19, ZyCoV-D showcases the potential of DNA vaccine platforms to provide rapid, locally developed solutions for future outbreaks, strengthening vaccine sovereignty in LMICs.

Delivery Platforms (Microneedles, Dermal Patches): Developed to improve compliance and distribution, microneedles and patches deliver vaccines intradermally, often without trained medical staff. Research began in the 1990s (Prausnitz et al., 1998).

Equity Relevance: Simplified logistics, reduced cold chain, and potential for self-administration increase equity in hard-to-reach areas.

Case Study: Microneedle Delivery Patches in Bangladesh and India

Microneedle patch delivery platforms represent a transformative innovation in vaccine equity. These patches, containing arrays of microscopic needles embedded with vaccine antigen or DNA plasmids, allow painless, self-administered immunization without syringes or trained healthcare workers. Pilot studies in Bangladesh and India, supported by PATH and Georgia Tech, tested microneedle patches for measles and influenza, showing comparable immunogenicity to intramuscular injection. Critically, the patches demonstrated thermostability, maintaining potency at ambient temperatures for months—an enormous advantage in LMICs where cold-chain logistics are a persistent barrier.

From an equity perspective, microneedle patch platforms address multiple bottlenecks simultaneously: they eliminate sharps waste, reduce workforce dependency, and enable community-level distribution even in remote regions. In countries like India, where rural populations are dispersed and vaccination teams face geographic and resource constraints, microneedle platforms could decentralize immunization and expand coverage. Economically, simplified logistics could reduce overall program costs, further enhancing sustainability.

Although commercialization is still pending, with large-scale GMP production and regulatory approval in progress, microneedle platforms embody the future of equitable vaccine delivery. By decoupling immunization from cold chains and clinical infrastructure, they offer a pathway for LMICs to leapfrog logistical barriers. Long term, combining

platform-agnostic antigen formulations (mRNA, DNA, protein subunit) with microneedle delivery could create a modular "vaccine library" deployable across geographies, empowering both North and South with scalable, adaptable, and accessible immunization solutions.

Digital Surveillance Platforms: Digital platforms integrate epidemiological data for real-time outbreak detection and vaccine demand forecasting. Systems like GISAID (Khare et al., 2021) and DHIS2 (DHIS2, https://dhis2.org) have enabled the global sharing of pathogen data.

Equity Relevance: Enhances early detection in LMICs, facilitating faster local vaccine deployment and reducing reliance on external alerts.

Case Study: Enhancing Supply Chain Efficiency through DHIS2: Lessons from Nigeria's COVID-19 Campaign

Although most countries has closely tracked the vaccination program and supply chain digitally including COWIN in India. A case study from an African LMIC need to be quoted. During the COVID-19 vaccination campaign, Nigeria adopted the District Health Information System 2 (DHIS2), a digital health data management platform widely used across low- and middle-income countries. The integration of DHIS2 enabled real-time monitoring of vaccine stocks, distribution, and uptake at national and sub-national levels. By digitizing data flows and reducing reliance on paper-based systems, Nigeria was able to track vaccine demand more accurately, prevent stockouts, and reduce wastage. According to WHO (2022), this approach improved supply allocation efficiency by nearly 30 per cent, ensuring that vaccines were delivered where they were most needed and in appropriate quantities. Beyond improving logistics, DHIS2 also enhanced transparency and accountability in vaccine distribution, while strengthening the country's overall health information infrastructure. Nigeria's experience demonstrates the critical role of digital tools in optimizing immunization campaigns and highlights the potential of scalable health information systems to support vaccine equity in resource-limited settings.

In contrast to other medical products, particularlysmall molecule therapeutics, vaccines do not have an abridged or generic pathway. To obtain a marketing approval, a non-originator vaccine manufacturer must conduct both safety and efficacy studies. Lack of a streamlined regulatory pathway, coupledwith substantial high manufacturing facilities, constitutes significant entry barriers and results in a highly concentrated vaccine production. Paradoxically, initiatives designed to facilitate vaccine access, led by the Global Alliance for Vaccines and Immunization (GAVI) and United Nations Children's Fund (UNICEF), furtherreinforce this concentration. Thusto promote a geographically diversified vaccine production, a range of structural and regulatory reforms are needed to reduce the entry barriers,

without compromising vaccine safety and efficacy. Such diversification willensure reliable supply at affordable prices, especially during epidemic outbreaks.

Skillsets and Capabilities in Vaccine Development and Manufacturing: Global North vs. Global South

The COVID-19 pandemic was a stark reminder for inequities between the Global North and Global South in vaccine access and distribution. Prosperous nations in the Global North were successful in securing the majority of early vaccine supplies through advance purchase agreements. These countries were even able to stockpile doses musch more in excess of their populations' needs. Meanwhile, many countries in the Global South despite carrying a disproportionate share of the global disease burden had a wait period of months to over a year before securing meaningful access (Dzau, Victor J et al. 2022). The equitable deployment of platform technologies for vaccine production depends not only on physical infrastructure but also on the human capital and technical capabilities available across regions. (The Guardian: website). Vaccine manufacturing can be broadly divided into two main categories: Drug Substance (DS) production, where the active vaccine component is generated, and Fill–Finish operations, where the DS is formulated, packaged, and prepared for distribution. While the Global North generally exhibits end-to-end capabilities, the Global South shows a more heterogeneous profile, often excelling in certain downstream or fill–finish stages but relying on imported DS or technology transfer for advanced platforms (Mukherjee, S. et al., (2023).

Drug Substance (DS) Capabilities: DS production involves generating the biologically active component of the vaccine, such as mRNA encapsulated in lipid nanoparticles, recombinant protein antigens, viral vectors, virus-like particles (VLPs), or DNA plasmids, under GMP-compliant conditions. The Core Skill Subsets are as follows:

i) **Molecular and genetic engineering:** This includes designing antigen constructs, optimizing codons, and selecting vectors.

ii) **Upstream bioprocessing:** Mastery of microbial, mammalian, insect, or plant cell systems; control of bioreactor parameters; optimization of expression yield and quality.

iii) **Downstream purification:** Chromatographic separation, filtration, concentration, and viral inactivation.

iv) **Analytical sciences:** Development of potency, purity, identity, and stability assays.

Table 1: Comparative Overview of Vaccine Platform Technologies and Equity Potential

Platform	Development Speed	Manufacturing Cost	Stability (Cold Chain Needs)	Required Infrastructure	Scalability	Equity Potential
mRNA	Very fast (weeks from sequence to GMP batch)	Moderate–High (LNP reagents, enzymatic synthesis)	Requires −20°C to −70°C storage (improving with new formulations)	IVT suites, LNP formulation units, GMP fill–finish	High with modular bioreactors and LNP skids	High — adaptable to modular/ containerized plants (e.g., BioNTainer)
Viral Vector	Fast (months)	Moderate	2–8°C stable for many vectors	Mammalian cell culture facilities, viral production BSL-2	High if cell culture capacity exists	High — uses existing bioreactor/ viral capacity in LMICs
VLP	Moderate (months–year)	Low–Moderate	Often stable at 2–8°C; some lyophilized stable at RT	Microbial, insect, or plant-based expression facilities	High in fermentation/ plant bioreactor setups	High — compatible with broad range of LMIC expression systems
Protein Subunit	Moderate (months–year)	Low	Often stable at 2–8°C; lyophilization enables RT stability	Microbial or insect cell production, protein purification lines	Very high — processes well established in vaccine industry	High — low cost and widely compatible with LMIC capacity
DNA Vaccine	Fast (weeks–months)	Low	Stable at RT for extended periods	Microbial fermentation (E. coli), plasmid purification	High — rapid microbial scale-up possible	Very high — ambient-stable, low-cost fermentation in LMICs

Source: Author own compilation.

v) **Process scale-up and technology transfer:** Transition from laboratory to commercial scale without compromising quality.

In global North, there is high integration between R&D and manufacturing, robust molecular design pipelines, strong expertise in single-use bioprocess systems, process analytical technology (PAT), automation, and access to advanced analytical equipment for rapid in-process control and characterization. The Global South excels in traditional vaccine DS production, such as whole-cell, inactivated, and some recombinant proteins. During the pandemic, experience with novel DS platforms like mRNA or next-generation viral vectors was limited without technology transfer. There was also a scarcity of GMP-trained DS personnel; many acquired skills through donor- or NGO-funded programs such as GTHB training hub from IVI and WHO.

Fill–Finish Capabilities: The fill–finish stage involves sterile formulation, filling of vials or prefilled syringes, sealing, labelling, and packaging under aseptic conditions. The core skill subsets include

i) **Aseptic processing:** Operation of sterile filling lines, isolators, and restricted access barrier systems (RABS).

ii) **Formulation science:** Optimizing buffer systems, adjuvants, and excipient compatibility.

iii) **Packaging under controlled conditions:** Container closure integrity, serialization, and cold-chain integration.

iv) **Quality Assurance and Sterility Testing:** In-line Inspection and Microbial Contamination Control.

In Global North, there are highly automated fill–finish lines with in-line quality inspection and real-time monitoring. Also there are specialized capabilities in lyophilization and prefilled syringe technology, with advanced digital batch record integration supporting regulatory compliance systems. Global South has well-established fill–finish hubs capable of rapid scale-up when bulk DS is supplied externally (e.g., COVID-19 fill–finish contracts in India, South Africa, and Brazil). There is a greater reliance on semi-automated or manual processes, which reduces throughput. Also there is limited lyophilization capacity and vulnerability to supply chain disruptions in critical consumables.

Bridging the Capability Gap

The following gaps have been identified in this area:

i) **DS Production:** The primary bottleneck in many LMICs; novel platform DS production often requires external technology transfer.

ii) **Fill–Finish:** Generally more developed in the South, because of focus on high volume and low cost and skill, but throughput and specialization (e.g., prefilled syringes) remain limited.

Following approaches have been adopted as Bridging Approaches to fill the capability Gap

i) Prioritize the establishment of regional biomanufacturing hubs that possess both DS and fill–finish capabilities to enhance local vaccine production autonomy.

ii) Promote rapid deployment of portable modular units (such as BioNTainer) for immediate DS production in resource-limited settings, ensuring timely response to local needs.

iii) Support comprehensive workforce development for bioprocess engineers, analytical scientists, and GMP quality specialists to strengthen local expertise.

iv) Encourage joint ventures between Northern and Southern manufacturers to harmonize process and quality standards, fostering knowledge exchange and alignment.

The Vaccine Library: A Forward-Looking Concept:

The WHO R&D Blueprint and CEPI's priority pathogen list emphasize a limited but high-concern set of viral families with epidemic or pandemic potential (Kumar, A., et al., 2022). The viral families chosen for vaccine library efforts include

a) **Coronaviridae** → SARS-CoV-1, MERS-CoV, SARS-CoV-2

b) **Orthomyxoviridae** → Influenza viruses (seasonal & pandemic strains)

c) **Filoviridae** → Ebola virus, Marburg virus

d) **Arenaviridae** → Lassa fever virus

e) **Paramyxoviridae** → Nipah virus, Hendra virus

f) **Flaviviridae** → Zika virus, Yellow fever (already licensed vaccines exist, but new candidates sought)

g) **Togaviridae** → Chikungunya virus

h) **Nairoviridae** → Crimean-Congo Hemorrhagic Fever virus

In total, eight viral families are consistently represented in vaccine library frameworks. To accelerate equitable vaccine access, the concept of a "Vaccine Library" has emerged, a curated, pre-validated repository of vaccine antigen and adjuvant designs, platform process templates, regulatory dossiers, and standardized analytical methods (Kis et al., 2019). The idea is modelled on the concept of compound libraries in drug discovery, where thousands of chemical entities are catalogued for rapid screening against new targets. Similarly, a vaccine library would include pre-characterized immunogens, delivery platforms (such as mRNA, viral vectors, recombinant proteins, and virus-like particles, or VLPs), and adjuvant formulations, all of which have been tested for safety, immunogenicity, and scalability. The advantage of such a library is speed and preparedness. Instead of starting from scratch during an outbreak, researchers and manufacturers can draw upon a pre-existing set of validated vaccine constructs and platforms, tailoring them to the pathogen of concern. For instance, mRNA technology enables the rapid adaptation of antigen sequences while utilizing the same delivery backbone.

At the public health level, a vaccine library would facilitate equitable access, allowing countries—particularly in Africa and other resource-limited regions—to benefit from pre-developed vaccine blueprints that can be locally manufactured. This concept strengthens pandemic preparedness, reduces time-to-market, and ensures a more resilient global immunization system.

Direct advantages associated with vaccine library are the following

i) Enable rapid initiation of manufacturing in any qualified facility by eliminating the need for de novo R&D in emergency situations.

ii) The library would store digital and physical master cell banks, plasmids, mRNA sequences, and VLP templates for priority pathogens.

iii) Shortens the time from pathogen identification to vaccine distribution in low-resource settings; reduces dependence on a few global suppliers.

iv) Library access would be coupled with training modules, ensuring that local personnel can deploy and adapt vaccine templates.

If systematically implemented under a global governance framework, the Vaccine Library could bridge not only technology gaps but also capability gaps, enabling the Global South to transition from fill–finish dependence to full end-to-end vaccine manufacturing autonomy.

Case study: CEPI's Vaccine-Enhancing Adjuvant Library

On 31 July 2025, the Coalition for Epidemic Preparedness Innovations (CEPI) announced the launch of the world's first vaccine-enhancing adjuvant library, a pioneering initiative designed to boost the potency and durability of vaccines against high-threat pathogens-including mpox, COVID-19, Ebola, and novel or unknown "Disease X" threats cepi.net.

Hosted by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), this repository comprises 25 ready-to-use adjuvants contributed by leading research institutions and medical companies globally. The library functions as a vaccine–adjuvant matchmaking service, streamlining the process for developers to identify the most effective combination for new vaccines, thereby accelerating response times to emerging outbreaks cepi.net.

Funded at a cost of US$ 2.5 million by CEPI, the initiative aims to reduce lead times in vaccine development by enabling rapid access to proven immune-enhancing formulations. cepi.net. This aligns with CEPI's broader mission to enhance global epidemic preparedness, emphasizing the development of rapid, equitable, and effective vaccine solutions in response to unpredictable infectious threats.

Conclusion

The COVID-19 pandemic underscored both the transformative potential of platform technologies in vaccine manufacturing and the persistent inequities in global vaccine access. Each platform-mRNA, viral vectors, virus-like particles (VLPs), protein subunits, and DNA vaccines-has demonstrated unique strengths in speed, adaptability, and scalability, while also facing challenges in infrastructure, cost, and delivery. The evolution of these technologies from highly specialized pipelines into modular platforms has been pivotal, allowing rapid repurposing for new pathogens and supporting a more distributed model of vaccine manufacturing.

For equity, modularity and adaptability remain critical. mRNA vaccines, despite their cold-chain constraints, have shown unprecedented speed in pandemic response and are now being adapted to thermostable formulations and decentralized, container-based manufacturing systems, such as BioNTainers, in Africa. Viral vector platforms, proven effective in Ebola outbreaks, offer cost-effective and relatively stable vaccines; however, scale-up challenges and immunity to vectors limit their repeated

use. Protein subunit vaccines demonstrated the importance of established, low-cost infrastructure, as seen in the rapid scale-up of Novavax and Zydus vaccines. DNA vaccines, with ZyCoV-D as the first licensed example, illustrate the promise of thermostability, needle-free delivery, and local innovation in the Global South. Meanwhile, delivery innovations such as microneedle patches and dermal devices are poised to democratize access by reducing reliance on trained personnel and cold chains. Complementing these biological platforms, digital surveillance and genomic monitoring provide the backbone for agile decision-making, ensuring that vaccine design keeps pace with viral evolution.

Case studies across continents, from India's ZyCoV-D to Cuba's protein subunit vaccines and the establishment of BioNTainers in Africa, highlight how platform technologies can empower regions historically excluded from vaccine innovation. The lesson is clear: equity is not just a function of scientific breakthrough, but also of who controls, adapts, and manufactures the platforms.

Looking ahead, the integration of these platforms into a global "vaccine library", a pre-validated repository of constructs, delivery systems, and modular manufacturing blueprints-will be central to preparedness. Equally important is the development of human capital: ensuring that both the Global North and South build parallel skill sets in upstream development, downstream processing, and fill-finish capabilities. Only through such distributed and equitable technological empowerment can future pandemics be met with timely, fair, and scalable vaccine access.

Policy Implications

Realizing this vision requires structural reforms. Intellectual property (IP) pooling, open licensing frameworks, and technology-transfer hubs must be strengthened to prevent the concentration of vaccine know-how within a few regions. Lessons from COVAX underscore the need to strike a balance between emergency procurement and long-term investments in local capacity. National governments, multilateral organizations, and private industry should co-invest in regional manufacturing hubs, particularly in Africa, South Asia, and Latin America, to reduce dependence on imports during crises. Moreover, regulatory harmonization across continents can shorten approval timelines, while global financing mechanisms must ensure that manufacturing scale-up in low- and middle-income countries remains economically sustainable. In this way, platform technologies will not only shape scientific outcomes but also become instruments of geopolitical balance, ensuring that access to vaccines is recognized as a universal public good.

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Reimagining Vaccine Security in the Post-COVID Era

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Abstract: This paper examines the question of vaccine access in India by situating the COVID-19 crisis within the longer history of state policy and global pharmaceutical politics. Despite possessing one of the world's largest vaccine manufacturing capacities, India witnessed an estimated 3.2-6.5 million excess deaths during the first two pandemic waves. This paradox underscores structural weaknesses in vaccine governance, particularly the state's retreat from building and sustaining public-sector capacity. Through historical and documentary analysis, the paper considers two cases: India's reliance on imported oral polio vaccines during eradication campaigns, and its approach to vaccine access during COVID-19. Both reveal how dependence on imports, private production, and intellectual property regimes has constrained equitable access. The paper revisits the Hathi Committee's (1975) call for healthcare as a "national charge", where social needs take precedence over market logics. In contrast, contemporary policy is increasingly shaped by public–private partnerships and the aggressive monopolisation of pharmaceutical markets, raising concerns over long-term vaccine security. The paper argues that India must reimagine its vaccine policy in the post-pandemic era by investing in robust public-sector capacity alongside private innovation. Such a shift is essential not only to resist the appropriation of health by market forces but also to reaffirm vaccine security and public health as fundamental responsibilities of the democratic state.
Keywords: vaccine security, India, public-sector, public health, pandemic

Introduction: Beyond the Biomedical

Almost a century after the 1918 influenza pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak in Wuhan in December 2019 brought the entire world to a halt. During the influenza pandemic, India suffered catastrophic mortality, making it the single worst-affected country (Kant and Guleria 2018). An equal or greater number of people died in India alone (an estimated 10-20 million deaths) compared to war casualties in World War I combined (Tumbe 2020). At that time, however, India was under colonial rule, and no effective antiviral treatment or vaccine was available for influenza. The spread of coronavirus disease (COVID-19), however, occurred under very different circumstances. In contrast to the influenza pandemic, effective vaccines became available within ten months of the World Health Organisation's (WHO) pandemic

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declaration, with deployment commencing in December 2020. Furthermore, India is home to one of the world's largest vaccine manufacturing capacities. Nonetheless, India witnessed an estimated 3.2-6.5 million excess deaths during the first two COVID-19 waves (2020-2021), a mortality toll unprecedented in the country's history since independence(Lewnard et al. 2023; Jha et al. 2022; Msemburi et al. 2023). It is very likely that COVID-19-related morbidity and vaccine-preventable diseases (VPDs) could have been minimised, if not fully averted. Using the empirical question of why the Indian democratic state was unable to minimise VPDs during COVID-19 as a starting point, this paper examines the normative question of vaccine access in the post-pandemic era.

The development of vaccines against SARS-CoV-2 was key to cutting the Gordian knot. This was made possible by immense advances in biotechnology over the last three decades. The COVID-19 pandemic provided an unprecedented opportunity to explore and adopt both existing and novel technologies (e.g. DNA and mRNA vaccines) that even developed nations had previously hesitated to pursue, owing to concerns over stability and safety. It is therefore important to examine how the adoption of these technologies influenced vaccine access during the pandemic and what implications this holds for the post-pandemic era (Alonso Ruiz et al. 2024). In this context, access to technology-its development, adoption, and transfer-significantly shapes the timely production, supply, and availability of vaccines. Nevertheless, the coronavirus crisis was also marked by vaccine nationalism and vaccine inequity (Zhou 2022; Privor-Dumm et al. 2023; Nunes et al. 2024). The indigenous development of vaccines in India has consistently influenced access, both domestically and across the Global South. Equitable vaccine access, therefore, emerges as a core issue at the intersection of public health and politics. Following Kaushik Sunder Rajan, I analyse global pharmaceutical politics through its "attempt to appropriate the regimes of governance that shape the modes and relations of production, distribution, and consumption of biomedicine" (Sunder Rajan 2017, 237). I examine two pivotal case studies, drawing on historical and documentary analysis, to address the complex question of vaccine access: the first concerns the routine polio vaccination programme, while the second focuses on the response to the COVID-19 pandemic.

The article is structured as follows. First, I provide a brief overview of the historical development of the vaccine ecosystem in India over the past century. The third section analyses the case of polio vaccination and eradication efforts in India, demonstrating how reliance on imports has had long-term consequences for public health. The fourth section builds on the lessons of COVID-19, discussing three key moments that underscore the state's abandonment of the public sector to its detriment. The penultimate section outlines possible ways forward in the post-pandemic era, arguing

that, for a population of 1.4 billion, India must pursue vaccine security by acquiring a diverse portfolio of vaccine technologies and developing manufacturing capacities in both the private and public sectors. Finally, the concluding section posits vaccine security as an essential responsibility of the state, advocating for a robust public sector alternative to market-driven production in line with the Hathi Committee's vision. Such reimagining, I contend, is necessary to resist the appropriation of health by market logics and to reaffirm the idea of health as a public good.

Evolution of India's Vaccine Ecosystem

The Indian population was no stranger to the idea of vaccines. The practice of variolation, an early smallpox inoculation method involving the deliberate exposure of a healthy person to material from a patient's sores, was already prevalent in India and China (Greenough 1980). Following Edward Jenner's experiments in 1796, which used cowpox material to induce immunity against smallpox, it took only six years for the first vaccination to be administered in India, facilitated by British colonial trade and military networks (Bartlett 2018). During the colonial period, state-funded public vaccine infrastructure began to take shape in response to repeated epidemic outbreaks. The foundation for vaccine research and development in India was laid with the arrival of Waldemar Haffkine in Calcutta in 1893. After successfully inoculating 900 people in Agra with an attenuated cholera vaccine, Haffkine proved the efficacy of the world's first effective human cholera vaccine (Lahariya 2014). He later arrived in Bombay in October 1896 and developed a plague vaccine within three months; a remarkable speed unmatched even during the COVID-19 pandemic.Rising vaccine demand led to the establishment of the Plague Laboratory in Bombay in 1899, later renamed the Haffkine Institute in honour of his enduring contributions to India's public health system. In addition, the first animal vaccine depot for smallpox vaccine lymph was set up in 1890, followed by the colonial government's founding of the Central Research Institute (CRI) in Kasauli in 1904 and the Pasteur Institute of Southern India (now PII) in Coonoor in 1907 (Lahariya 2014). Thus, by the early twentieth century, India had a publicly funded infrastructure capable of producing vaccines and sera for diseases such as smallpox, cholera, plague, rabies, and typhoid.

At the time of independence, the report of the Health Survey and Development Committee (1946), chaired by Joseph Bhore, offered a future imaginary for the public health system in India. It not only unambiguously diagnosed the level of health in India as low but also proposed the integration of preventive and curative healthcare(Bhore 1946). India's life expectancy at birth during the colonial era (1941) was markedly low, with males averaging 32.09 years and females 31.37 years (CBHI, n.d.). The Bhore Committee's assessment that malaria and tuberculosis posed far more harm than smallpox,

cholera, and plague together set the agenda for the Government of India in the field of public health. Vaccines offered the first line of defence against the scourge of infectious diseases like tuberculosis that debilitated millions of people. Indiabecame a member of the World Health Organisation (WHO) in 1948 and adopted WHO's health policies. In the next two decades, with partial support from international organisations including WHO, UNICEF, the Rockefeller Foundation, and the Ford Foundation, various institutions and programmes for public healthcare were initiated. For tuberculosis, the Bacillus Calmette-Guérin (BCG) vaccine became the chosen route to prevent new infections. In 1948, the Government of India started the BCG Vaccine Laboratory (BCGVL) at the King Institute, Guindy, Chennai. Later, in close collaboration with UNICEF and WHO, the BCG vaccination mass campaign reached across India by 1956(Lahariya 2014). Around the same time, global smallpox eradication discussions in the 1950s culminated in WHO's 1958 resolution (Bartlett 2018). Consequently, India joined the effort by launching the National Smallpox Eradication Programme in 1962. In combination with the use of a new heat-stable and freeze-dried vaccine and intensive search-containment campaigns, India achieved smallpox elimination by 1975. India's success contributed to WHO's 1980 global smallpox eradication declaration.

The next significant step for India was to begin its Expanded Programme on Immunisation (EPI) in 1978, following the launch of the EPI by the WHO in 1974. Although the programme was largely urban-centric, with hospitals offering diphtheria-pertussis-tetanus (DPT), BCG, oral polio vaccine (OPV), and typhoid-paratyphoid (later withdrawn in 1981) vaccines, it evolved into the Universal Immunisation Programme (UIP) in 1985 (Lahariya 2014). The UIP initially covered 31 districts and added the measles vaccine to its scope. By 1990–1991, the UIP had transitioned to full nationwide coverage with an upgraded goal of universal infant vaccination against six VPDs. Around the same time, in 1988, the WHO set a global target for polio eradication by 2000. In response to polio's endemic status in the country, India launched annual National Immunisation Days (NIDs) in 1995 to supplement routine immunisation. Supported by international partners and after sustained efforts from multiple stakeholders, India reported its last wild poliovirus case in the Howrah district in January 2011(Bartlett 2018). It has been estimated that since the launch of the EPI, "vaccination has accounted for 40 per cent of the observed decline in global infant mortality" (Shattock et al. 2024). The COVID-19 pandemic underscored, with unprecedented clarity, the critical role of vaccines as a pillar of preventive medicine in global public health. In the following section, I discuss how distinct modes of making, circulation, and use impact vaccine access and health outcomes.

Polio and Policy Shift

The case of polio vaccination in India was distinct in comparison to the smallpox campaign and other diseases targeted by the UIP. The difference lay in the complete reliance on imports and the private sector for sourcing polio vaccines. India's public sector vaccine manufacturers had developed substantial production capacity, and by 1990-91, with the sole exception of the OPV, the country had achieved self-sufficiency in the domestic manufacturing of all essential vaccines (Lahariya 2014). At the time when the EIP, later UIP, was launched in India, hundreds of vaccine-associated paralytic polio (VAPP) cases had been reported in the US and globally between 1965 and 1985 (Bartlett 2018). As a result, Sabin's oral polio vaccine was discontinued in the US by 1979, and Salk's inactivated vaccine was deemed critical for the final eradication phase. In contrast, as T. Jacob John, a pioneer in the fight against polio in India, notes:

"In 1978 the Government of India decided to use oral polio vaccine (OPV) to control polio, occurring then at the average rate of 500 cases per day. The primary vaccination schedule was three doses in infancy. The prevailing popular belief (based on theory, not evidence) was that vaccine viruses would spread in the community, immunise unvaccinated children, induce high herd effect, and control polio rapidly. The alternate choice, the injectable polio vaccine (IPV), marginally more expensive, was believed to protect only the vaccinated. Thus, OPV was (erroneously) considered the better 'public health' vaccine (John 2005)."

As noted earlier, India's public health initiatives were developed and implemented under the strong influence of multilateral donor agencies, which played a pivotal role in shaping these programmes. Yet these were strategic choices made by the country, too. Indigenously manufactured OPV by the PII Coonoor and Haffkine Institute was discontinued in the late 1970s in favour of imported vaccines (Madhavi 2005). Scholars have argued that, while an effective indigenous injectable polio vaccine (IPV) was available in India, OPV was promoted in developing countries not for its efficacy but to create new markets for multinationals, as demand for OPV in developed nations had ceased (Ibid.). The logics of capital thereby carved out a niche in opposition to the prevailing model of public-sector manufacturing. Later, in the 1980s, John's research proved that more than three doses (in practice, six doses) of OPV were required under Indian conditions to ensure immunity.

While launching the polio eradication efforts in the 1990s, India anticipated the future need for IPV and began developing its own public-sector supply. Despite progress, the government closed the project (John 2005). India now faces a double failure: vaccine-derived polio cases exceed wild ones (zero since 2011), and the ethically preferable IPV is priced out

of reach due to demand from wealthy nations. Following the global switch from trivalent OPV to bivalent OPV, India introduced IPV in routine immunisation nationwide in 2016, without any public-sector capacity and relying completely on the private sector. Nonetheless, due to global shortages, India's Expert Advisory Group recommended fractional-dose IPV (Haldar et al. 2019). Accordingly, India implemented a nationwide strategy of fractional-dose IPV in place of the full-dose formulation by June 2017.Yet, in 2024, a two-year-old child in Meghalaya contracted VAPP(Editorial 2024; Prasad 2024). Thus, polio eradication still remains elusive(Roberts 2024). As John and Vashishtha (2013) point out, "true polio eradication demands zero incidence of poliovirus infection, wild and vaccine". Had India chosen IPV almost five decades ago, the country could have eradicated polio much more efficiently (John 2005). The failure to develop and expand public-sector IPV manufacturing capacity continues to plague the country's UIP even today. John poignantly remarks, "history cannot be changed, only the future can be redesigned" (Ibid., 118). In the next section, I analyse how India's failure to enact such a redesign worsened its COVID-19 trajectory-a future that could have been altered with more imaginative health governance.

Public Healthcare in Emergency: Fraying at the Seams

The question of why the Indian democratic state was unable to minimise the morbidity and mortality from COVID-19, once vaccines became available (effectively making it a VPD), can be approached in multiple ways. Amongst others, vaccine access is certainly a critical starting point. At the onset of the pandemic, it became clear that vaccines would form a key response to the COVID-19 crisis. In India, this meant inoculating roughly 950 million adults. Nonetheless, on 25 March 2020, India implemented the most stringent nationwide lockdown in the world, and a year later, in March 2021, India's Minister of Health declared that India was 'in the endgame' of the COVID-19 pandemic (Lancet 2021). But as The Economist (2021)noted, "the plain fact is that, instead, covid-19 beat India". To be sure, even most developed countries did not emerge unscathed from the crisis (Msemburi et al. 2023). Yet complacency and delays in formulating and implementing a vaccine strategy impacted the Indian population (Inamdar and Alluri 2021; Scaria 2021; Moneylife News 2021; Sanghi 2021). Furthermore, the strain on vaccine production capacity in India adversely affected both its domestic population and resulted in critical shortages for LMICs reliant on international mechanisms, such as COVAX, for vaccine procurement. I analyse here the regimes of governance that shaped the relations of production, supply, and access to vaccinesduring the pandemic (Sunder Rajan 2017). Since the 1980s, the rise of neoliberalism and privatisation has pushed for global patent harmonisation. The World Trade Organization

(WTO), particularly through the TRIPS governance framework, integrates intellectual property rights into the international trading system. The shift to a product patent regime has had consequential effects on access to essential medicines. I trace below three critical moments where the long-term erosion of public-sector vaccine manufacturing directly compromised public health systems and opened profound vulnerabilities for managing future shocks. These three moments reveal the system fraying at the seams.

The first moment - in October 2020, when more than 100 developing countries came together to support a call launched by India and South Africa for a waiver on COVID-19-related IP rights as a potential solution to the unprecedented coronavirus crisis (Hunter et al. 2022). Despite the legal recourse available in the WTO's TRIPS provisions to grant concessions on the use of IP during a public health emergency, rich nations persistently refused access to essential knowledge and technologies related to COVID-19 diagnostics, treatments, and vaccines. In an open editorial, Dr Ghebreyesus, Director-General of WHO, argued that while boosting vaccine production was the key, it would not happen by itself, and added: "Flexibilities in trade regulations exist for emergencies, and surely a global pandemic, which has forced many societies to shut down and caused so much harm to business - both large and small – qualifies" (Ghebreyesus 2021). In the wake of the deadly Delta wave in 2021, which caused devastation in India, even the U.S. President endorsed the proposal, along with Russia and China. Nonetheless, the EU, UK, Germany, and other HICs continued to defend the interests of their pharmaceutical companies and opposed any suggestion that would challenge their monopoly rights or profits. In effect, as McMahon (2021) has demonstrated, patents functioned as private governance tools controlling public healthcare and harming equitable access globally. Impeding licensing through the TRIPS waiver meant wealthy nations constrained the possibility of global production of vaccines, which became one of the sources of inequitable and unjust allocation.

The second moment-at the peak of the second wave of COVID-19, when India became the worst-hit country in the world, a press release in April 2021 declared that the government would support the augmentation of manufacturing capacity for Covaxin (PIB 2021). India had approved two vaccines in January 2021 for emergency use, both manufactured by private companies, i.e., Covishield (Serum Institute of India) and Covaxin (Bharat Biotech). Though India's vaccination drive started on 16 January, by the first week of April, a mere 0.9 percent of adults were fully vaccinated (two doses) and another 12.7 million others had received the first dose(Varshney 2021). The phrase 'shortage' or 'out of stock' appeared across all vaccination centres. It was then that the government announced a financial grant through its 'Mission COVID Suraksha' to help upgrade and expand the vaccine production "capacities of Bharat Biotech Limited, Hyderabad as

well as other public sector manufacturers [emphasis added]" (PIB 2021). This quiet mention of public-sector manufacturers was a curiosity, and perhaps a surprise, to the general public. This augmentation was proposed as part of the 'Atmanirbhar Bharat 3.0' (self-reliant India) package, and yet, ironically, until then, government-owned public-sector vaccine production units had not been tapped into, even well after four months into the vaccine rollout in India. While China and Russia relied primarily on their public-sector capacity to tide over the crisis, India decided to capitalise on the facilities of three public-sector units only when the country was deeply in the grip of a public health emergency. According to the press release, Indian Immunologicals Limited (IIL), Bharat Immunologicals and Biologicals Limited (BIBCOL), and Haffkine Biopharmaceutical facilities were to be upgraded to achieve a production capacity ranging between 10 and 20 million doses per month within six months (Ibid.). In contrast, private companies, Serum Institute and Bharat Biotech, received support to boost their production to 100 million and 80 million doses per month, respectively. The dependency on the private sector was writ large.

The press release specifically focused on the augmentation of Covaxin production capacity, not only because it was a classical inactivated vaccine but also because it was free of any IP-related encumbrances. The viral strain and vaccine development were completed by the publicly funded National Institute of Virology, Pune, a laboratory of the Indian Council of Medical Research (ICMR)(MoHFW 2021). It was further developed and exclusively licensed to Bharat Biotech. But the company was struggling to boost production, and in the face of the devastating second wave of COVID-19, the government, as a last recourse, declared its intent to rope in public-sector manufacturing capacity 13 months after the pandemic was declared. A PIL filed in May 2021 requested the Supreme Court to issue directives to restart the vaccine production in public sector units (PSUs), granting full autonomy, and argued that the recent intent to augment capacity at three PSUs for Covaxin production was nothing more than an act of turning these PSUs into private-sector contract manufacturers (Mahapatra 2021; The Hindu 2021). The logics of capital, thereby, frayed the public sector at the seams.

The third moment - The Drugs Controller General of India (DCGI), in January 2008, through a notification, suspended the manufacturing licences of three public sector vaccine units (PIB 2010). Thus, vaccine production at CRI Kasauli, PII Coonoor, and BCGVL Chennai came to a halt. The Drugs and Cosmetics Act, 1940, in conjunction with the Drugs and Cosmetics Rules, 1945, are statutes that govern the safety, quality, and effectiveness of drugs and cosmetics by controlling their import, production, distribution, and sale. These statutes were amended in 2001 to establish Good Manufacturing Practices (GMP) in alignment with WHO's standards. Inspections of the

facilities at the three PSUs in August 2007 by an assessment committee found non-compliance with GMP, a basis on which the DCGI suspended the licences. These PSUs thus had to stop production of essential vaccines. The closure of PSUs, which were the backbone and primary sources of vaccine supplies for India's UIP, caused shortages and fatalities across multiple states(Frontline 2015; Varshney 2012). The government, in turn, opened the route for private sector companies to supply the vaccines, which immediately increased the cost of immunisation. Nonetheless, the government had failed to anticipate the consequences of licence suspension. The shortage was so severe that in 2008-09 the government illegally procured millions of DPT, DT, and TT vaccine doses from CRI (Varshney 2012). More than a decade later, as Madhavi notes, "currently, 80 per cent of the Indian government's need for vaccines is met by private firms in India and abroad. The prices are up to 250 per cent higher than those of the public sector, as a result pushing India's immunisation budget up seven times in only five years" (Madhavi 2020).

The state's abandonment of the public healthcare system, however, did not go uncontested. Taking cognisance of the controversial decision, the Parliamentary Standing Committee on Health, in its two separate reports tabled in February and December 2009, called for the revival of the three vaccine-producing public sector units (Chaudhuri 2022a). Subsequently, former Union Health Secretary S. P. Shukla and various NGOs filed a public interest litigation (PIL) in the Supreme Court against the closure of the PSUs. In September 2009, under public pressure, the government appointed a four-member enquiry committee chaired by Javed Choudhary, a former Health Secretary of the Government of India. The committee, in its report, found that the decision to suspend the licences of the three vaccine PSUs was "incorrect", guided by the "flawed appreciation" of the issue by the health ministry, and enacted through "illegal procedure" (Viswanathan 2010). Noting that the GMP inspection team did not recommend suspending production but only called for corrective action, the Javed Committee recommended restoration of the production licences and government support to make all three PSUs GMP-compliant within three years (Chaudhuri 2022a). The government accepted the report and revoked the licence suspensions in February 2010. In practice, however, the issue of chronic underinvestment and state abandonment of these units continued. While closing the three PSUs, the government had announced a plan to construct a centralised vaccine park in Chengalpattu, to consolidate all vaccine production into a single, state-of-the-art facility. Though the construction of the Integrated Vaccine Complex (IVC) at Chengalpattu was completed in 2016, the government has not made additional investment to make it operational, and the facility remains idle with an uncertain future (Ibid.). Similarly, whilst construction of the new GMP facilities at the three

PSUs was initiated after critical parliamentary committee reports, it was only around 2019-2020 that trial runs and production of vaccine supplies were initiated, and with a much negligible order book (Hooda 2023). As the Javed Committee.

concluded: "By reducing public-sector vaccine supply to zero, in one stroke a crippling blow had been inflicted on the health security of the country" (Dhar 2010). In the next section, I explicate the notion of vaccine security and reimagine it as an essential state responsibility.

Reimagining Vaccine Security

In a reflective piece commenting on India's polio vaccination policy, T. Jacob John clearly spells out one basic lesson in public health: ethics should guide [technical] intervention in the first place (John 2005). In the context of public healthcare in the post-pandemic era, where vaccines will likely continue to be a principal component of defence, close scrutiny of governing ethics becomes necessary. What form of ethics should be imagined in the post-pandemic era, where the threat of new and old infectious diseases turning into epidemics or even pandemics is ever-present? How must our ethical principles evolve to meet the enduring reality of vaccine nationalism and vaccine inequity? Consequently, what alternative imaginations can be conceived to address the normative question of vaccine access in the post-pandemic era? Below, I explicate the notion of vaccine security as a way to ensure equitable vaccine access and, following Kaushik Sunder Rajan, locate it within the broader conception of unlimited state responsibility.

For over a century, immunisation has proven to be the most cost-effective public health intervention for controlling infectious diseases. Any disruption in vaccine supply, however temporary, jeopardises public health by allowing preventable diseases to resurge, disproportionately harming the most vulnerable. But upon whom does the ethical duty to ensure equitable vaccine access fall? There is broad consensus that, especially during emergency situations like a pandemic, provision of vaccines becomes the state's responsibility. Srinivasan and Rao (2021) offer three important pragmatic rationales for considering vaccines a public good and a state responsibility: first, protection against infections or risks is outside one's control; second, substantial coverage is required to arrest the transmission of disease; third, it is most cost-effective if production and use are through the public sector. That is to say, charging for vaccines abandons the poor to preventable morbidity and mortality, a moral failure made worse by the market's inability to achieve universal coverage, which always excludes the most vulnerable and underscores the essential role of free, state-provided immunisation. Yet, as was the case during COVID-19, vaccines might not even be available with the state due to lack of capacity for research, development, manufacturing, and distribution to the last mile. And what could be the potential way out,

especially in the context of vaccine nationalism and vaccine inequity? In its final report, the Javed Committee made two key recommendations for the government's consideration: first, granting vaccine PSUs autonomy by registering them as independent entities under the Companies Act or the Societies Registration Act; second, forming a National Vaccine Security Advisory Board, comprising stakeholders such as public health specialists, paediatricians, administrators, technologists, and social activists, to advise on critical issues of vaccine security [emphasis added] policy (PIB 2010). The notion of vaccine security here is a key operational principle of interest.

Vaccine security indicates the ability of a country or region to ensure an affordable, reliable, timely, and sustainable supply of safe and effective vaccines for its population, under normal conditions as well as during public health emergencies. Both UNICEF and the WHO define vaccine security as "the timely, sustained, uninterrupted supply of affordable vaccines of assured quality" (WHO, n.d.). But what are the regimes of governance that have come to shape India's vaccine security? An important source in this regard is the National Vaccine Policy 2011, the first such document offering guiding principles for vaccination programmes in India.On the issue of vaccine security, the policy document notes, "India should be able to ensure quality, safety, and efficacy of all vaccines" (MoHFW 2011). It thus reduces vaccine security to safety concerns without acknowledging broader issues of affordability and sustained supply. As scholars have noted, the policy "is not designed to enhance national public capacities for public immunization programmes, but to justify spending public money on publicprivate partnerships (PPPs)" (Madhavi and Raghuram 2012). It heavily promotes PPPs as a governing framework for vaccine research and production. For example, for vaccine research and development it suggests that "a number of linkages need to be explored between academia, industry, and international institutions" (MoHFW 2011). The list of international institutions includes the Gates Foundation, the GAVI Alliance, and PATH, among others. Similarly, in relation to vaccine production and supply, the policy document acknowledges that the private sector has become a major supplier of vaccines to the UIP and adds that "the public sector industry should be revived to provide vaccines that have very low profit margins" (Ibid.). Thereby, profit for private players takes precedence over affordable, reliable, and sustainable supply. However, in contrast to the national vaccine policy, which advocates PPPs, the National Health Policy 2017 acknowledges the important role of the public sector. In particular, the document emphasises that "public sector capacity in manufacture of certain essential drugs and vaccines is also essential in the long term for the health security [emphasis added] of the country and to address some needs which are not attractive commercial propositions" (MoHFW 2017). The notion of vaccine security is closely related to the idea of health security, and yet on

the ground, the private sector has achieved complete dominance in vaccine production (Chaudhuri 2022a). For decades, public sector vaccine units ensured India's vaccine security but were lying idle amid the urgency for more COVID-19 vaccines. It is therefore essential to envision alternative approaches to ensuring India's vaccine security in the post-pandemic era. In what follows, I outline an alternative approach.

The 1990s was the decade marked by India's transition to neoliberalism from socialist principles. Nevertheless, the period preceding this transition provides valuable historical insight into how the question of access was normatively conceptualised at the time. The Indian Parliament in 1974 constituted the Committee on Drugs and Pharmaceuticals Industry, chaired by the Member of Parliament Jaisukhlal Hathi, to examine ways to promote growth and rationalise prices in the Indian drug industry to facilitate access to medicines. This was in the backdrop of the Indian Patents Act (1970), which marked India's transition from a product patent regime to a process patent regime. The Hathi Committee submitted its report in April 1975, emphasising that the pharmaceutical industry plays a critical function in sustaining "the health of the nation", both in relation to the population and the economy (Sunder Rajan 2017). Though the report focused on drug production, its observations also applied to the vaccine industry. By 1971, India's vaccine production was facilitated by 19 public sector and 12 private sector manufacturing units. The report criticised the "anti-social role of the multinationals" and held that healthcare must be seen as a "national charge" (Ibid.). The responsibility was thus located with the state. The Hathi Committee recommended creating public sector capacity to "make essential medicines available to large masses of our people at reasonable prices" (Ibid.). Today, access to essential medicines depends almost entirely on the survival of the private generic industry in the Global South. As Kaushik Sunder has argued, in contemporary times the prospect of building public sector capacity as a viable alternative now appears not just neglected, but politically inconceivable. But in the Hathi Committee's imagination, social needs took precedence over market needs. It offered an "ethics of production" that "should have essentially the character of meeting national needs as distinct from trade and commercial angle" (Hathi 1975). Despite the Hathi Committee's recommendations, India did not make significant investments in developing or maintaining public-sector infrastructure for drug development. Instead, public sector vaccine manufacturing was gradually abandoned by the state. India today has only seven public sector vaccine producers, a marked decline from its earlier capacity. Now, the multinational pharmaceutical industry's aggressive enforcement of drug monopolies threatens access to essential medicines. In the contemporary regime of governance, notions of access revolve around "what kind of market need best serves social needs" (Sunder Rajan 2017). In the context of

national vaccine policy, as Madhavi and Raghuram (2012)describe, India's policy is aligned with "the era of vaccines seeking diseases and governments seeking public-private partnerships". But can the public-private partnerships endure and ensure vaccine security?

Kaushik Sunder has argued that the idea of responsibility embedded in public-private partnerships or corporate social responsibility is limited in nature. He shows that such articulations of responsibility often erase the political, focus solely on the notion of the market system as a win-win, are not immune from withdrawal at will, and lack public accountability (Sunder Rajan 2017). As an alternative to the logics of capital, he posits Jacques Derrida's "idea of responsibility without limit" (Ibid.). In response to normative questions of access, the Indian courts have attempted to invoke this form of constitutional social responsibility (Gowda and Jena 2020). The Hathi Committee stressed the social responsibility of the state and maintained that the "leading role for the production of drugs and pharmaceuticals should rest with the state" (Hathi 1975). Five decades ago, the Hathi Committee imagined "a world constituted by limited (corporate) profitability and unlimited (state) responsibility" (Sunder Rajan 2017). Such a structure is only conceivable in relation to a democratic state. India's state-led vaccine producers and research institutes possess the technical know-how that makes the country unique in the Global South. Historically, the private sector has relied on state institutions and PSUs, often using vaccine technologies developed or co-developed in government laboratories (Chaudhuri 2022b). During the COVID-19 pandemic as well, public funding and state-provided risk capital were critical to vaccine development in India (Koshy 2024; Reddy 2025; Alonso Ruiz et al. 2024). I posit that India should recognise vaccines as a strategic sector and reimagine vaccine security in alignment with the Hathi Committee's vision of a strong public-sector alternative to solely market-driven production. Public healthcare must remain a core responsibility of the state.

Conclusion

The COVID-19 pandemic served as a catalytic event for biomedical innovation. The remarkably swift trajectory from development through validation to deployment of vaccines has been widely valorised as a landmark achievement in translational science. However, these celebrations often obscure deeper questions about how vaccine technologies are produced, whose knowledge and priorities shape them, and how access to such technologies is structured across geographies, institutions, and populations. In this paper, I began with the empirical question of why the Indian democratic state was unable to minimise VPDs during COVID-19. Through historical and documentary analyses of two case studies-one of routine vaccination (polio) and the other of a public health emergency (the

COVID-19 pandemic)-I showed that the failure to develop and expand public sector manufacturing capacity adversely affected morbidity and mortality rates. The primary question this paper examined was the normative one of vaccine access in the post-pandemic era. I have put forward here the notion of vaccine security as a way to ensure equitable vaccine access. Furthermore, I located vaccine security within the broader conception of unlimited state responsibility and argued the need to reimagine it in alignment with the Hathi Committee's vision of a strong public sector alternative to solely market-driven production. Such a reimagination of vaccine security as a social responsibility of the state becomes necessary to counter the "appropriation of health by logics of capital" (Sunder Rajan 2017).

There is a danger that such reimagination might be reduced to a simplistic debate about whether the public sector is better or worse than the private sector. There is no doubt that the growth of the private generic drug industry in India after the 1970 process patent regime has earned the country the status of the pharmacy of the Global South. Similarly, the ascent of private vaccine manufacturers represents a significant achievement. Their evolution from supplying the domestic immunisation programme (UIP) to attaining global dominance post-2005 is particularly noteworthy(Hooda 2023). Yet much of India's population (and the Global South) faced challenges in timely and equitable vaccine access during the pandemic. The contradictions of India's vaccine story reveal the entanglements of science, policy, and society. As Sunder Rajan (2017) maintains, the more substantive question is "the consequences of living in a world where a public sector alternative to the acutely felt problems of health care access is not even on the table". In practice, when considered as a question of providing basic healthcare or equitable vaccine access for citizens, exclusive reliance on market-based alternatives falls short. The Hathi Committee's vision of a strong public sector is therefore relevant. As a nation with a population of 1.4 billion (estimated to peak at 1.7 billion by 2050), India must work towards establishing vaccine security for its citizens by acquiring a portfolio of vaccine technologies and developing manufacturing capacity in both the private and public sectors.

The reimagination of vaccine security is critical in contemporary geopolitics, where the world is adrift in flux, as major powers work at cross-purposes to reshape the international system to their own advantage (Menon 2025). Vaccine security is a nation's capacity to guarantee an affordable and reliable supply of vaccines, encompassing robust supply chains, domestic manufacturing, and a strong governance framework. Beyond logistics, it is fundamentally an issue of political and epistemic sovereignty-control over the technology, knowledge, and means of production that determine health and wellbeing. It challenges dependencies shaped by global IP, trade, and geopolitics. As Chaudhuri (2022a) has emphasised, "the growth

of the private sector need not be and should not be at the cost of the public sector". Furthermore, India must treat vaccine production as a strategic sector, critical for safeguarding public health and providing a defence against biosecurity risks. A resilient public vaccine sector is essential to ensuring vaccine security in the post-pandemic era.

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Covid-19 Vaccine in India: Regulatory and Ethical Issues

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Introduction

On March 11, 2020, the World Health Organisation declared a pandemic of a novel respiratory virus, SARS COV-2, leading to a lockdown across the globe. A vaccine was viewed as the most important of pharmaceutical interventions against this virus as it was believed that extensive vaccination would lead to herd immunity and a halt to the pandemic. Research was launched at "warp speed", and within a few months, vaccine candidates were in various stages of research including in phase 3 clinical trials. Before the end of 2020, the US and the UK had launched mass vaccination programmes of covid-19 vaccines that had been granted emergency use approval.

This essay will document regulatory and ethical issues in two vaccines in the Indian government's covid-19 vaccination programme that are of critical importance in the post-pandemic era.

The vaccines were developed, tested and approved in a particular context - financial stakes with investments from industry, private philanthropy, and governments, and a highly politicised environment. India's private sector vaccine industry which supplies 60 per cent of the world's vaccines, stood to make super-profits with the covid-19 vaccine, through government contracts, private sales at market rates, and massive orders through global networks. For the Indian government, pulling off the largest vaccine rollout in the world would be a political coup, especially so by including a "made in India" vaccine in the programme.

The Two Vaccines Used in India

Two vaccines accounted for more than 90 per cent of the vaccinated population in India. More than 75 per cent were of a vector-based non-conventional vaccine developed in a laboratory in Oxford University in the UK, which then entered into an agreement with the pharmaceutical company Astra Zeneca Ltd (AZ). AZ then licensed it to the Serum Institute of India (SII) to manufacture it in India and market it under the name Covishield.

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The Indian Council of Medical Research (ICMR) collaborated with SII in the local clinical trials.

Covaxin was a conventional vaccine based on a killed virus, and developed by an Indian vaccine manufacturer, Bharat Biotech India Ltd (BBIL), in collaboration with the ICMR and the National Institute of Virology which isolated and studied the virus as well funded and conducted vaccine trials.

Both Covishield and Covaxin received emergency use approval (EUA) during the pandemic. No data on adverse events following immunisation (AEFIs), whether injuries or deaths, were made public for Covaxin. In the case of Covishield, the Oxford AZ vaccine which received EUA in Europe and the UK, data on AEFIs from those countries were made available in the public domain.

The time taken to develop a new vaccine after identifying promising vaccine candidates in laboratory research can be five to 10 years in clinical trials. The covid-19 vaccines were developed under accelerated timelines, with many shortcuts taken,due to the pandemic. Trials were conducted on smaller populations, for shorter periods, simultaneous phase trials were conducted, and emergency use approvals were granted without analysing the entire data of the phase 3 trials. In this context, the regulations on collection of long-term data on AEFIs on trial participants as well as the general population are particularly important.

So it is worrisomethatamong the ethical violations, particularly in the Covaxin trial, identified by journalists was lack of follow-up for serious adverse events and deaths during the trial period, in addition to violations of informed consent requirements (Bhuyan 2021). Additionally, the Drugs Controller General of India gave emergency use authorisation in "clinical trial mode" for BBIL Covaxin, based on data of phase 1 and phase 2 trials – even before recruitment of phase 3 clinical trials was complete (Pulla 2021). It is not possible to ascertain the quality of evidence used to approve Covishield and Covaxin either for emergency use or full approval. The anonymised data submitted to the regulators – even the composition of the expert group granting approval - is not available for public scrutiny. The minutes of the special expert committee gave little information on what basis the regulator has granted emergency or full approval. However, the information available suggests that decisions were not made on the basis of evidence alone (Srinivasan 2021), but because the government wished to launch an indigenously developed vaccine alongside the SII vaccine (Pal 2021). These facts may have a bearing on how the government and BBIL responded to independent post-approval studies.

Vaccination Without Informed Consent

It was known from the very start that most of the vaccines being developed – including Covishield and Covaxin - would not stop infection. Despite this knowledge, even while the government claimed the vaccine rollout was voluntary, the state governments issued notifications / resolutions that made vaccines almost mandatory. [Bhardwaj Johari 2022] For instance,the long period of the lockdown severely prevented many people from earning a living. People were required to carry vaccine certificates, failing which they could not enter their work places or public areas, or take public transport, thus severely restricting the movements of the unvaccinated. Such acts by both the central and state governments also gave an incorrect message and a false sense of security to the people that the vaccinated could not get the disease or spread the disease. However, it was known to the people in authority that the vaccines were specifically meant only to reduce the severity of the disease; they were not designed to be a tool of prevention, or to prevent the spread of the disease. [Bhardwaj Johari 2022]

Requirement to Follow Up and Investigate Adverse events Following Immunisation

Both the vaccines were granted full approval in January2022.

The duty of the regulator and manufacturer does not end with the vaccine's approval. The law requires post-marketing surveillance through Phase IV clinical trials, for rare serious side-effects that will become apparent only when the vaccine is used on a much larger population. This is especially important for vaccines that were approved with limited data for emergency use. Vaccine manufacturers have a duty to monitor and collect data on adverse events. This ensures safety of the vaccines. The process of vaccine approvals is designed to ensure rigorous scientific validation of the vaccine. The process for vaccine safety is embedded not in speed but in testing at every checkpoint, to ensure that people are not unintentionally harmed. It was an ethical and moral duty of the regulator and manufacturers to adhere to the law post the emergency approval, so as to ensure safety. India has had an AEFI programme since 1986, and monitoring of adverse events following immunisation is meant to be carried out for all licensed vaccines. However, doubts have long been raised about the quality of India's AEFI reporting programme (Barnagarwala 2022).

The need for effective follow-up was especially important during the pandemic, given that the vaccines were administered to crores of people on the basis of very limited data. Instead, the necessary rigour was consciously

compromised, and speed took priority over safety concerns. The government was required to publicise the need to report AEFIs; ensure that AEFI reports were collected and promptly investigated, and modify the programme on the basis of the findings. This did not happen. It has also been established that even when scientists reported their own experiences, or provided convincing scientific evidence of serious injuries corresponding to the known side effects of the vaccine, or deaths following known side effects of the vaccine, they were ignored. (Barnagarwala 2022)

It is not known if any such systematic follow-up of the covid-19 vaccines has been conducted, as complete findings have not been made public. And it is worrisome that the investigations of serious AEFIs that are available for scrutiny have not been conducted with transparency on the documents scrutinised and on the assessment process by which it is concluded that an AEFI is, or is not, caused by the vaccine (Bhardwaj Johari 2022).

Indeed, post the pandemic, academic research suggested the need for such long-term follow-up to document adverse effects of various vaccines, faced by the public where the vaccines were rolled out. Instead of supporting such studies, and accepting the lapses, the government and the manufacturers slapped defamation suits on academic researchers, forcing them to withdraw published research, claiming crores of rupees as damage to their reputations (Prasad 2024). The government did not bother to make its own data public. Nor did it bother to challenge the study or its interpretation (Kartikeya 2024). This suggests that the government views the concerns of the public as secondary. No attempt is made to build the trust of the people by being open, transparent and honest about the adverse events of the vaccines.In fact, during the trial phase too, a participant who experienced severe neurological problems requiring hospitalisation, andfiled for compensation, was slapped with a Rs100 crore defamation suit by the manufacturer of the vaccine candidate in trials (Khelkar 2020). What happened to the participant is not known.

The provision for emergency approval existed for vaccines and therapies before the Covid-19 pandemic, and continues to be applicable today. In the case of the approval process for other vaccines, the process that was being followed before the pandemic is being followed in the post-pandemic period.

The concerns regarding the covid-19 vaccines stem from the entire context in which they have been approved and administered to more than 140 million people, and the manner in which this was done. Questions have been asked about how approval was influenced by political considerations, ignoring evidence of unethical research that would have compromised the data on which approval was granted; how public health programmes are imposed on an entire country without transparency about the limited knowledge of the vaccine's safety; and, now that the pandemic is over, how there is no information in the public domain on post-marketing studies

and AEFI reports. Scholars who studied the issue based on the limited information available in the public domain have been threatened and forced to withdraw their research.

Cases have been filed before the Supreme Court of India for investigation of and action on injuries and deaths following the covid-19 vaccines, and for this to be made public;and compensation for these injuries and deaths. One such was filed by parents of young people who had died following the vaccine (Barnagarwala 2022). Another, following a class action suit in the UK against the AZ vaccine, calls for an expert panel to look at the Indian version of the vaccine, Covishield, as well as to establish a vaccine compensation system for those who suffered injury or death because of Covishield (Jain 2024).

Lessons for the post-pandemic era

The record of the industry-government alliance in the covid-19 vaccine since 2020 leaves much to be desired. The question is: what are the lessons for the post-pandemic era? Public health experts are certain that the covid-19 pandemic is not the last one, or even the most severe. Are we ready to face another pandemic? Will we give priority to speed over safety, and then forget about it? Will we not hold anybody accountable for not adhering to the law, for compromising on safety, for not collecting the long term data, for not being transparent and open about even the limited data collected, for not conducting a rigorous scientific evaluation of the data, for keeping the public in the dark?

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Advent of 'Second Green Revolution' and its Impact on Farmers' Lives: Analysis of Policy Change in India

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Abstract: This paper analyses the impact of legal and policy reforms during the 'second green revolution' phase on farmers' customary rights and livelihood, particularly in the context of the extension of private property rights to over plant varieties and seeds. The paper discusses conceptual narrations of plant genetic resources such as "common heritage", to "national resources" and now "private property resources". The paper also deals with North-South deliberations over the conceptual background of farmers' rights before various international organisations. The paper argues that the transition from the state interventionism that characterized the First Green Revolution phase to the state abstentionism that characterizes the present corporate-led Second Green Revolution phase, has influenced customary practices and traditional knowledge relating to agricultural activities, the breaking of the traditional supply chain leading to soaring costs of seeds and varieties, relaxation of land acquisition procedures etc.. The paper analyses the points of interference with the right to sustainable production of farmers. This paper traces legal and policy reforms by analysing primary policy documents such as Five Year Plans, the Economic Survey of India, Union Budgetary Speeches, International Conventions by various international organisations and national legislations such as the Bio-diversity Act, 2002 and the Protection of Plant Varieties and Farmers' Rights Act, 2001 along with the Seed Bills of 2004, 2011 and 2019.
Keywords: Second Green Revolution, Customary Rights of Farmers, International Law relating to Farmers' Rights, Agrarian Traditional Knowledge, North-South Dilemma

Introduction

In India, nearly 4,00,000 farmers committed suicide between 1995 to 2018 (Kannuri & Jadhav, 2021) and during previous four years between 2018-22, National Crime Records Bureau (NCRB) records steady increase in farmers' suicides, specifically mentioning 3.75% increase from 2021 in 2022 (Biswas, 2023). The latest NCRB Report titled, 'Accidental Deaths and Suicides in India', reports that there were 11,290 farmer suicides in 2022 alone. This statistics do not include the number of women farmers who committed suicides because most of them do not 'own' land according to official records

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(Centre for Human Rights and Global Justice, 2011). The analysis of suicide notes identifies the following reasons as common- increase in prices of seeds/ varieties, climate change and crop failures. Over the past two decades, the cost of cultivation has gone up. Even though productivity has increased, the profit level has not maximised to neutralise financial and emotional distress. Small farmers are indebted to money lenders and crop failures have increased their financial trauma (Joseph, 2020). This tragedy forms the critical starting point for our analysis. To understand this contemporary crisis, one must examine the fundamental restructuring of Indian agriculture that began in the post-1980s era, with the changes in the seed sector being a catalytic element. Therefore, this paper moves beyond documenting the outcomes to investigating the root causes through a historical lens. While analysing changes in Indian agriculture, especially in the seed sector, the changes that took place post-1980s reveals interesting findings. The attempt in the paper is to explain a historical evolution of technology in agriculture along with its influence on market oriented agrarian growth. The changes in policies and laws are equally analysed in the paper to reflect on the interlinkage between the political economy of the seed sector and legal change. The impact of legal change on agrarian practices is also part of analysis in the paper.

The economic policies post-1980s and 1990s resulted in privatisation of the agrarian sector. The private seed companies engaged in research and development pressured the government for enactment of legislation based upon the exclusive rights spectrum which resulted in providing monopoly rights over new varieties in India (Ramanna, 2006). It was during these negotiations that a new technological fix in agriculture - GM Crops - started penetrating to Indian agriculture (Aga, 2023). The GM crops were introduced to farmers as highly productive varieties and they adopted it for economic returns. These crops are very costly compared to other crops. There are several examples where GM seeds failed to germinate on farms. Cargill hybrid 900 M maize seeds, which were unapproved varieties (Jha, 2003), failed to germinate on farms of Bihar in 2002, highlighting the risks of an emerging but poorly regulated market. Furthermore, illegal variants of Bt cotton were cultivated before receiving formal approval, and even after its official introduction, it failed in the farms and caused financial crisis to the farmers. In 2003, the Parliamentary Standing Committee on Agriculture "said that the risk of reducing biodiversity and other environmental hazards does not make the sowing of Bt cotton a sensible proposition" (Krishnakumar, 2003). This crisis has persisted. A 2017 Parliamentary Standing Committee recommended to comprehensively assess the success of Bt cotton due to the high risks that accompany GM crops (PRS Legislative Research, 2025). A recent study published in the Nature, shows how Bt cotton leads to a greater resistance from pink bollworm in the crops (Kumar et al., 2025).

The industrialization of agriculture which aimed at enhancing the livelihood of small scale farmers failed in Indian farms. Instead, they were made prone to frequent crop failures and expensive farming practices. They have lost the traditional varieties from their farms and modern agriculture has consistently encouraged a cropping practice that is exploitative of both land and people (Ray & Ghosh, 2000).

It is in this background that this paper analyzes the impact of legal and policy reforms during the 'second green revolution' phase on farmers' customary rights and livelihood, particularly in the context of the extension of private property rights to plant varieties and seeds and migration of cultivators to the cities. The first part of the paper discusses conceptual narration of plant genetic resources, which has shifted from being "common heritage", to "national resources" and now "private property resources" and North-South deliberations over the conceptual background of farmers' rights before various international organisations. The second part analyses transition from the state interventionism (the First Green Revolution phase) to the state abstentionism (Second Green Revolution phase), that has dramatically influenced customary practices and traditional knowledge relating to agricultural activities, breaking of the traditional supply chain leading to soaring costs of seeds and varieties, relaxation of land acquisition procedures etc.. The third part would discuss the policy changes that changed the governance regime over the plant genetic resources in India which has a close linkage with farmers' access to primary resources for sustainable agriculture. The fourth part would analyse the contents and conclude the paper indicating the urgent areas of attention.

PART-I: Conceptual Discussions on 'Plant Genetic Resources': Analysis of International Principles

Principle of 'Common Heritage'

"The history of exchange of genetic resources is the history of mankind" (Esquinas-Alcazar, Hilmi, & Noriega, 2013). The quotation denotes the importance of farmer-to-farmer exchange of resources in keeping the germplasm alive. Plant Genetic Resources that we utilize today are the result of age old effort of the farming community. It would never have been possible if these resources were kept under private custody. Until the end of the 19th century, crop genetic resources considered as goods belong to the public domain termed as part of "common heritage." It was after the Paris Convention 1883 that agricultural innovations became subject matter of the Intellectual Property framework.

"Use of the right to the earth's surface which belongs to the human race in common would finally bring the human race ever closer to a cosmopolitan

constitution" (Kant, 1795/2013). This quotation is one among the first which sowed the seeds for academic study of iterating the principle of 'common heritage of mankind'. The crux of the principle is that the resources of nature neither belong to nor are owned by anyone. It is open to all for the benefit of another. The logic behind the same is that the natural resources are not created by a single person. It is a collective effect of toil and hard work of generations together. The resources have been passed over to present generations and we all had the legacy of enjoying it for free.

Frakes has identified five components of the Common Heritage such as no public or private appropriation, no legal ownership over commons, equitable sharing of benefits internationally, no military or weaponry installations on commons and preservation of commons for the benefit of future generations (Frakes, 2003). Weiss and Taylor both argued for extending all natural and cultural resources, wherever located, that are internationally important for the well-being of future generations" (Weiss, 1989). The UNESCO Declaration on the Responsibilities of the Present Generations towards Future Generations also mentioned that "'the present generations may use the common heritage of humankind, provided that this does not entail compromising it irreversibly" (UNESCO, 1997, art. 8).

The principle of common heritage holds that genetic resources, whether the resources are found in farmers' fields or breeders' labs or gene banks, belong to the public domain (Busch, 2002). The Food and Agriculture Organisation's (FAO) 22nd conference adopted a resolution (Resolution 8/83) The Undertaking was based on "the universally accepted principle that plant genetic resources are a heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations" (Article 1). During the negotiations on International Undertaking on Plant Genetic Resources (IUPGR), the developing countries were pushed through and adopted the resolution. However, "Canada, France, Germany, Japan, the United Kingdom and the United States officially reserved their position with respect to the FAO undertaking as it explicitly specifies that the term "plant genetic resources" also includes newly developed varieties and special genetic stocks" (Prathapan & Dharma Rajan, 2011).

Private Property Regime

Agriculture is hugely becoming subordinated to multinational companies and capital investment. The resources like seeds and varieties that were available free for centuries met with a cultural shock when it was brought under the private property framework. "From the time people first began cultivating and harvesting cereal grains, plants and their products have been a necessary component of the material foundations upon which human societies are formed" (Kloppenburg, 1988). Advances in biotechnology have

allowed for increased commodification of seeds by relying on intellectual property framework. Most of the biotech companies have created genetically engineered crops and have attained monopoly over it. The after-effect of this is increasing dependency of the farmers over MNCs for resources and the farmers tend to buy the seeds and varieties at the instructed prices (Straub, 2006).

The cornerstone of the reasoning of intellectual property rights is labour-mixing theory propounded by John Locke wherein he contends that every man has a 'natural right' to monopolise the fruits of 'labour of his body and of his hands' (Locke, 1823/2012). Though Adam Smith had disinclination to uphold any type of monopoly, according to which would lead to inequality and poverty (Smith, 1762/1994), got only lukewarm support in the western world. The utilitarian perspective to grant incentive to create widely was adopted and legislative frameworks to incentivise the inventor to create new property resulted in the modern IPR regime.

The justification behind the grant of intellectual property rights is that it helps the innovator to accumulate capital for further innovations and piracy of the creation is prohibited. The biotech industry invests many years and millions of money in research and development of genetically engineered crops (Dutfield, 2003). IPR systems reinforce the industry's capital accumulation tendencies that results in decrease of genetic diversity and replacing of traditional landraces with the new varieties (Leskien & Flitner, 1997).

While monopoly rights promote ownership rights to the individuals, the farmers' rights regime advocates for collective rights. "Farmers' rights are group rights, assigned to the collective interests of those who have nurtured crop germplasm" (Brush, 1992). The entire perspective of farmers' rights is different as their interest is not to capture monopoly rights over the resources to the exclusion of others. There is ample apprehension that if farmers' rights are implemented by the national government, they may only serve the interests of the elite/rich farmers who would be able to approach the Government machinery for approval of varieties. Others who are involved in the nurturing of varieties, especially agricultural labourers and tribal farmers would be isolated and left without any benefits. We have seen the arguments that the Green Revolution has benefitted only the rich farmers as the prices of the seeds and fertilisers were quite high. In order to prove IPR criteria, such distinctiveness, stability and uniformity, the farmers need to prove with scientific precision which itself may be cumbersome for the farming community. IPR would only increase marginalisation and increase in costs of cultivation and will benefit only the capital class. IPR tends to "facilitate control over seeds and related knowledge by agri-businesses at the expense of small and subsistence farmers" (Cullet, 2004).

National Sovereignty

The understanding was that "farmers' varieties were regarded as common heritage; modern varieties become private property through intellectual property rights" (Bjørnstad, 2004). This was not accepted by many countries for the reason that access to landraces/traditional varieties was necessary to produce new varieties by the breeders. Hence there were discussions on fairness and equity while accessing the germplasm (Swanson, 1997) which led to Convention on Biological Diversity, 1992. The solution derived during this convention was to adopt 'national sovereignty' , one of the principles of CBD. The state had control over the genetic diversity of the nation and any outsider needed to take prior permission, mutual transfer agreements etc. with the community/state to access the genetic resources. This was an impasse as developed countries were quite sure about supremacy of their negotiation skills over the 'access and benefit sharing' deliberations. There is also a view that the enabling provisions of sovereignty such as benefit sharing and prior informed consent proved in many cases to be 'bureaucratic, overly restrictive, and time-consuming' (Ten Kate & Laird, 2003). Followed by this FAO adopted a resolution in 1991 and declared the further erosion of the concept of common heritage by stating that "the concept of mankind's heritage is subject to the sovereignty of the states over their plant genetic resources".[1]

In the beginning of the adoption of the CBD, the national sovereignty principle was considered to be one of the progressive steps towards acknowledging the contributions of farmers and local community towards development of PGR. Also there was a fear in the minds of developing countries that in the current economic regime common heritage principle would become a window for drain of genetic resources. Hence national sovereignty principle considered to be self-determinative from the part of the nation relating to appropriation of its germplasm. "The demand of the developing countries in the CBD in 1992 for sovereign rights over genetic resources and equitable sharing of commercial benefits was based on little scientific input" (Rajan & Prathapan, 2009). The scientific board of the CBD consisting of politicians and professional negotiators were actually impeding any positive actions on the basis of scientific evidence (Laikre et al., 2008). This shift from common heritage under FAO to state sovereignty under CBD was inadequate to prevent the loss of biodiversity (Kloppenburg & Kleinman, 1987) (Rosendal, 2003) (Rosendal, 2006) or in clear terms did not end 'biopiracy'. Nor did it result in any returns to the community under the 'access and benefit sharing' arrangement. The Bt. Brinjal issue in India stands as an example for biopiracy wherein Monsanto did not take any permission for accessing the traditional variety of Brinjal to act upon and come up with the Bt. Version (Abdelgawad, 2012). The result was merely a defensive moratorium, suspending the release of the crop (Millar, 2012),

not the positive action of benefit-sharing, revealing a framework capable only of preventing harm rather than delivering equity.

While the Convention on Biological Diversity, 1992 strongly recommends national sovereignty over the genetic resources and access and benefit sharing mechanism for granting access, these principles need to be discussed to understand its repercussions in terms of utilization of resources for free by farmers. This was a strategic move by developing countries to counter the "common heritage" model, which they felt benefited the Global North and enabled biopiracy. The issue of biopiracy arises only because of the intellectual property regime. The propertisation of natural resources has received recognition by discovering a new principle of 'national sovereignty' under the Convention on Biological Diversity. Any legal regime which restricts involvement of farmers and farming communities in creating and maintaining genetic resources would hamper the food security and availability of crop genes within and outside of their places of origin. Plant genetic resources should be approached under a free use regime embedded in the 'common heritage' framework rather than privatisation of natural resources, while also addressing the flaws of the common heritage model by legally requiring benefit-sharing.

In the popular sense, the terminology 'National Sovereignty' means sovereignty of the people. In India, state ownership over natural resources is a contested idea, as it often interferes with community-based rights, a tension recognized in laws like the Forest Rights Act, 2006. This suggests sovereignty should be exercised as a custodianship on behalf of the people, with communities participating in decision-making—not as absolute state ownership that can be leveraged for commercial deals that may not benefit local communities. In the context of plant genetic resources, this manifests as policies that prioritize commercial intellectual property rights of large corporations over the customary rights of farming communities.

The effect of all these efforts from FAO to CBD left without any change in the situation from where the discussions started on farmers' rights. The IPR regime gives economic rights over the resources by allowing privatisation and creates artificial competition among countries. This cannot be the ideology in the case of basic necessities like food security of a nation (Ramanna, 2006). The farmers being the first in the food production and supply, greater focus should be on their preferences rather than creating artificial barriers on their utilization and development of plant genetic resources (Salgotra & Chauhan, 2023). The negative effects of implementing intellectual property regimes reported decades ago from Colombia, Mexico and Costa Rica in terms of enrichment of crop genetic resources (Sampath, Gehl, & Tarasofsky, 2002), have not abated but intensified. Contemporary analyses confirm that these regimes continue to facilitate biopiracy (Ambler, Garcia, & Fernandez, 2021), and restrict farmers' seed

systems (ETC Group, 2023), ultimately threatening global food security (International Panel of Experts on Sustainable Food Systems [IPES-Food], 2023). National sovereignty principle arises from the ignorance of the fact that plant genetic resources are not distributed equally in every country. The interdependence is so inevitable to ensure food to the hungry. As mentioned before, the national sovereignty principle was introduced in order to win over the developing countries during the negotiation process for accessing the resources of the developing nations (Vogel, 2024). The trade regime that promoted acquisition of IPR across the globe and trading of resources found it less complex than the principle of 'common heritage' for the reason that they need not give open access to their resources and the ambiguity of the concept itself was clear from CBD itself.

The origin of ownership rights over the resources has narrowed down the principle of common heritage and the Food and Agricultural Organisation in contrast to its 1983 resolution[2] adopted a resolution in November 1989 that "plant breeders' rights were not incompatible with the IUPGR". This acknowledgement of plant variety rights has benefited enterprises of the North, which were engaged in commercial seed production (Blakeney, 2001). "Since the primary aim of the international legal regime should be to meet the food needs of every individual, areas that are well-endowed in natural resources should not be allowed to restrict the flows of agro-biodiversity resources" (Kameri-Mbote, Annie, & Cullet, 1999). In short, the principle of common heritage should apply to the farmers and commercial breeders promoting exchange and dissemination of new knowledge, while also ensuring the implementation of access and benefit-sharing (ABS).

PART-II: Transition From First Green Revolution Phase to Second Green Revolution Phase in India

Though India started with planned economic development post-independence, the major criticism was that economic benefits served only the rich and it bypassed the poor (Panagariya, 2024). There was enough criticism to state that the planned policies gave priority to industrial development whereas considering the Indian condition the agriculture should have been given more priority (Krishnan, 1959, p. 110). The successive droughts from 1957 necessitated large scale imports of food from the US under PL 480 scheme of basket-case. At the initial phase, state intervention was meant to create the conditions for the development of industrial capitalism and there was relative neglect of agriculture (Cough & Sharma, 1973). However, from the First Plan itself 'Outlays on Agriculture' was part of the plan documents with a substantial agenda to reform irrigation and more importance on land reforms front. Nehru did not share the belief that privatisation of existing public assets was an answer to the resource problem, nor did he believe

that mainly through public sector, resource mobilisation could occur, but he strongly believed that public sector would "spearhead the change" (Chakravarty, 1989, as cited in EPW, 1989).

In the Third Five Year Plan, the Chapter on Review of Earlier Plans emphasised on "self-sufficiency in food production" and the move towards it led to Package Programmes. The research on new genes for fertilizer response in India started with Norman Borlaug's visit to India in 1963 and the first trial of 1964 with semi-dwarf varieties became successful which led to the birth of Green Revolution in India.

During Indira Gandhi's initial years, the food crisis continued to worsen. The pressure on the balance of payments skyrocketed. There was a decline in foreign aid which constrained public investment, leading the government to tighten licensing controls on private industrial investment to channel capital towards priority sectors and thereby conserve foreign exchange. The establishment of irrigation and power projects, agricultural universities, research laboratories, fertiliser plants etc. helped the government to exercise control over production, procurement and supply of increased productivity during the Green Revolution Period (Chandra, Mukherjee, & Mukherjee, 2007). Economic conditions in India during the mid-sixties, on the eve of the introduction of the new high yielding seed varieties, were the worst ever during the post-Independence period: per capita income reached its low water mark; major industries were severely hit by recession; unemployment was mounting (Dasgupta, 1977). The increase of foreign debt, depletion of foreign exchange reserves coupled with US's displeasure of PL 480 scheme in 1965 forced Indian to arrange for substantial imports. India responded with politically unpopular devaluation accompanied by liberalisation in 1966 and agreed to liberalise its trade restrictions by reducing export subsidisation and import tariffs (Devika & Miller, 2002). Within ten days of the finance minister's announcement of devaluation and the liberalisation of foreign exchange controls, the US announced resumption of economic aid to India (Frankel, 2005).

By the beginning of 1967, the division of the agrarian society was solidified into two dominant classes, one of rich peasantry and the other constituting poor farmers and agricultural labourers. With the failure of land reforms of the 1950s and 60s, the poor farmers and labourers became dependent on public aid for better production. The emphasis on agriculture and introduction of the green revolution was adopted from the realization that US import of food, known as 'ship-to-mouth' would not solve the issue of availability of food. The high yield varieties came with demanded many other inputs such as fertilizers, seeds, water, power or credit etc. However, the strong Government interference during the process through subsidy for resources, research, multiplication, certification of seeds by public sector, procurement and supply by public sector etc., (Frankel, 1971). However,

Indian poor peasants were beyond reach of the benefits accrued from the Green Revolution. Nayyar states that economic benefits of this regime of subsidies, explicit and implicit, accrued disproportionately more to the rich peasantry (Nayyar, 1998).

It is an agreed position that the production advances of the Green Revolution are no myth. The reason was strong support from the Government. There were institutional mechanisms as well as policy formulations to make sure the availability and affordability of resources including seeds, irrigation facilities, fertilisers, power, credit etc. Indian Council of Agricultural Research which was established under colonial rule in 1929 was of immense help in research and development of seeds, multiplication and certification processes. Today there are 99 ICAR institutes and 53 agricultural universities spread across the countries contributing to food security of the nation. For procurement of food grains, the Food Corporation of India was established in 1965 and in the same year Agriculture Prices Commission was also set up to suggest minimum support prices by assuring a remunerative and stable price environment. The National Seeds Corporation was established in 1963 to produce, process and market hybrid seeds. The Seed Act, 1966 was also passed to control the quality of seeds. Apart from institutional support for development and distribution of seeds, procurement of seeds and availability of returns on procurement, there were policy formulated subsidies available for seeds, fertilisers, credit facilities etc. The presence of public investment increased profitability of agriculture (Sebby, 2010). The state investment in farming infrastructure such as irrigation and other technologies facilitated the farmer to invest more in the newly developed high yielding varieties of seeds and fertilizers knowing that their chances of high yields are increased (Das, 1999).

Green Revolution strategy completely supported by the Government to achieve "improved productivity growth despite increasing land scarcity and high land values" (Pingali & Heisey, 2001). From 1950-51 to 1975-76 agricultural output recorded an unprecedented growth rate of 2.6 per cent per annum compared with the paltry rate of 0.8 per cent registered during the first half of the century and in 1971-72. "India became self-sufficient with grain imports declining to nearly zero" (Kapila, 2013). It is a well-supported argument that these outputs would not have been possible without strong government interventions which provided them adequate incentives, subsidies to access the inputs, credits immediately after nationalisation of banks etc. The speed with which Indian research institutes produced high yield varieties and distribution through outreach programmes via seed cooperatives and district seed stalls ensure the availability of HYVs (Gulati & Narayanan, 2003). In short,

> "Throughout the green revolution, Indian agriculture was under a strictly regulated policy regime characterised by wider restrictions

> on production through licensing requirements and barriers to entry as well as controls on pricing, movement and private trading of agricultural produce. On the external front, too, the sector was burdened with various tariff and non-tariff barriers to agricultural trade flows" (Gulati & Fan, 2008).

Though there are arguments that the benefits of cultivation of HYV did not reach the small farmers. The argument was that there was a rich farmer lobby strategising the hijacking of incentives by the Government. But, State institutions at block and district level worked efficiently and farmers could approach for seeds and fertilisers at subsidised prices. The productivity increase ensured availability of food grains at cheaper rates to the poor. There was a substantial decrease in rural poverty.

However, the enormous cost of this state-led model created a fiscal crisis. As a result, the development process became more dependent on private initiatives as the government failed to raise resources by the eve of the fourth plan. The fourth five-year plan also suggested a special intensive program in selected areas to produce some "very high-yielding, fertilizer responsive and non-lodging varieties of paddy, wheat, maize, jowar, bajra" (Planning Commission, 1969, p. 27). By 1969, the government sought to spur private investment in the manufacture of fertilizers, pesticides and seeds by removing price subsidies on these inputs except in remote backward areas. In 1973, adoption of liberal economic policies became necessary due to huge inflation in prices of agricultural goods following the impacts of oil shock and the war with Pakistan.

In order to deal with the rise in prices, the IMF recommended stringent fiscal discipline to reduce subsidies and complementary economic policies to freeze wages, increase imports, promote exports, and provide incentives to private investment. The main thrust of both the IMF and the World Bank recommendations were to open the economy for private multinationals to invest in fertilisers, seeds, agro-chemicals etc. Though the private sector was involved in the seed sector from 1920 onwards, post-independence, it was the IMF and World Bank which pressed the entry of multinational seed companies to the Indian market. During the 1980s the pressure on the Government to open up and relax the import rules resulted in flow of private sector companies into the market. The Government had to formalize the Seed Policy that favoured the breaking away of Public Sector hold and entry of private sector into the seed market. By 1985, the presence of the private seed sector was quite prominent in the market. And by 1987, the foreign companies were allowed to invest in the production of hybrid seeds and agricultural biotechnology products which paved the way for the entry of multinational corporations, which were earlier restricted under the Monopolies and Restrictive Trade Practices Act, 1969 and the Foreign Exchange Regulation Act, 1973 (Rao, 2004).

The green revolution varieties increased productivity and hence there was more demand for high yield seeds/varieties. The sudden surge in seed demand resulted in appointment of a Seed Review Team to review performance and requirements of the seed industry. As per the recommendation of the team there was establishment of a quality infrastructure for seed production, certification, and storage. The World Bank–assisted National Seeds Project (NSP) was implemented in three phases across the country and lasted for almost two decades (1976–1995) (Shreedhar, Gupta, Pullabhotla, Ganesh-Kumar, & Gulati, 2012). This project provided an infrastructural boost to the seed production industry and gave rich economic dividends. It also encouraged the private sector by granting concessional loans to the R & D based companies (Shreedhar, Gupta, Pullabhotla, Ganesh-Kumar, & Gulati, 2012). This helped the private sector industries to focus also on production apart from distribution and the Government came up with policies such as New Seed Policy, 1988 and New Industrial Policy, 1991 to allow imports of seeds on a higher scale to promote foreign investment in seed sector for private seed sector development.

The second green revolution phase started with the Seventh Five Year Plan (1985) that called for private and foreign investment in agriculture especially in agri-biotechnology, genetic engineering, photosynthesis, tissue culture, bio-insecticides and pheromones. The technologically advanced countries who were in search of new markets established their subsidiaries in India. The year 1986 can be identified as the start of plant breeding in the private sector with emphasis on hybrid seed production (Ramaswami, 2002). The private sector ventured into research and development of new varieties in India. The New Seed Policy, 1988, the Plants, Fruits and Seeds Order (Regulation of Import into India order) 1989 and The New Industrial Policy of 1991 allowed seed companies to import commercial vegetable seeds with no quotas, to import commercial seeds of foreign varieties and complete liberalization of the seed sector. It removed restrictions on direct foreign investment and also to free the domestic entrepreneur from the restrictions of MRTP Act.

After the liberalisation of India's economy the subsidies were reduced drastically and private seed companies took over multiplication and distribution of seeds. The public sector was confined to wheat and rice varieties and the private seed sector dominated the commercial crops. Further deterioration came when one of the Washington Consensus agendas, propertisation of resources was deliberated in India. Due to the adoption of this agenda, the protection of private intellectual property rights was placed over the community rights of plant genetic resources. Thus, the seeds and varieties which were considered as common property resources were slowly taken over by the private sector. Under their prerogative they advocated for monopolisation of the same. The state opened the sector to private players

while retaining, though often struggling to effectively enforce, regulatory mechanisms. This impacted the farmers in terms of assistance to accessing the seeds, varieties, fertilisers, pesticides, weedicides, etc.

In India, before the adoption of the New Seed Policy in 1988 there were no large private sector investments in the agriculture sector. Agricultural research was mainly concentrated in public sector research institutions, roughly around 25 agriculture universities carried out research and breeding. The change in the seed and IPR policy has resulted in growth of more than 500 private seed companies in India by 2016, especially 24 of the top listed companies are linked to Multinational Companies (Agritex, 2016, as cited in Ali, 2016). The accompanying technology and the introduction of intellectual property protection fuelled intense competition among these companies. This initially led to a surge in the production of hybrid seeds, and later, with the approval of Bt cotton in 2002, paved the way for the production of genetically modified (GM) crops.

The scenario is very different in India where farmers depend on an informal system of sharing of seeds and collection of seeds for re-sowing. The new seeds with higher yields, less chemical use attracted poor farmers to these GM seeds. Initially GM seeds gave higher yield in 2002 to 2006 and in "2006 nearly 3.28 million hectares were under Bt. cotton cultivation" (Acharya, 2006). The farmers understood the consequences of new engineered plants as it costs Rs. 1850 for 450 gm (AP govt, 2007) whereas the price for non-Bt. cotton variety is at Rs. 450 to 500. The use of Bt. cotton widely by the farmers also resulted in the loss of their traditional varieties (Glover, 2010). Bt cotton, while showing little real benefits, leads to long term negative impacts and increased resistance to various infestations including pink bollworm (Kranthi & Stone, 2020). The ultimate phenomenon of this Second Phase of Green Revolution today is increased rates of farmers' suicides due to non-payment of huge debts (Newman, 2007), as it has been a key contributing factor for the same.

The Eighth and Ninth Five Years further liberalized the economy and the private seed companies increased to 400-500 by 2006-07 (GoI., Seednet, n.d.). The seed policies introduced during this period helped the private seed companies to establish their presence in the Indian seed market. By 2009, "the composition of the seed industry, by volume of turnover, has reportedly reached a ratio of 60:40 between the private and public sectors" (Sangar, Abrol, & Raina, 2010). The policy shift in favour of private sector companies and its impact on farmers is important to analyse in the context that now private share in total quality seeds is 66.75 percent in 2021-22, while that of public sector only being limited to 33.25 percent (Dadlani, Das Gupta, & Dadlani, 2025).

The argument that privatisation of the seed sector would lead to growth in productivity in agriculture has been criticized by agrarian economists.

Uma records that the growth of agricultural GDP decelerated from over 3.5 per cent from 1982-1997 to only around 2 per cent during 1998-2005. She also recorded a sharp decline in the growth rate of productivity of all the crops in the decade of 1995-1996 to 2004-2005. The accurate decline rates were 0.82 per cent and 0.56 per cent per annum respectively on wheat and rice compared to the previous decade. She also states that there was instability and variation in food grains output post-green revolution period (Kapila, 2013). Mahendra Dev also records that the share of agriculture and allied activities in the GDP declined from 57.7 per cent in 1950-51 and 22 per cent in 2002-03 (Dev, 2012). The public investment witnessed steady decline from the Sixth Five Year Plan to the Tenth Plan. The privatisation of the seed sector combined with withdrawal of state from control of seeds has not benefitted the agrarian economy, but rather has been a major contributing factor in its decline. This has also resulted in reduction in capital formation in agriculture which was 15.05 in 1980-81 at the peak of the Green Revolution to 10.04 per cent and 6.91 post-privatisation respectively in 1991 and 2001 (Birthal, Joshi, & Narayanan, 2011).

Post-1985, the production in wheat and rice has not gone up as we experienced in the First Green Revolution period between 1964-1988. The production rate today is the legacy of First Green Revolution varieties in rice and wheat. However, the high input use has polluted ground water, resulted in soil erosion and decrease in outputs over a period of time.

There were pertinent shortfalls in public investment in the agrarian sector and in the provision of agricultural services post- trade liberalisation, in the 1990s. The average annual growth of GDP in agriculture and allied sectors slowed down in the post-reform period when compared to the earlier period, while the growth of crop output (especially foodgrains) decelerated (Government of India, 2001). The Economic Survey, 2024-25 indicates that the GDP percentage of agriculture dropped from 45.9% in 1970-71 to 16% in 2024-25. The experience of the 1990s clearly demonstrates that the trade liberalisation along with reduction of public investment and effort is responsible for the inability to benefit from trade liberalisation by stepping up and diversifying agricultural output in a cost-effective way (Rao, 2001). The 12th Five Year Plan states that public investment in agriculture stagnated in the Eleventh Plan which was mainly because of a large shortfall in planned investment in irrigation. Private investment averaged 15.6 per cent of agricultural GDP as against expected 12 per cent which turned agriculture more input intensive (Planning Commission, 2012). The Eleventh Plan document had highlighted that public investment in agriculture as per cent of agricultural GDP had halved between the 1980s and at the end of the Ninth Plan (Planning Commission, 2012, pg. 12).

The reports comparing the agrarian production in India and China also indicate the same point. Though in China, the average holdings are

smaller which is 0.6 hectares compared to India's 1.33 hectares, the small farmers in China are producing about 40% more rice and wheat than India (Krishnamurthi & Khandelwal, 2011). The reason for decrease in production and increase in farmers 'suicides have been noted as reduction in agricultural subsidies and lack of access to public credits. The public incentive system for small farmers and "sizable public investments in agriculture and rural electrification in China holds important lessons for India" (Kishore, 2015). The ignorance of rural agrarian population is also undermining the strength of socio-political mobilisation of the community by fragmenting it and so, perpetuating economic insecurity. There should be realisation that food security not only depends upon strategy for food distribution, but also more on food production. The land, credit, seeds, fertilisers and cooperatives of farmers run on public funds are inevitable assurances to ensure food production in India. Instead of simply reviving the past models, India must therefore find a contemporary balance, harnessing market efficiency while ensuring the state protects vulnerable smallholders and invests in rural public goods.

PART-III: Legal Policies Based on Private Property Framework

In September 1986, the Punta del Este declaration of the General Agreement on Tariffs and Trade (GATT) ministerial meeting introduced debates on intellectual property rights over agriculture. Trade liberalization, privatisation of resources, property rights under legislation are part of ten points of Washington consensus. The trade negotiations on Agriculture started in 1986 which reached its successful ending in the Uruguary Round. After protracted negotiations the Uruguay Round was adopted at the Marakkesh ministerial meeting in April 1994. The pressure on India to follow ten points of 'Washington consensus' increased. Adoption of those points by India could be witnessed from 1985 onwards in India. The effects were witnessed in the Indian agriculture sector, especially in the seed sector by privatisation and monopolisation without considering its negative effects on Indian farmers. In order to facilitate privatisation and monopolisation, many new policies were adopted from time to time.

During the Green Revolution period India was completely state interventionist in order to ensure subsidies, credits and assistance. The developed countries who were self-sufficient in technology and production had to search for new markets to sell off their products. The advent of the intellectual property regime ensured protection of their technology while selling their products to developing countries. In short, while imposing the global trade regime and exporting their products to India in order to ensure further dependency privatisation of seeds/varieties were made essential.

While discussing the effect of the Seed Control Order, 1983, it is clear that it was enacted to ensure the availability of good quality seeds to the end users, especially farmers. By way of the Order, the Central Government exercised control over the production, supply and equitable distribution of seeds on the grounds of non-availability of goods at fair prices or adequate quantity. The objective behind the Act enshrines the principle of equitable distribution and opposed the laizzes faire theory of dominance in the market.

The Seed Control order was enacted to bring seeds under the control of the Essential Commodities Act, 1955. The Essential Commodities Laws are socio – economic penal legislations enacted to establish control over production, supply, distribution, trade and commerce of necessary goods. These essential goods include 15 items at present such as medicinal drugs, foodstuffs, petroleum products, fertilizers, hank yarn made from cotton, raw jute and jute textiles, etc., with power given to the Central Government to include any item of necessity whenever it feels so, in the interest of the general public to the list (Mohanty, 2011). Therefore the Central Government could control the trading of seeds and avoid black marketing of supplies. As per the Essential Commodities Act, the distribution of commodities is provided through licenses. Seed being a commodity, the distribution licenses are granted only to certified seeds. The license to the dealer was given under the Order for a three years period. Licensee is under the obligation of displaying stock position on daily basis with price of seeds. The licensee is also under obligation to distribute the seeds in adequate quantity and quality and at cheaper prices.

Post-seventh five year plan, the pressure on the Government to open up and relax the import rules resulted in flow of private sector companies into the market. The Government had to formalize the Seed Policy that favoured the breaking away of Public Sector hold and entry of private sector into the seed market. The important policy initiative in the Seed Sector was the Industrial Licensing Policy of 1987 which de-reserved the Indian seed industry. This allowed more than 40% foreign ownership to sell, produce and market seeds (Kolady, Spielman, & Cavalieri, 2012). This was followed by New Seed Policy, 1988 which introduced significant deregulation and attracted several national and multinational companies into the seed business (Reddy, Tonapi, Bezkorowajnyj, Navi, & Seetharama, 2007).

The New Seed Policy of 1988 allowed seed companies "to import commercial vegetable seeds with no quotas, to import commercial seeds of foreign varieties of coarse grains and oilseeds for only two years after which seed companies had to produce the seed inside India" (Pray, Ramaswami, & Kelley, 2001). This policy permitted the import of selected seeds under Open General License (OGL), to render high quality seeds to the farmers to maximize yield, productivity and profits. "While the import of horticultural crops including flowers need recommendation

from Directors of Horticulture, import of crop seeds require permission from ICAR" (Santhy, Vijaya Kumari, Vishwanathan, & Deshmukh, 2009). The reduction in import duties, import restrictions on germplasm, seed-processing technology etc. led to more participation of foreign companies in the seed sector and growth of hybrids in India.

Followed by this policy, there was adoption of the Plants, Fruits and Seeds Order (Regulation of Import into India order) 1989 for the purpose of regulating the import of agricultural items into India without license. The import of seeds and planting materials increased thereafter and through different amended policies to the order during 1998, 2000 and 2001. The seed import regime was more liberalized and the Plant Quarantine (Regulation of import into India) Order, 2003 replaced the Plants, Fruits and Seeds Order, 1989. This Order, 2003 is to ensure safety aspects of seeds during imports and for the same, the agricultural imports are classified as prohibited plant species and restricted species. The order includes provision for regulating the import of soil, moss, germplasm and GMO's for research, insects, microbial cultures and bio-control agents, timber and wooden logs. Plant Quarantine mechanism under this Order was to prohibit the import of commodities contaminated with weeds, alien species, and packaging material of plant origin unless the material has been treated. Though this order aimed at safety checks, the machinery failed to adopt any bio-safety measures. By this Order, 2003, the import of plants, fruits and seeds became smoother without adequate safety check and the presence of bio-tech crops increased by 7.2 million farmers in India, elected to plant almost 15 million hectares of Bt cotton in 2011 (International Service for the Acquisition of Agro-Biotech Applications [ISAAA], 2012).

The New Industrial Policy of 1991 led to further liberalization of the seed sector. It removed restrictions on direct foreign investment and also freed the domestic entrepreneur from the restrictions of the MRTP Act. The withdrawal of state control from seed sector diverting certified hybrid seeds, synthetic seeds and certified high yielding plantlets developed plant tissue culture under the list of industries for automatic approval of foreign technology agreements facilitated seed trade devoid of regulations. The Nehruvian plans received the final blow when foreign capital and multinationals were given a free hand in the market which was detrimental towards the customary practices in trade and indigenous and small scale industries of the nation. The cumulative result of the shift in policies relating to the seed sector is the increase of private sector companies to the extent of about 500 companies operating in India (Dev, 2012). By 2005, the ratio of sale of seeds between public and private companies was 76-24 which indicated private sector dominance in the market (Rabobank, 2006). NAAS paper titled, 'Accelerating Seed Delivery Systems for Priming Indian Farm Productivity Enhancement: A Strategic View Point', reports that in 2016-17, this ratio became 48.4-51.6 (NAAS, 2018).

Simultaneously, it is also important to analyse the discussions in the international scene relating to trade in agriculture. Since the Paris Convention, 1883 inventions relating to agriculture had become part of intellectual property rights. Moreover there was wide acceptance of private property rights over agri-inventions among developed countries. This was manifested through enacting Plant Patent legislations across the developed countries. The United States enacted their first Plant Patent Act in 1930. Understanding the scope of privatisation of agricultural related innovations and its growing trade possibilities, the developed nations thought of harmonizing a regime for protection of new plant varieties which resulted in the International Convention for Protection of Plant Breeders' Rights (UPOV) 1961. While the discussion to strengthen the plant breeders' rights regime was strong, the developing countries under the Food and Agriculture Organisation advocated for the rights of farmers. It was a movement to ensure the customary rights of the farmers to access the new varieties which are monopolized/privatized by the breeder companies.

The International Undertaking on Plant Genetic Resources 1983 stressed the need to ensure 'common heritage' principle for protection of plant genetic resources. FAO realised that monopolisation of plant germplasm would impede cultivation/livelihood of farmers and food security of developing countries. It is also true that all new varieties are development/improvement/modification over the initial varieties. Initial varieties are in the majority of cases varieties available in the natural environment for free and such bio-resources are majorly located in developing countries. Plunder of germplasm from developing countries and further development of varieties and acquiring intellectual property rights to sell it back to the farmers at exorbitant prices is against equity and justice. The multinational companies were unhappy with the demand for farmers' rights.

The 'access to varieties and seeds' became an issue thereafter among developing nations where the majority of the population live depending upon agrarian operations. The developing countries took up the issue under the Food and Agriculture Organisation in 1983 upholding the principle of 'heritage of mankind' against monopolisation. However, lack of cooperation from Northern Hemisphere and United Nations Environmental Programme by convening Convention on Biological Diversity, 1992 distorted the concept of 'common heritage' subject to national sovereignty and private property rights. The seed lobby welcomed the approach and finally private seed companies in India voiced for breeders' rights under Seed Association of India from 1989 onwards. The first draft of Breeders' Rights legislation came out in 1993/94 in India which invited wide criticism from farmers' movements and civil society organisations for hindering the community-based activities relating to agriculture.

The state control over the resources was further curtailed by the enforcement of the IPR measures given under the Trade Related Aspects of Intellectual Property Rights (TRIPs), 1994. Article 27.3 (b) of TRIPs asked the member nations to enact legislation for the protection of new plant varieties. The Indian government under the lobbying of Seed Association of India, which is an association of the private seed sector, succumbed to their demands and enacted legislation for plant breeders' rights. However, civil society organisations resisted this bill with agitations and succeeded in enacting a legislation which includes farmers' rights as well. However, liberalisation of the seed sector and further granting them monopoly rights only helped the capitalists to grow and acquire IPR rights.

The Protection of Plant Varieties and Farmers' Rights Act (PPVFRA), 2001: Sui Generis Experiment

The Indian Legislation on Plant Variety, titled Protection of Plant Varieties and Farmers' Rights Act (PPVFRA), 2001, is unique as it has tried to include breeders' rights and farmers' rights in the same legislation. While some hail it as a landmark being the first of its kind across the world, some others critique it as incapable of producing any significant outcome for farmers (Gopalakrishnan, 2001). "The law emerged from a process that attempted to incorporate the interests of various stakeholders, including private sector breeders, public sector institutions, non-governmental organizations and farmers, within the property rights framework" (Ramanna, 2003). The Indian Plant Variety legislation has tried to grant some form of farmers' rights and has tried to regulate the tragedy of anti-commons, which refers to "underuse of resources arising from multiple ownership or rights to exclude others from use" (Ramanna, 2003).

The appreciation of the PVP Act, mainly, is based on the fact that farmers' rights have been incorporated as a separate chapter recognising some of the core rights of farmers. Whereas the critique is mainly based on the fact that the PVP Act treats farmers at par with modern commercial breeders. This approach does not take into consideration the essential difference in working, preferences and concerns between modern commercial breeding and the traditional farming system. These "two systems rely on and promote different knowledge systems and identify innovations differently and reward inventors in different ways" (Cullet, 1999).

Broadly, the major reason for these seemingly unrealistic normative and procedural manifestations could be attributed to the fact that the PVP Act was originally designed for the registration of new varieties bred by modern corporate breeders. Farmers' rights were included subsequently at the instance of the Joint Parliamentary Committee without changing the rest of the provisions of the framework (Dhar, Pandey, & Chaturvedi, 1995).

It is with the advent of intellectual property rights that the activities of farmers over the genetic resources were restricted by law. The exclusive rights regime attracted more private enterprises to invest in agricultural research and monopolize their inventions to the prevention of others. V.W. Ruttan cautioned against this institutional change stating that

> "if agricultural research were left entirely to the private sector the result would be serious bias in the allocation of research resources and other areas such as research on open pollinated seed varieties, biological control of insects and pathogens, and improvements in farming practices and management, would be neglected" (Ruttan, 1982). Intellectual property Rights regime which promotes individual monopoly rights over the resources is treated as anti-thetical to the common heritage concept over the natural resources.

It is this invasion of individual proprietary rights which converted the natural farming practices or responsibilities exercised by farmers to the 'privilege' or 'rights' point of view. The western model rights regime on plant varieties - exclusive rights paradigm - has not only resulted in inequitable distribution of resources, but has also failed to protect cultural and indigenous knowledge attached with the genetic resources appropriated from the southern countries. Until the intellectual property law sheds its stringent rights outlook and protects traditional knowledge associated with genetic resources, "intellectual property law will under-value and under-compensate the contributions and agricultural concerns of the developing countries that safeguard the vast majority of the world's plant genetic resources" (Ewens, 2000). "Currently there is a debate between advocates of indigenous farmers' rights in their folk varieties and the dominant world system, which vests intellectual property rights only in users of those resources for industrial agriculture" (Cleveland, Soleri, & Smith, 1999).

If we analyse the effects of registration under this Act since its enactment in 2001, there is a concerning disconnect between India's vast agrobiodiversity and the number of varieties officially registered. A particularly worrying trend is the significant underrepresentation of the public sector and State Agricultural Universities (SAUs), which have released numerous varieties but registered relatively few. Although ICAR institutions initially led in registrations when the process began in 2007, the private sector and applications for Farmer Varieties (FVs) have since gained considerable momentum. This shift raises critical questions about the equity and social justice embedded in the current intellectual property framework. While the Act's goal of stimulating agricultural innovation is commendable, there is an urgent need for closer monitoring of the intellectual property regime at all levels. This vigilance is necessary to prevent the misappropriation and privatisation of valuable genetic resources

that rightly belong in the public domain. Special scrutiny should be applied to the registration of traditional varieties by farmers and groups to ensure these shared resources are not unduly converted into private property (Devi, Antony, & Umaiban, 2024).

The private property regime grants the right to exclude others from making, using, offering to sell or selling the protected plants. Now the interpretations of Courts (Monsanto Canada v. Schmeiser, 2004) even make the farmer guilty of infringement if a patented transgenic plant is transplanted to his property via natural pollination, not by any of his deeds (Monsanto Canada v. Schmeiser, 2004).[3] In addition the reality of liberalisation is the most pertinent factor to be reckoned with in the context of the present issue and hence this researcher situates the entire debate relating to protection of customary rights of the farmers against the evolution of the political economy of India across several decades spanning from post-Independence till the enactment of monopoly regime over plant genetic resources.

Seed Governance: Law and Policy

The issue of 'access to seeds' needs to be discussed on the background of the shift in the policies of the Central Government. The impact of withdrawal of State from regulating seed trade coupled with promotion of monopolisation of seeds and varieties goes against the welfare ideals such as equity with growth and protecting the interests of the downtrodden and marginalized. Access to seeds is recognized as an important issue in India whereas 80% of the farming population is small and marginal farmers who may not be able to withstand the expense of seed resources. The price of BT Cotton hybrids increased from Rs. 62 in 2006 to Rs. 131 in 2007 and further to Rs. 274 in 2008 (Arora & Bansal, 2012). For the financial year 2025-26 these seeds were priced at Rs. 635 for Bollgard I and Rs. 901 for Bollgard II, by the Ministry of Agriculture and Farmer Welfare (Shagun, 2025). Considering that almost 20% of the farmers in India live below the poverty line (Hindustan Times, 2019), fixed at Rs. 1632 for rural areas (DD News, 2025), the cost of a single essential input consuming such a large share of their incomes is untenable. This is against the cherished goals of our Constitution and creates socio-economic disparity and tension.

The next policy that needs to be discussed to understand the anti-farmer policy of the state is the Seeds Bill, 2019. The primary objective of the Seeds Bill is to regulate the quality of seeds so as to make available sufficient good quality seeds for farmers. The Seeds Bill, 2004 was tabled before the parliament immediately after the Seeds Policy, 2002 that aimed at reducing the direct involvement of government in seed production and marketing, and to actively encourage the private sector to engage in research and development of new varieties (Saggi, 2006). The Bill of 2004

was vehemently opposed by farmers, civil society organizations and other stakeholders that resulted in preparation of three more editions of the Bill in 2008, 2010 and 2011. The Bill states that it is to "provide for regulating the quality of seeds for sale, import and export and to facilitate production and supply of seeds of quality and for matters connected therewith or incidental thereto" (Choo, Jalonen, Hong, & Sim, 2009).

The Seeds Bill, 2019 envisages two kinds of registration systems. First, the Bill requires all seeds for sale to be registered, barring farmers' varieties.[4] Such seeds need to meet the minimum standards of registration (Choo, Jalonen, Hong, & Sim, 2009). Second, the Seeds Bill makes registration of every dealer, producer and seed processor mandatory. The Seeds Bill specifies the transactions which are covered under the framework. They are: selling, keeping for sale, offering to sell, importing or exporting or otherwise supplying any seed by himself, or by any other person. Hence, the Seeds Bill seeks to ensure the quality, availability, efficacy and safety of seeds through a compulsory registration system. "The Bill provides for registration of 10 years for annual and biennial seeds, and 12 years for long duration perennials. It also allows for re-registration for the same duration" (Seed Bill, 2011). In short, the dealer will get the commercial marketing of registered seeds for 20 years for annual and biennial varieties and 24 years for perennials. This is absolute monopoly over seeds under the Bill, 2019 and re-registration provision curtails access and availability in terms of price increase and withholding from the market for demand.

But the bill had to face many criticisms as a result of which it was not passed. The proposed Seeds Bill, if enacted, would have severe implications upon farmers' rights. The link between the Seeds Bill and farmers' rights can be explained in the following ways. Though the Seeds Bill, 2004 does not make any distinction between commercial seed producers and farmers, the Seeds Bill, 2011 defines the term 'dealer' as a person who carries on the business of buying and selling, exporting, or importing seed, and includes an agent of a dealer. The Bill, in Section 2(11), defines a "farmer" as any person who owns cultivable land or any other category of farmers who are doing the agricultural work as may be notified by the Central/ State Governments. Most importantly, the access to seeds depends upon pricing and saving of seeds. The Bill does not contain any provision regarding price controls or fixing of royalty by MNCs, and actively creates the legal conditions for abuse by monopolies without any counterbalancing safeguards for affordability, thereby failing to protect farmers from exploitative markets.

Further, the Bill does not have any provision objecting to grant of marketing license of seeds. There is no pre-grant opposition or pre-registration publication of the application under the Bill. This lack of transparency creates a significant risk of approving spurious or sub-standard seeds without public scrutiny. The registration procedure for dealers not subjected to any production of materials that shows parental lineage. This

facilitates biopiracy, as companies can register derivatives of traditional varieties without the consent or benefit-sharing with the local farming communities. Moreover, there is no forum for communities to object to such approvals.

The Bill retained recognition to foreign seed certification that should not be acceptable for the reason that seeds need to be tested for performance in the Indian climatic conditions before registration. Also there is room for allowing private organizations which fulfil the criteria to conduct field trials. This provision will be a floodgate to allow seeds of private companies to get marketed at length. Likewise, the Bill provides for seed testing laboratories in the Government or non-Government sector. The other institutional machinery, both the Central and State Seed Committee which will be constituted to oversee implementation of the Seeds Act is not adequately represented with any member from the farmers' community. "In the latest version of the Bill, Seed Inspectors will have to take prior written permission from the Joint Secretary who is incharge of seed, Department of Agriculture, Cooperation and Farmers Welfare, Government of India, and with prior written authorisation of the Executive Magistrate, to search any place where they believe the Seed Act is being violated." (Seed Bill, 2011). This is in order to take precaution against harassing the farmers who are usually ignorant of seed regulations and are involved in transactions without any exemption for innocent violation under the Act. Lack of provisions to deal with GM seeds further aggravates the concerns of field/genetic contamination and other hazards including economic and ecological losses. Seed Legislation should not be another regime that promotes any kind of monopoly rights over the seeds (Krishnakumar, 2003). The pro-agribusiness features of the Bill need to be balanced in view of farmers' rights and their supply chain of affordable seeds.

In conclusion, the Seeds Bill, 2019, represents a fundamental conflict between a regime of corporate monopoly rights and the foundational rights of farmers. In order to promote sustainable agriculture and raise productivity, two essential rights of the farmers are: access to seeds and protection of plant genetic resources (PGR). Article 19 of the United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP) lays down that the peasants have the right to seeds, protect traditional knowledge, and equitably share benefits from plant genetic resources. For sustainable agriculture, genetic resources are so essential that the majority of the time farmers depend upon traditional varieties for consumption at individual level and rest they sell in the market. In today's context, the policies aiming at incentivizing Multinational corporations only result in increasing the price of the resources, like seeds/varieties, fertilizers, insecticides etc. The intellectual property rights regime raises the affordability question around access to new resources for farmers.

On the occasion on completion of 75 years of independence, NITI Aayog released a paper in July, 2023, titled, 'From Green Revolution to Amritkaal', which evaluates the past agricultural policies of India and their effectiveness, while laying down the plan for the next 25 years, till 2047 (until when India targets to become a developed nation) (NITI Aayog, 2023). This plan for the next 25 years is problematic, as it pushes for export competitiveness (Sec 2.3.4 of the paper) and integration with global value chains necessitates compliance with strong IPR regimes. This undermines the farmer-centric sui generis system of the PPVFRA. Its advocacy for market reforms and e-commerce (Sec 2.4.2) facilitates corporate entry into the sector, inevitably leading to the farmers dependent on high-cost seeds. The call to liberalise the land lease market (Under "Way Forward") risks facilitating the relaxation of land acquisition procedures, potentially displacing farmers. The focus on private sector and frontier technologies (Sec 2.4.3) deepens farmer dependence on corporate inputs, further eroding their autonomy and customary practices. Therefore, the Plan codifies "state abstentionism" into strategy, creating a conducive environment for private capital at the expense of farmers' rights and traditions.

A more contemporary issue that exemplifies the shift of genetic resources from common heritage to private property, is the new CRISPR gene-editing technology and the IPR issues surrounding it. The Indian scientists can use this technology for academic research, but not for commercial purposes, as the patent is held by entities like ERS Genomics (Chaurasia, 2024). This blocks the commercialization of publicly-developed seeds, replicating the Bt cotton dependency trap, and soaring costs of seeds. This demonstrates a big failure of national legislation like the PPV&FRA, which was designed as a sui generis system to protect farmer rights, but its effectiveness stands nullified and overridden by international IP frameworks like UPOV (Chaurasia, 2024). Therefore, the CRISPR patent issue powerfully validates this paper's central argument, as the state's transition to "abstentionism" is evident here, that prioritizes corporate gains over farmer rights. We therefore need to move away from state abstentionism, as otherwise each new technological wave will continue to dramatically influence customary practices and traditional knowledge, further consolidating corporate control and marginalizing the farmers.

PART IV: Effect of New Policy Changes on Farmers in India

The structural transition in the seed sector and policy changes relating to control of plant genetic resources have affected food production and farmers' lives. It is a corollary that the food production gets affected when they face difficulty in relation to viability of farming. As we have discussed earlier,

privatisation of seeds and varieties which are essential for food production would create accessibility related issues in the longer run. The affordability and availability will be real challenges if farmers' access to seeds and varieties are challenged. We should keep in mind that the majority of the agrarian population still rely on agriculture as their main occupation.

It is evident that the economic reforms and legislations during the liberalisation period were not much of benefit to the farmers in India. The protection of plant varieties which forms part of plant genetic resources were granted under Intellectual Property Regime to comply with Trade related aspects of Intellectual Property Rights, 1995. It is here that it is relevant to ask a question whether these movements to privatise and monopolise plant genetic resources have helped the farmers to any extent. The latest NCRB Report titled, 'Accidental Deaths and Suicides in India', reports that there were 11,290 farmer suicides in 2022 alone. The experts such as Uma Kapila (Kapila, 2013), Mahendra Dev (Dev, 2012), C H Hanumantha Rao (Rao, 2001), Pradip Baijal (Baijal, 2002), Bhalla and Singh (Bhalla & Singh, 2009) state that the agrarian productivity went down during 1997-2005. "While the Indian economy was growing at a fast pace, the agricultural sector was experiencing stagnation and the relative share of the agricultural sector in the national economy began to decline steadily" (Jodhka, 2012). The financial sector reforms after 1991 diminished the government led credit arrangements for agriculture (Satish, 2007). This is corroborated by a recent Reserve Bank of India (RBI) Internal Working Group (2019) report, which acknowledges that despite achieving overall Priority Sector Lending (PSL) targets, banks have consistently failed to meet the specific 18% sub-target for agriculture, indicating a persistent systemic bias against the sector, despite schemes like Kisan Credit Cards (KCC) etc (Reserve Bank of India, 2019).

The suicide notes also state that one of the reasons for their tragic death is increase in prices of seeds. While analysing these factors together, it is evident that neither the privatisation nor exclusive rights regime has improved the living and working conditions of farmers. It is here we need to rethink whether the adoption of these policies has served the domestic interest considering the fact that the majority of the population is involved in agrarian operations. The neglect of agriculture worsened post-liberalisation. It is true that from the beginning of planned economic development, the major thrust was on development of the industrial sector. The agrarian policies were more concentrated on policies of land reforms. The permanent migration of agricultural labourers also results in scarcity of labour in farming. However, the saddening fact is that the agricultural land is being fragmented and given away for development at large scale. This has resulted in migration of agricultural labourers to form part of urban poor.

One of the justifications for legalising intellectual property regime is that it reduces biopiracy from developing countries. Then the question which follows is whether the intellectual property regime ensures protection from 'biopiracy'. It enhances competition to own and manipulate the resources to obtain monopoly. The protection of germplasm requires registration in order to be protected under the law. It is evident that registration only adds difficulty to the farmers whereas the breeders are having separate wings to deal with registration procedures. The farmers in developing countries rather than buying seeds from monopolies would prefer to continue their practices such as exchanging and bartering of seeds in order to ensure they have diverse crops available in their farms. It is here we look at the possibilities, either institutional or policy level, to ensure that the farmers' customary rights and practices are not disturbed and interfered with to ensure food security and sovereignty of the nation.

While thinking about the way forward, as suggested by Schedule III of the National Food Security Act, 2013, agrarian reforms are suggested as one of the means for revitalisation of agriculture. Considering the fact that the tillers are involved right from the first activity to the last, through ploughing, harrowing, sowing, weeding and harvesting and they have knowledge accumulated through the ages, it is the tillers who have essentially contributed to agrarian production. Control over the land should therefore pass directly from non-tilling owners or tenants to working tenants, to crop sharers and to farm servants and others regularly employed as landless labourers.

Activation of seed co-operatives and Credit based institutions would be useful for the farmers to revamp their farming activities. Seed Co-operatives have many success stories to speak about in the Indian context. The Seed Co-operatives grew during the green revolution period in order to ensure availability of good quality, healthy, disease free and true type seed of particular variety of a crop to small and marginal farmers. Maintaining good seeds and circulating among networks of seed cooperatives would help them go to the retailers from whom they get impure seeds at higher prices with the prescription of higher use of fertilisers.

Recent studies confirm that member-driven farmers' organizations offering diverse services achieve greater sustainability and success through financial autonomy and reduced external reliance. The Farmer Co-operative Banks that are member-driven and -controlled, and that provide a diverse portfolio of services, are more likely to be sustainable and have a positive impact on rural livelihoods (Ma, Marini, & Rahut, 2023). It is also essential for the government to invest more in seed research and development to avoid monopolisation of new seeds and varieties by the private sector.

The panchayat has the responsibility of implementing special measures for benefitting the small and marginal farmers by giving them special

allowances for inputs. Out of the total 138 million landholders in India, 85% are smallholder farmers, 67% being marginal (Dadlani, Das Gupta, & Dadlani, 2025). According to the latest Agricultural Census, the highest percentage share of total operational land in 2015-16 was observed in marginal category (24%) followed by semi-medium (23.8%), small (22.9%), medium (20.2%) and large category (9.1%). In total, they contribute 51.2% to the total output of the country (Dadlani, Das Gupta, & Dadlani, 2025). While considering the fact that more than half of the food grains are produced by small and marginal farmers, though they own less than half of the operational holdings, thus establishing that their productivity is much higher, there should be separate schemes to sustain them in agriculture by distributing high yield seeds, fertilisers and credit for power, irrigation, preparation of land etc.

Conclusion

Article 39 (b) and (c) of our Constitution read along with Article 37[5] talks about the responsibility of the state not to subscribe to ownership and control of material resources of the community in such a way as to go against the common good. Neither can operations of the economic system ever be allowed to create concentration of wealth nor means of production to the common detriment. By now it is clear that multinational seed companies have market motives over the food security or welfare of agrarian communities. The innovations should be made accessible to farmers. Therefore, the state has to take initiative to establish institutions or identify institutional partners to subsidise the accessibility and affordability crisis in the agrarian sector.

Having conceded to substantial policy shifts we went on to create a new legal regime through statutes such as the Protection of Plant Varieties and Farmers' Rights Act (PPV & FRA), 2001, the Seeds Bill, 2004, 2019 etc. The PPV & FRA has tried to treat breeders and farmers at equal footing by flouting the principle that unequals can never be treated alike. The farmers being the cultivators, conservators and maintainers of plant genetic diversity, the registration procedures as well as exclusive nature of rights impede their age old agrarian practices which are the basis of continuing enrichment of plant diversity and subsistence farming in order to prepare the ground for legal entry of multinational seed companies. It is needless to point out that these new legal statutes are in violation of Articles 39 (b) and (c) read with Art. 37. The new trajectory of law and policy interventions to encourage use of biotech or GM crops in India have not contributed to increase in food crop production. The changes on the policy and legal front adopted since the onset of neo-liberalism constitutes a huge risk not only to our food security but to the lives of millions of farmers who live on agriculture. It is therefore necessary to revisit policy perspectives and adopt a welfare-based approach.

Endnotes

[1] This resolution became part of the International Undertaking in 1991

[2] IUPGR declared the principle that PGR should be freely exchanged as a "heritage of mankind" and should be preserved through international conservation efforts.

[3] Monsanto has filed 90 lawsuits against 147 farmers in the United States alone on the same point.

[4] The Sees Bill, 2004 stated for compulsory registration of all seeds which was later modified by eliminating farmers' varieties from the ambit of registration

[5] Article 37 of the Indian Constitution, "Application of the principles contained in this Part The provisions contained in this Part shall not be enforceable by any court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws".

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Genetically Modified and Genome-Edited Plants in Indian Agriculture: Time to Revisit Policy

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Abstract: India's experience with genetically modified (GM) crops began with the approval of Bt cotton in 2002, which demonstrated clear benefits in yield enhancement and reduction in pesticide use. However, the development and release of other GM crops, such as Bt brinjal and GM mustard (DMH-11), have encountered prolonged regulatory hurdles, judicial interventions, and public skepticism. The emergence of CRISPR-based genome editing offers new possibilities for precision crop improvement under a differentiated regulatory framework. This paper reviews India's legal, institutional, and policy evolution regarding GM and genome-edited crops, situates it within the international context, and highlights the Supreme Court's recent directive (2024) for formulating a comprehensive national policy. Drawing from global and Indian evidence, it proposes a balanced, science-based, and farmer-centric approach to managing biotechnology innovations that enhance productivity, ensure biosafety, and strengthen India's agricultural resilience.
Keywords: Genetically modified crops, Genome edited crops, Policy on GMOs and genome edited plants, Bt- cotton, Bt- brinjal, Herbicide resistant mustard.

Introduction and Historical Background in Indian Context

India got acquainted with the recombinant-DNA (r-DNA) based genetically modified (GM) Bt-cotton technology for the first time in early 1991, when the possessor of the technology, Monsanto Inc., USA, approached the Government of India through the Ministry of Science and Technology to sell its technology package to the country. The Department of Biotechnology (DBT) was the competent authority to deal with r-DNA-based GM technologies; therefore, the technology-transfer discussions and negotiations were piloted by the DBT.

Bt-cotton technology of Monsanto, in essence, is the genetic modification of the conventional cotton variety Gossypium hirsutum L., known as Coker-312, which is genetically modified to contain within its genome a transgenic DNA construct that, besides other nucleotide sequences in the construct, also carries a gene derived from the soil bacterium Bacillus thuringiensis (Bt). This gene codes for a protein named Cry I Ac, which

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is toxic to lepidopteran pests upon ingestion. The Bt-Cry I Ac protein is expressed in all body parts of the Bt-cotton plant; consequently, lepidopteran pests cannot do much harm to the plant.

One major reason for low cotton yield in India has been that lepidopteran pests destroy a large proportion of the cotton bolls by feeding on them. To prevent such losses, large quantities of chemical pesticides have to be applied multiple times in non-Bt-cotton fields. The advantage of planting Bt-cotton seeds, among other agricultural benefits, is that much smaller quantities of chemical pesticides are required and the cotton yield increases substantially. During the negotiations with Monsanto for procuring their Bt-cotton technology, the average Indian yield of cotton lint per hectare of cultivated land was about 150–180 kg, while the induction of Monsanto's Bt-cotton technology promised to raise the yield more than threefold, with a concomitant and substantial reduction in pesticide use. The proposal was therefore extremely attractive.

The negotiations for transfer of Bt-cotton technology from Monsanto to the Government of India, however, could not materialise, although the Indian negotiators acquired much technical and economic knowledge in the process. The Bt-cotton technology of Monsanto was being field-evaluated in the USA in 1993, and it obtained USDA approval for commercial cultivation there in 1995. In the meantime, after the failure of negotiations for technology transfer to the Government of India, an Indian private company—Maharashtra Hybrid Seeds Company Limited (Mahyco), Mumbai—started negotiating directly with Monsanto and struck a business deal. Mahyco then approached the Government of India to introduce the said Bt-cotton technology in 1994.

The proposal was examined by the DBT, and a permit was issued to Mahyco to import 100 grams of Bt Coker-312 seeds on 10 March 1995. Mahyco was also permitted to carry out planting and related experiments in a fully contained environment. The contained-environment experiments were started in 1996 under the supervision of the Institutional Biosafety Committee (IBSC) of Mahyco, approved by the Government under the Indian Environment (Protection) Act 1986 and the 1989 Rules, as well as by the Review Committee on Genetic Manipulation (RCGM) of the DBT.

Simultaneously, along with experiments on Monsanto's Bt-cotton technology, copious enthusiasm arose in the country to develop different kinds of other GM plants at various institutions and companies, as described later. There was a high momentum in transgenic research in Indian agriculture. However, India later lost that momentum after 2005. A mix of regulatory caution, public contestation (for example, the 2010 moratorium on Bt brinjal), and court interventions (beginning with Writ Petition No. 260 of 2005) (Supreme Court of India, 2005) produced a de facto policy freeze that discouraged sustained public and private R&D investment.

Laws and Rules for handling transgenic substances were already in place in India, starting in 1986. The manufacture, use, import, export, and storage of genetically modified seeds, plants, and planting propagules in India are governed by the Rules and Laws enumerated under the country's Environment (Protection) Act, 1986 (Government of India, 1986) and the associated 1989 Rules (Government of India, 1989). Genetically modified substances (GMS), living or non-living, are those in which the genetic materials have been modified by human intervention using modern biotechnological methods such as recombinant-DNA technology—distinct from natural breeding, selection, mating, or cross-pollination between parents of choice.

As India is also a signatory to the international treaty known as the Cartagena Protocol on Biosafety, which aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, while also taking into account risks to human health, the country was well prepared to handle transgenic substances, including genetically modified organisms (GMOs) and LMOs, both for domestic use and for trans-boundary movements. Further details on GMOs and LMOs are provided in Article 3 of the Cartagena Protocol on Biosafety (Convention on Biological Diversity, Cartagena Protocol on Biosafety).

India's engagement with recombinant-DNA crops, therefore, dates to the early 1990s. After a multi-tier biosafety evaluation led by the DBT and the Genetic Engineering Approval Committee (later renamed the Genetic Engineering Appraisal Committee, GEAC), Bt cotton was approved on 26 March 2002. Subsequent adoption exceeded 90 percent of the cultivated cotton area, with reported yield improvements and a reduction in insecticide sprays. Yet, outside cotton, no GM crop has been commercialised.

It is interesting to recapitulate that as the country made progress in the elucidation of data and information on Bt-cotton technology starting from 1994, several Indian institutions and commercial organisations became interested in developing transgenic agricultural crops of various kinds (Ghosh, 1997a, 1997b). The Central Tobacco Research Institute, Rajahmundry, developed transgenic tobacco plants containing Bt-Cry A(b) and Cry 1C genes; the Bose Institute, Calcutta, developed rice containing Bt-toxin-expressing proteins; the Tamil Nadu Agricultural University worked on rice containing reporter genes such as hph or gusA; and the South Campus of Delhi University (SCDU) developed the bar–barnase–barstar system in Indian mustard with a view to developing transgenic hybrid seeds of mustard for higher yields. SCDU also developed rice containing selectable marker genes such as hygromycin and gus. The National Botanical Institute, Lucknow, attempted to develop transgenic cotton containing Bt-toxin genes; the Indian Agricultural Research Institute (IARI), New Delhi, experimented with brinjal and tomato to incorporate Bt-toxin genes; IARI, Shillong,

worked on rice containing Bt-toxin genes; and the Central Potato Research Institute, Shimla, developed potato containing Bt-toxin genes. Proagro PGS (India), New Delhi, developed the bar–barnase–barstar system in mustard to increase yield through hybrid production and was permitted to carry out multiple open-field experiments on smaller plots to generate information on environmental and food- or feed-safety issues. They made considerable progress in generating such data. Proagro PGS (India) was also interested in developing cauliflower hybrids using the bar–barnase–barstar system and conducted experiments in glasshouses/greenhouses to develop cauliflower and cabbage seeds containing Bt-Cry 1 H and Cry 9 C genes. Mahyco, Jalna, in collaboration with Monsanto, USA, worked on developing Bt-Cry 1 Ac genes in agricultural crops and vegetables. Rallis India, Bangalore, engaged in developing chilli, bell pepper, and tomato lines into which they attempted to insert Snowdrop (Galanthus nivalis agglutinin, GNA) lectin genes encoding a mannose-binding protein with insecticidal properties.

Most of these experiments were carried out in glasshouses or greenhouses under contained conditions, except a few—such as those on Bt-cotton and the bar–barnase–barstar system-based mustard plants. All experiments were authorised by the RCGM of the DBT under the Environment (Protection) Act 1986 and the 1989 Rules. Unauthorised open-field experiments were dealt with severely under the provisions of the law. Most experiments on GMOs were progressing well, with some showing encouraging results that raised hopes that many new GMOs might soon be authorised for commercial cultivation once environmental and animal-health safety were scientifically established on the basis of the then-current knowledge.

During the systematic conduct of trials for generating environmental-safety as well as food- or feed-safety data under the leadership of the RCGM of DBT, scientifically developed protocols were followed, and the efforts were appreciated by many sections of the scientific community. An article acknowledging this appeared in Nature (Jayaraman, 1989). However, most of these efforts were abandoned at different stages during the later years—after 2002—mostly because of strong opposition to introducing transgenic plants in Indian agriculture by various groups, including certain activists, sections of the public, some political leaders, and even a number of scientists. Further, as India did not pay heed to improve the Bt- cotton that was approved, requiring the introduction/ induction of more of useful genes in cotton genome against cotton pests, Indian dominance in cotton yield in global context could not be maintained as cotton production and exports started declining from 2020-21, because the cotton pests became increasingly resistant to Bt- proteins, thereby resulting in increased production costs, increase in the price of genuine Bt- cotton planting materials and shrinkage of margins by the cotton growers. Many of the cotton growers had, therefore, diverted their land from cotton growing to other crops like pulses, paddy, and oilseeds. As a consequence, India could

not maintain its number one global leader position in cotton production after 2020-21, and the country had to resort to importing cotton to feed the needs of its textile industry.

This paper combines global and Indian evidence, highlights genuine risks, and outlines a practical policy agenda that benefits farmers, protects biodiversity, and enhances India's innovation capacity. The focus is on balanced regulation, transparency, and farmer-centred seed-development systems.

Global Evidence on GM Crop Impacts

Independent syntheses across different regions report four consistent effects of first-generation GM traits—namely insect resistance and herbicide tolerance—on agricultural outcomes. These include (i) yield increases, (ii) reductions in chemical insecticide use, (iii) higher farm incomes, and (iv) contributions to climate-change mitigation, although with variations depending on crop, trait, and local context. Table 1 summarises the key findings drawn from major international studies.

Table 1: Synthesis of Global Evidence on GM Crop Impacts

Outcome	Direction of effects	Indicative magnitude (range)	Example sources
Yield	↑	~10–25% (context specific)	(Klümper, 2014) Klümper & Qaim 2014; (Brookes, 2005) Brookes & Barfoot 2005
Insecticide use	↓	~20–40% fewer sprays/applications	Klümper & Qaim 2014 Brookes & Barfoot 2005
Farm income	↑	Positive gross margins after seed costs	Brookes & Barfoot 2005; (Brookes, 2022) Brookes G. 2022 & (Reddy & Prasad, 2025) Reddy, A. A., & Prasad, Y. 2025 (Indian gain)
Climate change mitigation	↑	Assists in reducing agricultural greenhouse gas emissions	(Kovak, Blaustein & Qaim, 2022) Kovak E, Blaustein-Rejto D & Qaim M. 2022

Source: Authors own adaptation.

Notes: Arrows indicate the direction of change (↑ increase; ↓ decrease). Ranges are indicative and vary by region and season; benefits are not universal and depend on stewardship, resistance management, and seed quality.

Indian Regulators' Response After Bt-Cotton Approval in 2002 to GMOs and Gene-Edited Plants

GMOs. The moratorium on Bt brinjal announced in 2010 signalled a phase of heightened regulatory caution and public mistrust toward GM crops in India. In 2022, the Genetic Engineering Appraisal Committee (GEAC) approved the environmental release of GM mustard (DMH-11); however, subsequent litigation led to a 2024 directive by the Hon'ble Supreme Court of India requiring the Union Government to formulate a comprehensive national policy on GM crops. The Court also called for clarity on the institutional roles of the Department of Biotechnology (DBT), the GEAC under the Ministry of Environment, Forest and Climate Change (MoEF&CC), the Indian Council of Agricultural Research (ICAR) under the Ministry of Agriculture and Farmers Welfare (MoA&FW), and State regulators, together with the establishment of robust post-release monitoring mechanisms.

Genome-Edited Plants. In 2022, India introduced a calibrated framework distinguishing site-directed-nuclease (SDN) categories. Edits achieved through SDN-1 and SDN-2 approaches—entailing small, precise alterations without insertion of foreign DNA—were exempted from transgenic GMO provisions, provided that the notified procedures were followed. By contrast, SDN-3 approaches involving insertions continue to be regulated in the same manner as conventional GM organisms. This differentiated regulatory pathway aims to facilitate low-risk, high-value trait improvements while maintaining an appropriate level of biosafety oversight.

International Regulatory Comparison (Genome Editing), Compared with Indian Stand

A comparative overview of regulatory approaches toward genome-edited plants across major jurisdictions reveals a pragmatic trend: countries tend to apply lighter-touch oversight where edits are indistinguishable from conventional breeding outcomes, while retaining full GMO scrutiny for constructs containing inserted transgenes. Table 2 presents an indicative summary of current regulatory treatments.

Table 2: Treatment of Genome Edited Plants (Indicative Overview)

Jurisdiction	SDN 1/2	SDN 3	Notes
United States	Often not regulated as GMO if comparable to conventional breeding	Regulated when transgenes/plant pest sequences trigger oversight	USDA SECURE rule emphasises product based triggers (Congressional Research Service, 2023)

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European Union	Historically regulated as GMO; proposals for proportionate oversight under discussion	Regulated as GMO	Landscape evolving; member state debates ongoing (Voigt, 2023)
China	Streamlined variety registration guidance for gene edited crops	Regulated	Emphasis on food security traits (Zhu, 2022) Laws conservative but more lenient than European Union (Genetic Literacy Project)
Japan	Not regulated as GMO when no foreign DNA remains	Regulated	Case by case notifications (Kondo, et.al, 2022)
India	Administrative exemption pathway for SDN 1/2; notification required	Regulated as GM	DBT/GEAC guidance operational (Department of Biotechnology, 2022) since 2022

Source: Authors own adaptation.

A pragmatic global pattern thus emerges: jurisdictions are increasingly moving toward product-based, science-driven regulation for genome-edited crops, while maintaining rigorous oversight for transgenic insertions.

Case Studies on GMOs and Gene Edited Plants from India and the Region

Bt cotton (India). Adoption of Bt cotton in India has stabilised above 90 percent of the cultivated area. Numerous studies report yield improvements and significant reductions in insecticide use targeting bollworms. Economic evaluations estimate total benefits of approximately ₹ 3.47 lakh crore up to 2022 (Reddy & Prasad, 2025), driven by increased yield and savings in input costs. Nevertheless, inadequacy of science-based interventions including refuge compliance integrated with directives in the up to the district level in the policy issues persist: pink-bollworm resistance in certain regions and over-reliance on hybrid seed types underscore the need for integrated

resistance-management strategies and the revitalisation of public-sector varietal pipelines to widen farmer choice and foster seed-price competition.

Bt brinjal (India vs. Bangladesh). Despite scientific evidence indicating reduced pesticide use and higher marketable yields under field conditions, India imposed a moratorium on Bt brinjal in 2010 owing to public concerns about biosafety and transparency. By contrast, Bangladesh approved its commercial cultivation in 2014. Farmers there have consistently reported lower spray frequency and improved fruit quality, highlighting the critical importance of transparent trials, participatory varietal selection, and effective extension services (Shelton, et. al, 2020 & Ethen, et. al, 2025).

GM mustard (DMH-11, India). The GEAC's 2022 decision approving environmental release of GM mustard (DMH-11) reignited debate over herbicide tolerance (Hsiao, et. al, 2021), potential out-crossing (Bakshi, 2022), and the validity of claimed yield advantages. The 2024 Supreme Court directions have now mandated formulation of a coherent national policy, establishment of rigorous post-release monitoring frameworks, and enforcement of stewardship protocols before large-scale cultivation can commence.

Genome-edited rice (India). Indian public-sector institutes have developed two CRISPR-edited rice lines targeting drought tolerance, nitrogen-use efficiency, and yield components. It has been reported (Latha, 2025) that the development of these two varieties—DRR Dhan 100 (Kamala) and Pusa DST Rice 1—was based on processes and Cas-9 proteins described in Indian Patent No. 397884 (ERS Genomics, 2022). Translation of these innovations to farmer fields will depend on regulatory clarity, freedom-to-operate in genome-editing tools, and robust breeder-seed systems ensuring timely and affordable access to improved varieties.

Scientifically Documented Challenges

Resistance evolution. Pink bollworm resistance to Cry toxins has emerged in regions where refuge compliance is weak. Stewardship therefore, requires the deployment of pyramided traits—that is, the assembling of multiple genes in cultivars that enable simultaneous expression of stacked insecticidal proteins to develop durable resistance. The use of seed-mix refuges, integrated pest management (IPM) practices, and systematic resistance monitoring are essential to sustain the efficacy of Bt technology in the long term.

Gene flow and biodiversity. Certain crops possess interfertile wild relatives, and thus gene flow from GM crops to related species cannot be ruled out. Risk assessments should therefore, incorporate spatio-temporal isolation measures, consideration of the biology of the introduced trait, and landscape-level monitoring. Corrective actions must be triggered if threshold levels

of gene flow or environmental impact are exceeded, in order to preserve biodiversity and ecosystem integrity.

Seed-market structure. The predominance of hybrid seed systems in cotton has limited farmers' varietal choice and, in some cases, led to higher seed costs. Strengthening public-sector breeding programmes and licensing of high-performing public varieties can increase competition, lower prices, and improve access for smallholders. Revitalisation of publicly bred, open-pollinated varieties is particularly important for ensuring affordable seed options in marginal regions.

Herbicide externalities. Herbicide-tolerant cropping systems require strict adherence to label recommendations, crop rotation, and the inclusion of non-chemical weed-management methods to mitigate the evolution of herbicide-resistant weeds and to reduce environmental risks. Training of farmers, proper equipment calibration, and enforcement of good agricultural practices are indispensable for minimising negative ecological effects.

Data transparency. Fragmented or restricted access to biosafety-trial data has often fuelled mistrust among stakeholders. Establishing open-access data portals, publishing plain-language summaries of biosafety results, and ensuring peer-reviewed dissemination of key findings can substantially improve the legitimacy and public acceptance of regulatory decisions.

Farmer Perspectives and Socio Economic Outcomes

Household surveys and district-level panel studies consistently report higher net returns with Bt technology under typical field conditions, accompanied by labour and time savings due to reduced pesticide spraying. The aggregate benefits, however, are heterogeneous across regions. Factors such as agro-ecological conditions, seed quality, counterfeit seeds, availability of extension support, and fluctuations in input prices critically influence the magnitude of benefits realised by farmers.

In several cotton-growing states, Bt technology has contributed to improved profitability and lower exposure of farm workers to hazardous pesticides, with many farmers acknowledging both economic and health advantages. Yet, the extent of these benefits has not been uniform. Poor quality control of seed stocks, inadequate refuge implementation, and occasional pest resurgence have tempered gains in certain locations.

Complementary investments in institutional credit, precision agronomy, and price-discovery mechanisms can substantially enhance the long-term returns from biotechnology adoption. Access to reliable market information, crop-insurance coverage, and transparent procurement policies are equally important for reducing production and price risks faced by small and marginal farmers.

Overall, evidence indicates that genetically modified crops—when supported by good agronomic practices, quality seed distribution, and robust extension networks—can significantly raise farm incomes and improve livelihood resilience, particularly under conditions of climatic stress.

Intellectual Property (IP) and Freedom to Operate (FTO)

CRISPR/Cas systems are covered by overlapping patents in several key jurisdictions, resulting in complex intellectual property (IP) landscapes for genome-editing technologies. For public-sector breeding programmes in India, practical options to ensure freedom-to-operate include: (i) using licensed research toolkits that incorporate humanitarian-use clauses, (ii) deploying alternative nucleases or domestically developed genome-editing tools that are not encumbered by restrictive patent claims, and (iii) exploring patent pools or government-enabled licensing frameworks for food-security crops.

Parallel investments in public-sector seed production, certification, and distribution systems are equally important to ensure that genome-edited and GM varieties are accessible and affordable to farmers. Strengthening breeder-seed and foundation-seed pipelines, coupled with the establishment of regional seed hubs, can guarantee timely supply of high-quality planting material.

In the longer term, India could benefit from creating a national platform to coordinate licensing negotiations for essential biotechnological tools, thereby preventing duplication of efforts among public institutions. Such a mechanism would facilitate open innovation, promote domestic R&D capacity in molecular breeding, and help align IP management with the larger public-interest goals of agricultural productivity and sustainability.

Public Perception and Communication

Trust deficits surrounding genetically modified and genome-edited crops often stem from opaque regulatory processes and polarised public messaging. Misunderstandings between scientists, policymakers, and civil-society groups have magnified fears about environmental and food-safety risks, even when scientific evidence has been largely reassuring. Addressing this gap requires deliberate, transparent, and sustained communication strategies.

Remedial actions include: (a) creation of open-access trial-data portals and proactive public disclosure of biosafety results; (b) implementation of farmer-participatory on-farm demonstration trials to showcase benefits and safety under local conditions; (c) institution of independent biosafety audits whose summaries are published in plain language for wider comprehension; and (d) integration of outreach efforts through existing state-level extension systems, including Krishi Vigyan Kendras, agricultural universities, and civil-society organisations.

Clear and consistent risk communication is essential. Public messaging must distinguish between hazard—the inherent property of a substance or trait that could cause harm—and exposure—the degree to which humans or ecosystems actually encounter it. Framing regulatory assessments around this distinction can help citizens evaluate risks rationally and develop confidence in the science-based decision-making process. Ultimately, open dialogue, credible intermediaries, and visible accountability are key to rebuilding public trust in agricultural biotechnology.

Climate Resilience and Food System Priorities

Trait pipelines aligned with India's agro-climatic vulnerabilities—such as heat stress, drought, salinity, flood submergence, and emerging pest pressures—can play a vital role in reducing climate-related agricultural risks. Genetically modified (GM) and genome-edited technologies, when judiciously applied, offer powerful tools to build such resilience by introducing traits that strengthen physiological tolerance, improve water-use efficiency, and enhance nutrient uptake.

Genome editing, in particular, is ideally suited for fine-tuning complex quantitative traits such as stomatal regulation, root architecture, and grain-quality attributes that are difficult to improve through conventional breeding alone. GM traits, on the other hand, continue to be indispensable for conferring durable insect resistance, tolerance to biotic stresses, and biofortification in select crops where single-gene insertions deliver significant benefits.

Prioritisation of future research and deployment should therefore be guided by district-level vulnerability maps and region-specific climate projections. Integrating biotechnology interventions with national programmes such as the Pradhan Mantri Kisan SAMPADA Yojana (PMKSY) and the National Food Security Mission (NFSM) can help ensure that innovations target the most climate-sensitive geographies. By doing so, India can not only enhance the adaptive capacity of its food systems but also contribute meaningfully to its commitments under the Paris Agreement and the Sustainable Development Goals (SDGs).

Way Forward: Suggested Seven Policy Actions

National policy and mandates. Notify a science-based national policy that clearly delineates the respective roles and responsibilities of the Department of Biotechnology's Review Committee on Genetic Manipulation (RCGM), the Ministry of Environment, Forest and Climate Change's Genetic Engineering Appraisal Committee (GEAC), the Ministry of Agriculture and Farmers Welfare's Indian Council of Agricultural Research (ICAR), and the State-level regulators. This policy should institutionalise mandatory post-release surveillance and monitoring mechanisms to ensure transparency and accountability.

Tiered, time-bound approvals. Establish predefined decision timelines and adopt a tiered, risk-proportionate approach to data requirements for product evaluation. Decisions on approvals or denials should be accompanied by transparent reasoning and made publicly available. Enforceable stewardship plans must form an integral part of the approval process, ensuring scientific credibility and public confidence.

Farmer-centric seed systems. Reinvigorate public-sector varietal breeding, seed multiplication, and certification systems to reduce dependence on a narrow set of private hybrids. Encourage healthy competition by licensing high-performing public varieties and curbing counterfeit seed markets through traceability systems and strict penalties.

Resistance and stewardship. Mandate Integrated Risk Management (IRM) and Human Resource Management (HRM) plans as preconditions for approval and commercial deployment. Under IRM, outline a holistic, organisation-wide approach for identifying, assessing, managing, and monitoring the full spectrum of perceived risks. Under HRM, prepare a systematic plan of action to train an adequate number of farmers and personnel with the necessary skills and competencies to achieve compliance and ensure long-term sustainability of the technology.

Intellectual property and tool access. Facilitate CRISPR and related tool licensing for public research institutions. Consider the creation of patent pools or the use of statutory licences for public-interest crops. Parallelly, support domestic R&D efforts aimed at developing indigenous genome-editing tools to strengthen India's technological sovereignty.

Open data and communication. Publish trial protocols, summary biosafety data, and real-time monitoring dashboards in the public domain. Fund State-level risk communication programmes aligned with Krishi Vigyan Kendras and local agricultural universities to make information accessible to farmers and the general public in regional languages.

Climate-linked prioritisation. Fast-track approvals for traits addressing major climate vulnerabilities such as drought, heat, salinity, and nutrient deficiencies. Align regulatory and funding priorities with district-level vulnerability mapping and public procurement incentives to ensure that biotechnology advances serve both environmental sustainability and national food-security objectives.

Concluding Remarks

India's agricultural future hinges on raising productivity in a sustainable manner under increasing climate stress and shrinking natural-resource bases. Genetically modified (GM) and genome-edited crops are not silver bullets, but within well-defined and robust regulatory guardrails—and with a strong

farmer-first design philosophy—they can serve as powerful complements to agronomic, irrigation, and market reforms.

A coherent national policy, supported by transparent oversight and an integrated multi-agency mechanism, is urgently needed to convert India's stalled promise in agricultural biotechnology into measurable economic and social gains. Reinvigorating public-sector research, enabling private-sector innovation through clear and predictable regulations, and investing in effective extension systems can together enhance farmer welfare and national food security.

If these reforms are implemented with scientific rigour and social responsibility, India can regain its leadership in agricultural biotechnology, contributing not only to domestic prosperity but also to global efforts toward climate resilience and sustainable development.

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