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Working Paper

Vaccine global value chains and regional production capacity in Asia and the Pacific

ARTNeT Working Paper Series, No. 217

Provided in Cooperation with:
Asia-Pacific Research and Training Network on Trade (ARTNeT), Bangkok

Suggested Citation: Pananond, Pavida; Cuervo-Cazurra, Alvaro (2022) : Vaccine global value chains and regional production capacity in Asia and the Pacific, ARTNeT Working Paper Series, No. 217, Asia-Pacific Research and Training Network on Trade (ARTNeT), Bangkok

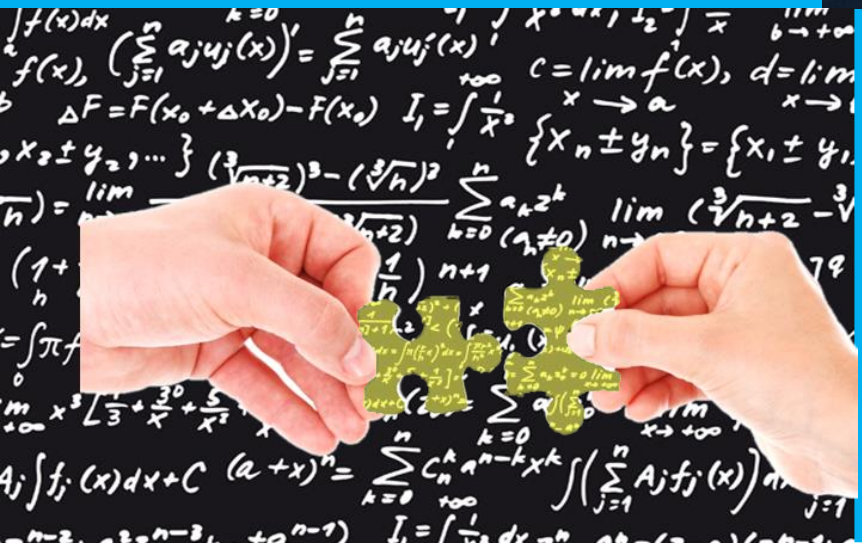
This Version is available at:
https://hdl.handle.net/10419/266154

ARTNeT

UNITED NATIONS ESCAP
Economic and Social Commission for Asia and the Pacific

Special Series on Trade and Health

Vaccine Global Value Chains and Regional Production Capacity in Asia and the Pacific



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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

Working Paper

No. 217| 2022

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ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

WORKING PAPER

Vaccine Global Value Chains and Regional Production Capacity in Asia and the Pacific

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Please cite this paper as:

Pavida Pananond and Alvaro Cuervo-Cazurra (2022). "Vaccine Global Value Chains and Regional Production Capacity in Asia and the Pacific", **ARTNeT Working Paper Series** No. 217, October 2022, Bangkok, ESCAP

Available at http://artnet.unescap.org

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Abstract

The coronavirus disease (COVID-19) pandemic has highlighted the crucial role of vaccines in public health management and economic recovery. Its worldwide impact has raised national security concerns and implications on health policies, particularly on Asia Pacific countries' readiness to cope with the next pandemic. This report explains the rise of COVID-19 vaccine production of key vaccines and differentiates them into two different approaches: the internalization-driven production, in which the leading pharmaceutical multinationals control most of the vaccine production in a few locations; and the externalization-driven production, whereby lead companies extend their vaccine production to various regions. These two approaches are led by various factors, including vaccine technology, strategy and missions of the vaccine producers, and the availability and capacity of qualified contract manufacturers in host countries. Pros and cons for each approach need to be considered to limit the impact of nationalistic interests and policies that have been part of the delay in vaccine distribution in some countries. The ultimate objective of a vaccine policy is a speedy and efficient administration of vaccines in the population, not national production, even if the latter is a desirable goal for politicians.

Keywords: COVID-19, vaccines, Global Value Chains, multinationals, global supply chains, Asia-Pacific

JEL Codes: F10, F23, I18

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1. Introduction

The coronavirus disease (COVID-19) pandemic has highlighted the crucial role of vaccines in public health management and economic recovery. The race for development, production and distribution of COVID-19 vaccines has spotlighted how different countries take part in the global vaccine value chain. Because vaccine production is a complex process that involves different types of companies, a better understanding of how firms in different countries take part in the global value chains of vaccine production is instrumental in public policy planning regarding the promotion of local production of vaccines. Building on the experience of the COVID-19 vaccines, we analyze the preparedness and regional capacity of Asia-Pacific countries in the global supply chains of vaccines.

This report explains the rise of COVID-19 vaccine production of key vaccines and differentiates them into two approaches: internalization-driven production, in which the leading pharmaceutical multinationals control most of the vaccine production in a few locations; and externalization-driven production, whereby lead companies extend their vaccine production to various regions. These two approaches are driven by multiple factors, including vaccine technology, strategy and mission of vaccine producers and the availability and capacity of qualified contract manufacturers. Reflecting on the experience with the development and distribution of COVID-19 vaccines helps to understand better how countries in the Asia-Pacific region can prepare for the next pandemic and how relevant parties and authorities can design appropriate policies for this purpose.

The main message of this report is that preparing for the next pandemic can be done through various means, of which local production is just one. The main objective of governments during pandemics should be to achieve the necessary inoculation of the population in the most effective and fastest manner. Being part of vaccine production is one way, but not the only way, to achieve this goal. Vaccine production comprises a chain of technologically advanced steps, each requiring high technological capacity and skilled personnel. A country's readiness for vaccine production depends on an interaction of factors at the firm, value chain and country levels. Countries with sufficient technological capabilities can focus on production participation. Countries with a limited technological capacity need to focus instead on ensuring speedy access to vaccines produced elsewhere and effective and equitable access to distribution. Countries with higher technological capacity can encourage collaboration and participation in vaccine value chains for local production. The more complex the stage of vaccine production, the higher the need for technological capacity. Taking part in vaccine production should not be considered as an alternative to ensuring the efficient and fair distribution of vaccines.

This report has five main sections. The first provides some background by discussing the development of the vaccine industry, its production stages, and key players. The

second section looks at the nature of COVID-19 vaccine value chains and how different vaccine producers have created their supply chain and production capacity. Vaccine value chains in the Asia-Pacific region are also discussed. The third section addresses how and why these vaccines differ in their production approaches. The fourth section addresses public and policy concerns about vaccine production. Lastly, the report concludes with policy recommendations reflecting on the differences between countries and how to best prepare public health policy given the lessons learned from the COVID-19 pandemic.

2. The Vaccine Industry

Vaccines are different from other medicines in that they are preventive remedies given only periodically. The principal recipients of most vaccines developed during the twentieth century are infants and young children. The United States Centers for Disease Control and Prevention (CDC) best practice guidelines for immunization (CDC, n.d.) recommend that vaccines given to infants and young children be taken in specific doses spread out from birth up to 18 years of age. Many provide lifetime protection. Similarly, most vaccines recommended for adults are administered in a fixed number of doses over a given period of time. Most vaccines are purchased on a tender basis by governmental or non-governmental organizations rather than on the private markets by individuals. They are subsidized as part of the government provision of primary health care under the logic that the costs of the vaccines are minimal compared to the costs of treating the diseases in an unvaccinated population and the economic impact of the spread of communicable diseases.

Despite the crucial nature of vaccines, the industrial base of vaccines declined in the 1980s and 1990s, resulting in a concentrated market dominated by a few pharmaceutical multinationals. The industry became concentrated for three main reasons. First, the high costs of research and development and the uncertainty of success serve as entry barriers. Only a few large companies with strong research and financial capabilities can afford this risk and are willing to take it. Second, the high capital investment necessitates global economies of scale, which erodes the number of potential competitors. A third and more significant reason is the lower profitability of vaccines compared to other drugs that have to be taken over long periods of time, sometimes for life, versus vaccines that can provide lifetime protection.

As a result, the number of companies producing vaccines for the United States market reduced from more than 25 companies in the late 1970s to 5 companies three decades later (Institute of Medicine, 2004). Globally, only four large manufacturers, namely GlaxoSmithKline, Pfizer, Merck, and Sanofi, control 90 per cent of global vaccine value. Similarly, more than 60 per cent of global vaccine volume is produced by five leading manufacturers—the Serum Institute of India, GlaxoSmithKline, Sanofi, Bharat Biotech International Limited, and Haffkine (WHO, 2020).

Prior to the COVID-19 pandemic, the relative significance of vaccines in the overall pharmaceutical industry was limited. Market Information for Access to Vaccines (MI4A), an initiative of the World Health Organization (WHO), estimated the global market value for vaccines to be $33 billion in 2019, representing a mere 2 per cent of the overall pharmaceutical market (WHO, 2020). Vaccines are less financially rewarding for private companies compared to drugs for two main reasons. First, the frequency of drug use far exceeds that of vaccines. While patients must take some drugs daily, vaccines are given only occasionally (Thomas, 2002). The required number of doses in each country is tied to the size of the birth cohort and the number of doses per vaccine (UNIDO, 2017). Therefore, the set upper limits of vaccine demand restrict potential financial returns for vaccine manufacturers. It gives the buyers, Governments in many cases, the ability to negotiate better prices or terms, given that they can predict their needs.

Second, the nature of vaccines reduces potential financial returns for pharmaceutical manufacturers when compared to drugs (Kremer and Snyder, 2003). Vaccines are likely to interfere with the spread of diseases, thus reducing demand for the product. Moreover, there is higher information asymmetry between patients and pharmaceutical manufacturers in vaccines than in drugs. Pharmaceutical companies do not know whether vaccine recipients will contract the disease, and consumers may be less willing to pay for preventive treatments. In contrast, when patients are prescribed drug treatments, pharmaceutical companies can estimate who they are and can charge higher prices for drugs because consumers know that they have the disease and are seeking treatment and want to regain their health. On top of that, vaccine prices are often controlled by Governments that purchase and distribute them because vaccines are often prescribed as part of national health policy. In contrast, treatment drugs are purchased by individuals, who pay all or part of the cost depending on their insurance agreements. These specific features of the vaccine industry often dampen financial incentives for drug companies to undertake vaccine production. Thus, fewer pharmaceutical companies continue with vaccine production, while many have preferred to focus on other types of drug products.

In addition to the microeconomics of vaccine production, the intellectual property rights exercised by the small set of existing pharmaceutical multinationals are viewed as powerful entry barriers for newcomers. While proponents of intellectual property rights consider them as crucial in incentivizing innovation, opponents argue that intellectual property rights enable pharmaceutical companies to strengthen their monopolistic control and limit access to medicines, especially in poorer economies (Sell, 2020). The complex nature of the vaccine industry combined with its multi-layered manufacturing processes and the advanced technologies needed for bulk production and quality control, not to mention geographically dispersed distribution networks, are among the factors that limit the number of players to a handful of global pharmaceutical multinationals and leading contract manufacturers. Often, such capital- and

technology-intensive investment is beyond the capabilities of many companies and countries.

As a result, vaccine production, in terms of global data on vaccine trade flows, vaccine ingredients, and firm-level data on subsidiary locations, has been heavily concentrated among 13 economies, which are referred to as the "Vaccine Club." Evenett et al. (2021) identified these 13 economies as Argentina, Australia, Brazil, Canada, China, the European Union, India, Japan, Korea, Russian Federation, Switzerland, the United Kingdom and the United States. Vaccine Club members are not only final vaccine producers but are also producers of vaccine ingredients, and they sourced as much as 88.3 per cent of key ingredients from each other between 2017 and 2019. In addition, these countries are also home to 91 per cent of these companies' subsidiary locations (Evenett et al., 2021: 2).

Another important characteristic of the vaccine industry is its highly segmented markets, in which high- and low-income countries are supplied by different countries. For the global vaccine trade, the three largest global exporters of vaccines are the European Union, the United States, and India. The European Union as a bloc (ignoring intra-European Union trade) is by far the largest exporter of vaccines to the world, both in terms of volume (44 per cent of total global exports) and value (60.3 per cent), with the United States taking second place in terms of export value (22 per cent of total global value traded and 15 per cent of volume). Exports from the European Union and the United States are higher in value relative to volume because they supply vaccines mainly to high-income countries. While the European Union supplies 60 per cent of the vaccines imported by high-income countries, it only supplies 12 per cent of the vaccines imported by low-income countries (Guetta-Jeanrenaud, Poitiers and Veugelers, 2021).

The opposite was the case for India. Despite being the second-largest vaccine exporter by volume (24.7 per cent), India represents little more than 2 per cent of global export value. This discrepancy results from India's exporting exclusively to low-income countries, representing 80 per cent of their import volume (Guetta-Jeanrenaud, Poitiers and Veugelers, 2021). Such a highly segmented market reflects the licensing patterns of the leading pharmaceutical multinationals. Rather than selling directly to low-income countries, these pharmaceutical multinationals license their patents to producers in emerging economies to produce and supply vaccines to low-income countries while reserving markets in high-income countries for their own production.

Market segmentation of vaccines based on income groups has been possible due to the increasing role of manufacturers in emerging economies. Vaccine manufacturing has generally been undertaken by advanced economy firms that are better endowed with research expertise and sophisticated manufacturing abilities to ensure effectiveness and quality. However, this situation has changed with the growth of manufacturers headquartered in emerging countries. Mid-size manufacturers, mostly in the Asia-Pacific region, are increasingly expanding their portfolios to compete in

regional and new vaccine markets, offering additional and often more affordable choices (WHO, 2020). China and India have become leading global vaccine producers in addition to the few established pharmaceutical multinationals from emerging economies. India is home to Serum Institute of India, the world's largest vaccine manufacturer by volume. The Serum Institute of India has partnered with many pharmaceutical companies to produce vaccines for diseases ranging from polio to measles. Its business model has been based on becoming the manufacturer of generic vaccines that are no longer protected under patents and then supplying them to low- and middle-income countries, including India's vast domestic market (Frayer, 2021).

Demand growth in emerging countries, along with advances in immunology and biotechnology, are among the reasons that increase the attractiveness of the vaccine industry (Smith, Lipsitch and Almond, 2011). Nonetheless, vaccine production had not changed much prior to the COVID-19 outbreak. For example, from 2015 to 2019 the production capacity for influenza vaccines only increased from 1.47 billion to 1.48 billion doses, despite an increase in the potential maximum annual production capacity from 6.37 billion to 8.31 billion doses (Sparrow et al., 2020). Nevertheless, public health crises like the COVID-19 pandemic drastically changed the vaccine industry and created a different market.

A sudden rise in global demand prompted vaccine manufacturers and Governments to act in unique ways. A variety of government reactions, from supportive measures like financial support to prohibitive ones like export controls, affected the value chain of vaccines like never before. Due to complex production methods, sophisticated technologies, meticulous quality control and reliable distribution, making vaccines available globally requires a strong partnership between private manufacturers, regulatory authorities, and national and international health services. To better understand the complexity of vaccine production, the next section explores the vaccine value chain in more detail.

3. Vaccine Value Chain

Getting a new vaccine from the laboratory to people's arms worldwide is challenging. Before COVID-19, the entire process had never been completed in less than four years and often took more than a decade (Bown and Bollyky, 2022). That WHO and other national regulatory authorities approved some COVID-19 vaccines by December 2020, less than a year after public reports of the SARS-CoV-2 emerged, was an anomaly in the pharmaceutical industry.

The speed of such development can be attributed to many factors, from strong government support and investment supporting firms' research and development, to the broad-based partnership and alliances that already exist in the pharmaceutical

industry. Thanks to declining trade barriers and advancements in communication and transport technologies, over the past two decades the value chain of vaccine production has become disaggregated in a similar way to other global industries such as automotive and electronics. Through a combination of externalized contracts and direct subsidiaries, pharmaceutical multinationals can fragment the value chain into different stages, each of which can be handled by specialized manufacturers that are geographically dispersed.

Through contract development and manufacturing organizations (CDMOs), pharmaceutical firms have engaged independent and specialized biotech companies or academic institutions to take part in different activities in the pharmaceutical industry (Bown and Bollyky, 2022). Despite their relative anonymity compared to leading pharmaceutical multinationals, many CDMOs have become regionally or globally prominent as specialized operators handling various parts of the industry. At the same time, some major pharmaceutical companies, such as Pfizer and GlaxoSmithKline, have also developed CDMO-like services to offer to other firms and manage their operations better (Bown and Bollyky, 2022: 475). This process enables pharmaceutical companies to maximize their production efficiency without bearing the costs of undertaking all the production stages. The fragmentation and the rise in contract manufacturing in the pharmaceutical industry can be compared to other global industries such as semiconductors (Bown, 2020). To provide context, relevant theoretical concepts on the governance of global value chains are discussed next to explain why and how these different business models are adopted.

3.1 Global value chain governance: theoretical concepts

Governance analysis of global value chains allows one to understand how relationships in a chain are controlled and coordinated. Gereffi (1994: 97) defines governance as ‘authority and power relationships that determine how financial, material and human resources are allocated and flow within a chain’. In practice, governance analysis can help explain the different roles of value chain participants, their locations, how they interact and how they draw their influence and power within the value chain (Fernandez-Stark and Gereffi, 2019).

There is a variety of governance alternatives for global value chains. Gereffi, Humphrey and Sturgeon (2005) identified five types of governance structures that can explain the relationship among lead firms in global value chains and their supply base. Market (inter-firm relationships) and hierarchy (intra-firm relationships) represent two polar types of governance, while modular, relational and captive relationships are three different structures that lie between the two ends. These structures are determined by three variables: the complexity of the information shared between actors in the chain; the codifiability of information exchanged between actors; and the level of supplier competence to meet the requirements set by lead firms. Market governance involves transactions that are relatively simple and regulated by price rather than power or relationship. These arm’s-length exchanges require little or no

formal cooperation between actors, and the costs of switching to other partners are low for global value chain participants. Hierarchy, on the opposite end, characterizes vertically integrated relationships within which lead firms exert full control over the operations of value chain activities.

Between these two polar ends lie three governance structures that represent different degrees of the variables discussed earlier. Modular governance occurs when transactions are relatively easy to codify, and suppliers are highly capable of taking full responsibility to meet production specifications. Relational governance reflects more complex transactions between actors that cannot be easily codified and transmitted. This results in frequent interactions and knowledge exchange between parties. Trust and mutual reliance are needed in addition to high degrees of competence of suppliers to enable global value chain exchanges, making switching costs rather high for lead firms as well as suppliers. Captive governance represents a more asymmetric relationship in which suppliers depend on lead firms, which are the main buyers and have control of knowledge that could help suppliers in their upgrading.

This classification of global value chain governance types emphasizes two issues: the nature and complexity of the exchange among global value chain participants; and suppliers' capabilities. Such a view may place more emphasis on the role of lead firms and how they drive the value chain forward through their interactions with other firm participants. The mechanism through which relationships in value chains are exchanged is set between two opposites – make (undertaking an activity within a firm's hierarchy) or buy (doing the same thing through market mechanisms) – emphasizing the internalization of transactions and exchanges among value chain participants.

This view may overlook how the value chain of many global industries is also based on governance relations beyond the boundaries of lead multinational enterprises. To put more emphasis on the diversity and complexity of global value chain governance, Pananond, Gereffi and Pedersen (2020) argued that global value chain exchanges may also be driven by supplier firms, and these exchanges may be undertaken beyond intra-multinational firm mechanisms. Addressing the role of suppliers in global value chains and the diverse forms of relationships among global value chain participants should add more insights to the analysis of vaccine value chains, particularly given the rising importance of vaccine producers and other actors headquartered in the developing world.

3.2 Stages of vaccine production

The entire process from developing a vaccine to delivering shots to the public can be divided into five major stages (Bown and Bollyky, 2022). The first involves the preclinical stage of research and development to identify ways to induce the human immune system to react to the antigens the same way that it would to the virus. The second stage comprises multiple rounds of clinical trials, with a smaller group of people in earlier phases to larger ones in later trials.

The third stage is the manufacturing of vaccines, and this stage has two major phases: creating the bulk antigen; and formulating it into a drug product. The first phase is also known as active ingredient production, bulk production, or primary manufacturing, whereas the secondary manufacturing often involves combining the drug substance with other ingredients, such as excipients, adjuvants, and preservatives (Kis et al., 2020). Although the WHO-approved COVID-19 vaccines are based on different vaccine technology platforms, the main production stages are similar. Scaling up these processes for the global demand is a major undertaking for any vaccine producer. High capital investments are required as creating new production facilities includes creating and maintaining hyper-clean rooms, acquiring specialized equipment such as bioreactors and filtration pumps, and employing skilled personnel able to handle the mass-production lines of vaccines. Bulk antigen production is the most cost-intensive and complex step in the production process. Formulation processes can include combining the purified antigen with adjuvants to enhance the immune response in the body, stabilizers to ensure that the product remains potent until it is administered, or preservatives to ensure sterility in case of multi-dose vials (UNIDO, 2017).

The fourth stage of vaccine production process focuses on preparing the vaccines for distribution. The formulated vaccine or drug product is filled into vials, plastic tubes, ampoules, or syringes. This process may take place in a separate manufacturing facility that fills and finishs (cap the vials and then label and package), resulting in different names for the fill-finish phase, including form-and-fill, fill-and-finish, or fill-to-finish (Bown and Bollyky, 2022). This stage of vaccine production requires specialized assembly-line equipment and facilities under strict temperature and sterility controls. Because this process is broadly similar for most vaccines, and less complex than vaccine substance production, multiple types of vaccines can be formulated and filled in the same facility (UNIDO, 2017).

Once the filled vials are inspected, they are then packaged to undergo final quality control testing in the fifth stage of vaccine distribution and delivery. Some vaccines are transported frozen and in concentrated form, therefore requiring on-site dilution before being administered to the public. To better understand these processes, the value chains of COVID-19 vaccines are addressed next.

4. COVID-19 Vaccine Value Chains

4.1 Governance and production

As of April 2022, 10 vaccines had been approved for emergency use by WHO (tTable 1). These vaccines use several distinct technology platforms in their production: mRNA (Moderna, Pfizer-BioNTech); adenovirus vector (Johnson & Johnson, Oxford-AstraZeneca); and inactivated virus (Sinopharm, Sinovac, Bharat Biotech). It should be noted that some of these vaccines are based on the same formulation but adopt different trade names when produced by different facilities to be distributed in diverse

geographical areas. For example, AstraZeneca vaccines are produced under two names, Vaxzevria and Covishield, with the latter being produced by the Serum Institute of India mainly for distribution in developing economies. Similarly, the Serum Institute of India also partners with Novavax, a biotechnology company based in the United States, to use the same vaccine formulation under a different trade (Covovax).

Table 1: COVID-19 vaccines approved by the World Health Organization

	Developer	Manufacturer	Own production sites	Contract development and manufacturing organizations (CDMO)/ Technology transfer (TT)
Non-replicating viral vector	Oxford University (United Kingdom)	AstraZeneca	United Kingdom, United States	*CDMO: 17* *TT: 9* *17 countries*
	Serum Institute of India (Covishield)	Serum Institute of India	India	*TT from AstraZeneca*
	Janssen Pharmaceuticals (Johnson & Johnson / United States)	Janssen Pharmaceuticals	Belgium	*CDMO: 10* *TT: 1* *8 countries*
Protein subunit	Serum Institute of India (Covovax)	Serum Institute of India	India	*TT from Novavax*
	Novavax		Czech Republic	*CDMO: 11* *TT: 4* *12 countries*
mRNA	BioNTech (Germany)	Pfizer (US)	Belgium, Germany, United States	*CDMO: 20* *TT: 5* *16 countries*
	Moderna (US)	Moderna	United States	*CDMO: 15* *TT: 0* *9 countries*
Inactivated virus	Beijing Institute of Biological Products (State-owned enterprise / China)	Sinopharm (State-owned enterprise)	China	*CDMO: 0* *TT: 7* *8 countries*
	Sinovac (China)	Sinovac	China	*CDMO: 0* *TT: 9* *8 countries*
	Bharat Biotech (India)	Bharat Biotech	India	*CDMO: 2* *TT: 4* *2 countries*

Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.

The pharmaceutical industry uses a range of organizational strategies for vaccine manufacturing. On one extreme are vertically integrated companies or organizations that perform most of the five stages of vaccine production in their facilities. However, the vaccine production process can also be fragmented, and specific stages of vaccine production are completed by independent companies. The rising importance of strategic alliances and partnerships that extend beyond the scope of any specific company has become a prominent feature of the vaccine industry, making the transfer

of technology to external partners a crucial part of the industry. According to WHO (2011), technology transfer to an alternative site occurs at some stage in the life cycle of most products, from development, scale-up, manufacturing, production and launch, to the post-approval phase. Technology transfer is a systematic procedure for the sender unit to pass documented knowledge and experience gained during development and commercialization to an appropriate, responsible and authorized party, or the receiving unit. This process can involve contract manufacturing between the sending and the receiving units, which may or may not be separate entities (WHO, 2011).

Despite the prevalent use of contract manufacturing at different stages of vaccine production, some pharmaceutical entities may still opt for an end-to-end process, in which all stages of production are done within the same entity. This practice may be adopted in smaller biotech companies, or specific subsidiaries of pharmaceutical multinationals but the challenge of scaling up to meet global demands makes it less common. For COVID-19 vaccines, the only two vaccine developers who exclusively adopted end-to-end production are Sinopharm and Sputnik V. The former was developed by the China National Pharmaceutical Group and the latter by Gamaleya Research Institute of Epidemiology and Microbiology, a medical research institute within the Ministry of Health of the Russian Federation. Most other vaccine makers engage a range of contract manufacturers in their production process.

To examine how vaccine developers organize their value chains, two features of global value chain governance – the nature of the lead developers and the governance type used in that chain – can be compared (Pananond, Gereffi and Pedersen, 2020). These features are important for understanding how vaccine developers may employ different production strategies. Vaccine value chains can be driven by either the lead firm or institute that draws its power from its technology in vaccine development, or the supplier whose power in the value chain is derived from its production prowess. In vaccine value chain governance, two different approaches can be observed. Under one approach, the vaccine value chain is vertically controlled within an internalized set of relationships. Under the other approach the vaccine value chain is organized like a network, led by a key actor with an extensive range of CDMO partners undertaking different activities. As seen in Table 2, most COVID-19 vaccines, namely Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, Janssen, Novavax and CureVac, are organized as networks of partners, driven by lead vaccine developers. With only the exception of the Serum Institute of India, which emerged as a supplier to other vaccine developers, vaccine developers rely on a range of partners for producing COVID-19 vaccines. Understanding the nature of governance for these COVID-19 vaccines helps shed light on their production strategy.

Table 2: COVID-19 vaccine value chain governance types

		Global value chain governance	
		Global value chain as vertically integrated multinationals	Global value chain as networks (Contract development and manufacturing organizations)
Global strategy	Lead firm-centric strategy	Sinopharm Sputnik	Pfizer-BioNTech Moderna Oxford-AstraZeneca Johnson & Johnson/Janssen Curevax Novavax
	Supplier firm-centric strategy		Serum Institute of India

Source: Based on Pananond, Gereffi and Pedersen (2020).

4.2 Production capacity and geographical distribution

The discussion in this part examines vaccine production capacity and geographical distribution of eight WHO-approved COVID-19 vaccines, namely Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, Janssen, Novavax, Bharat Biotech, Sinovac and Sinopharm. This list excludes Covishield and Covovax, produced by the Serum Institute of India, the vaccines developed by Oxford-AstraZeneca and Novavax, as their production activities are included under each vaccine developer. Unless indicated otherwise, the analysis is based on the data provided by the United Nations Children's Fund (UNICEF) COVID-19 Vaccine Dashboard.[3]

The pandemic has transformed the global vaccine manufacturing landscape, with capacity increasing almost fourfold by the end of 2022. Prior to the pandemic, the vaccine production capacity averaged around 5 billion doses annually (Airfinity, 2021). In 2021, manufacturers produced 12 billion COVID-19 vaccines (Guzman et al., 2022), and the projected capacity for 2022 is 18.7 billion doses for the base case, and even a higher 20.9 billion doses for the high case. The push to scale up vaccine production globally has also expanded manufacturing beyond the set of companies and countries that traditionally controlled vaccine production. Many middle-income countries, in particular Brazil, China and India, have become crucial players in global and regional production. Nonetheless, their role may still be restricted to simpler activities such as fill-finish, and their participation in the global value chain of vaccines is still determined by large, multinational pharmaceutical companies.

Production capacity varies widely between vaccines. In early 2021, China rapidly emerged as the largest producer, led by their Sinovac and Sinopharm vaccines (Airfinity, 2021). However, the efficacy of their vaccines was questioned when newer variants emerged, leading to a much slower growth in new contracts over time. For example, the growth of new contracts for non-Chinese vaccines expanded by about 10 per cent from September 2021 to March 2022, whereas the figure for Chinese

[3] The UNICEF COVID-19 Vaccine Dashboard is the public resource that provides the latest information on the world's COVID-19 vaccine market and the Covax facility vaccine deliveries. See https://www.unicef.org/supply/covid-19-vaccine-market-dashboard.

vaccines was only 1 per cent (Airfinity, 2022). Pfizer-BioNTech and Moderna are expected to produce the most doses in 2022, enabling them to see the most revenue increase compared to other vaccines, thanks to higher demand and costs for their vaccines.

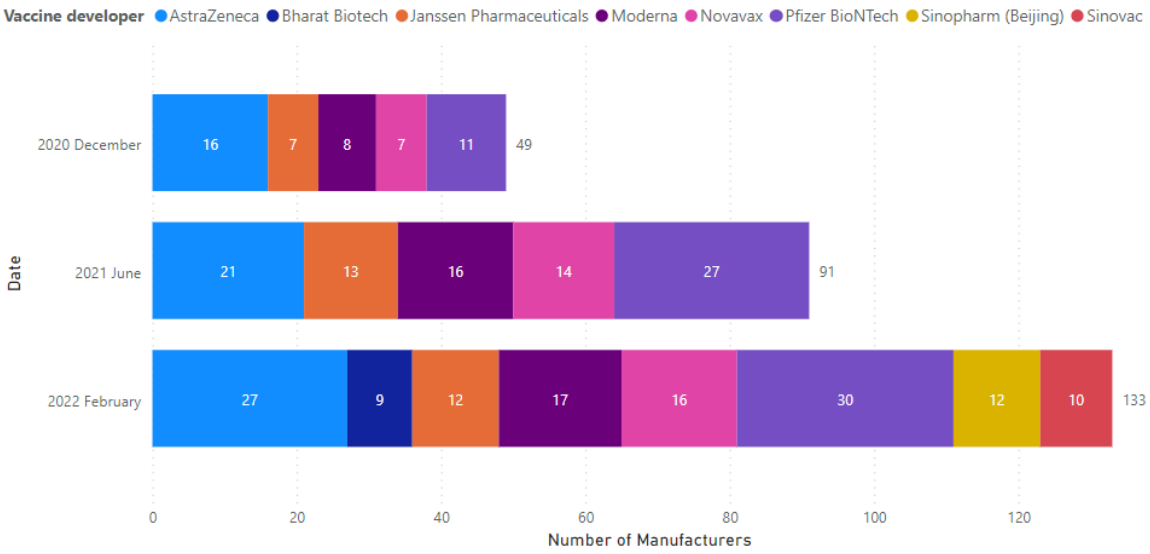
In addition to vaccine efficacy, a key factor that led to the stronger growth of non-Chinese vaccines is the ability to scale up production. Much of the production capacity increase has been facilitated by vaccine partnerships. Some examples of key partnerships include the Serum Institute of India with AstraZeneca and Novavax, Pfizer and GSK, as well as Janssen and Merck (Airfinity, 2022). Splitting up the vaccine value chain, particularly between the two key stages of vaccine manufacturing and and fill-finish, lies at the heart of the vaccine value chain (Bown and Bollyky, 2022). This process ultimately affects how many doses, how quickly vaccines can be produced, and where they are produced. The following analysis shows how different vaccine producers organize this process for eight COVID-19 vaccines. Figure 1, 2, 3, 4, 5, and 6 and Table 3 show details of the production activities. Four main features of vaccine production can be observed.

First, the growth of COVID-19 vaccine production capacity was facilitated by the addition of manufacturers at different stages of the supply chain. Figure 1 and 2 show the growth in the number of vaccine manufacturers of different developers at three points in time—December 2020, June 2021 and February 2022.[4] The growth was most rapid between 2020 and 2021, as key major vaccine developers increased their production capacity. Figure 1 shows that all the major vaccine developers generally doubled the number of their manufacturers, with Pfizer-BioNTech recording the highest growth (Bown and Bollyky, 2022). This rapid increase explained why Pfizer-BioNTech dominated production capacity in 2021 and is also forecasted to do so in 2022. According to the Global Health Innovation Center of Duke University,[5] production capacity forecasted for 2022 will be primarily driven by Pfizer-BioNTech (4 billion), Moderna (3 billion), and Oxford-AstraZeneca (2.4 billion). The rapid expansion of production capacity results from vaccine developers' extensive use of outsourced contracts to external manufacturers. Figure 2 shows that the increased production capacity was based more on CDMOs and technology transfer contracts than on vaccine developers' own facilities. The use of externalized contracts to increase the agility and capacity of production has been a crucial factor to meet demand.

[4] The data for December 2020 and June 2021 are based on Bown and Bollyky (2022), which analysed the production chains of six vaccines, namely Pfizer-BioNTech, Moderna, AstraZeneca, Janssen, Novavax, and CureVac. But figures 1 and 2 do not include Curevac as it has yet to be approved by WHO for emergency use. We rely on data of 10 vaccines approved by WHO as of February 2022, available on UNICEF COVID-19 Vaccine Market Dashboard (i.e. Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, Janssen, Novavax, Bharat Biotech, Sinovac, Sinopharm, Covishield and Covovax). However, figures 1 and 2 show only details of eight vaccines as the latter two are both produced by Serum Institute of India and their production activities are included under AstraZeneca and Novavax.

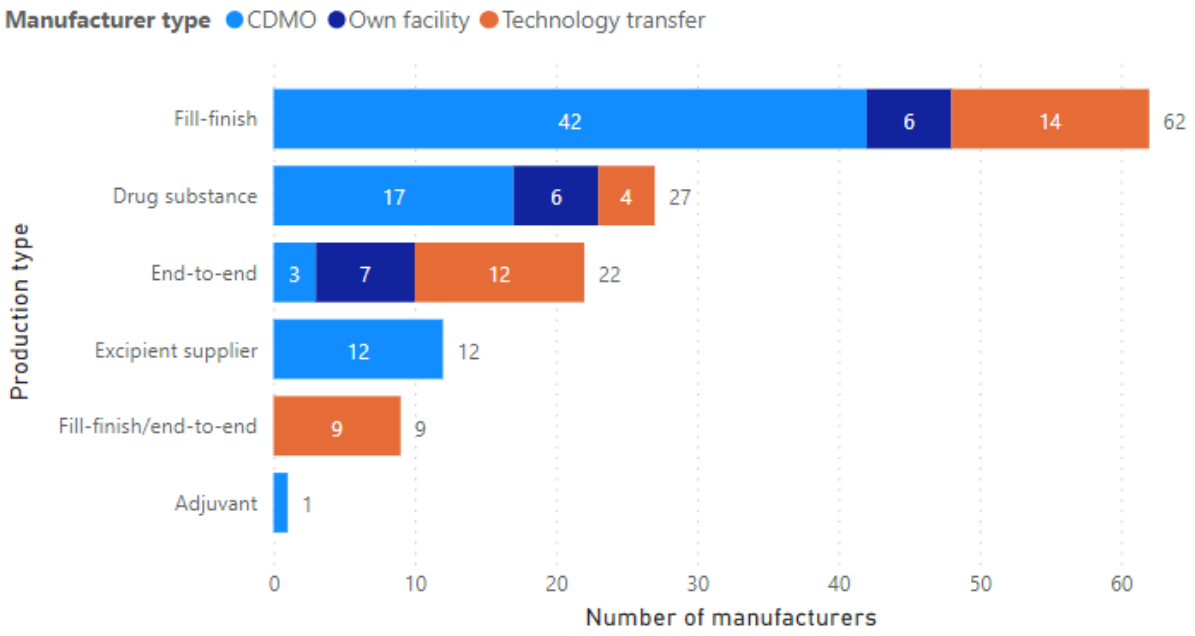
[5] Duke University Global Health Innovation Center launched a Speedometer Initiative to aggregate and analyse publicly available data on COVID-19 vaccines and therapeutics. See https://launchandscalefaster.org/COVID-19.

Figure 1: Growth of COVID-19 vaccine production by the number of manufacturers of each vaccine



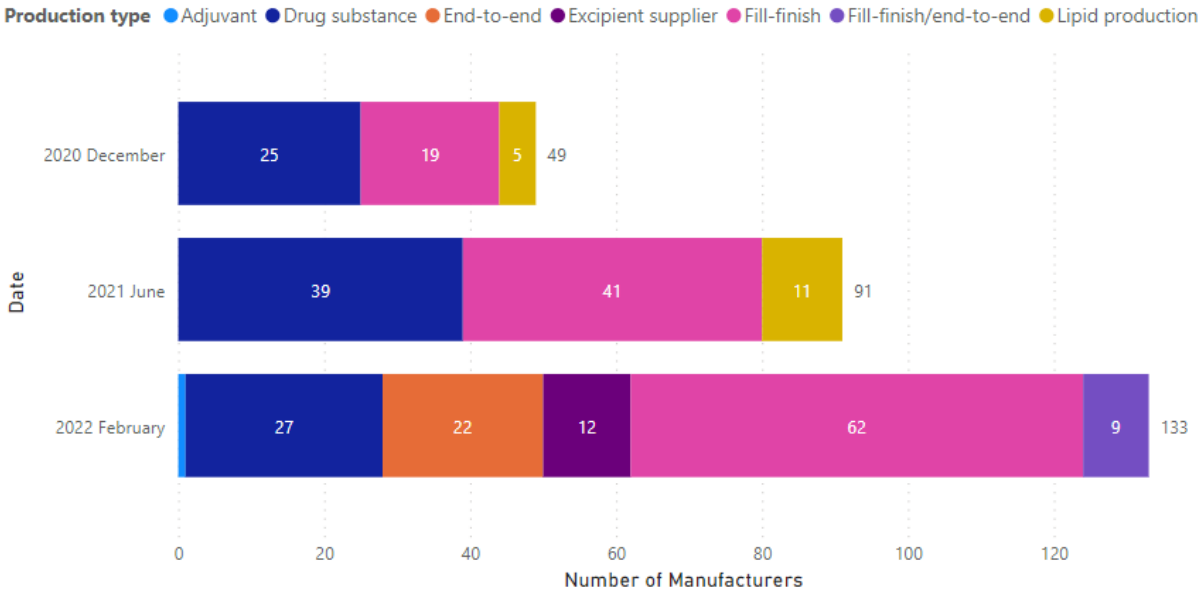
Source: Created using data from Bown and Bollyky (2022) for the number of manufacturers in December 2020 and June 2021; and UNICEF COVID-19 Vaccine Market Dashboard for February 2022.

Figure 2: Type of contract and type of activity for vaccine manufacturers as of February 2022



Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.

Figure 3: Growth of COVID-19 vaccine production by type of activity



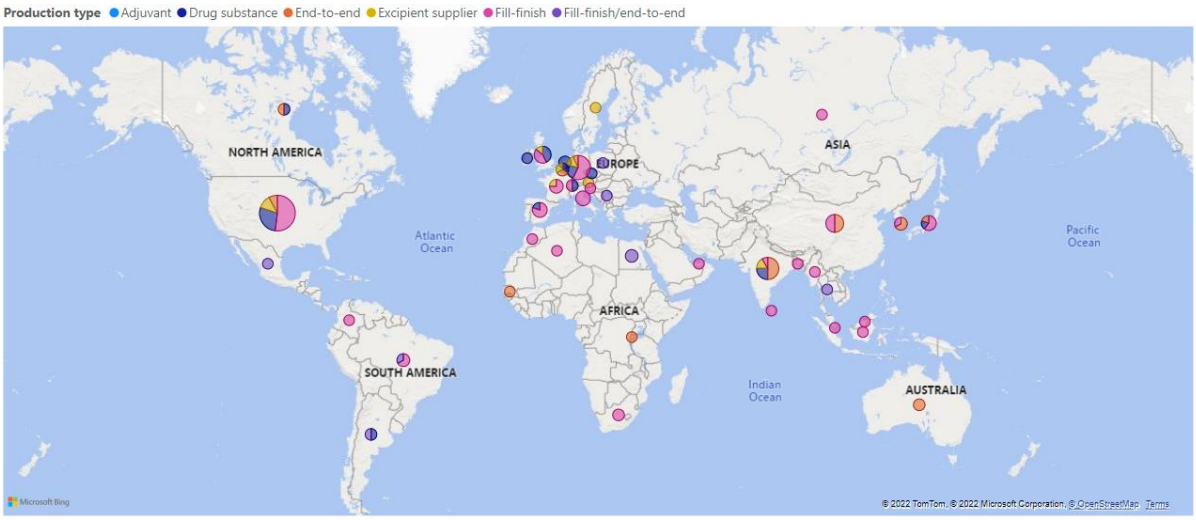
Source: Created using data from Bown and Bollyky (2022) for the number of manufacturers in December 2020 and June 2021; and UNICEF COVID-19 Vaccine Market Dashboard for February 2022.

Second, a closer look at the type of manufacturing activity reveals that the largest increase in number of manufacturers over the past two years came from the fill-finish stage (Figure 3). In addition, Figure 2 shows the important role CDMO manufacturers play in this stage, with almost 70 per cent of the capacity being under this type of manufacturing.

Third, despite the swift expansion of manufacturing capacity, vaccine production remains geographically concentrated. As discussed earlier, lead developers and activities in the vaccine value chains have been concentrated in 13 economies of the Vaccine Club. A 2020 survey on vaccine manufacturing capacity by the Coalition for Epidemic Preparedness Innovations revealed similar findings of geographical concentration of vaccine production. India had the largest production capacity for active ingredient production, followed by Europe and North America. Europe had the largest production capacity for RNA-based drug substances. For drug bulk production, the base-case estimates showed that China had the largest production capacity, followed by North America and the rest of Asia and Oceania.[6] Figure 4 and 5 show the geographical locations of vaccine productions by type of activities along the value chain and type of organizational partnerships as of February 2022.

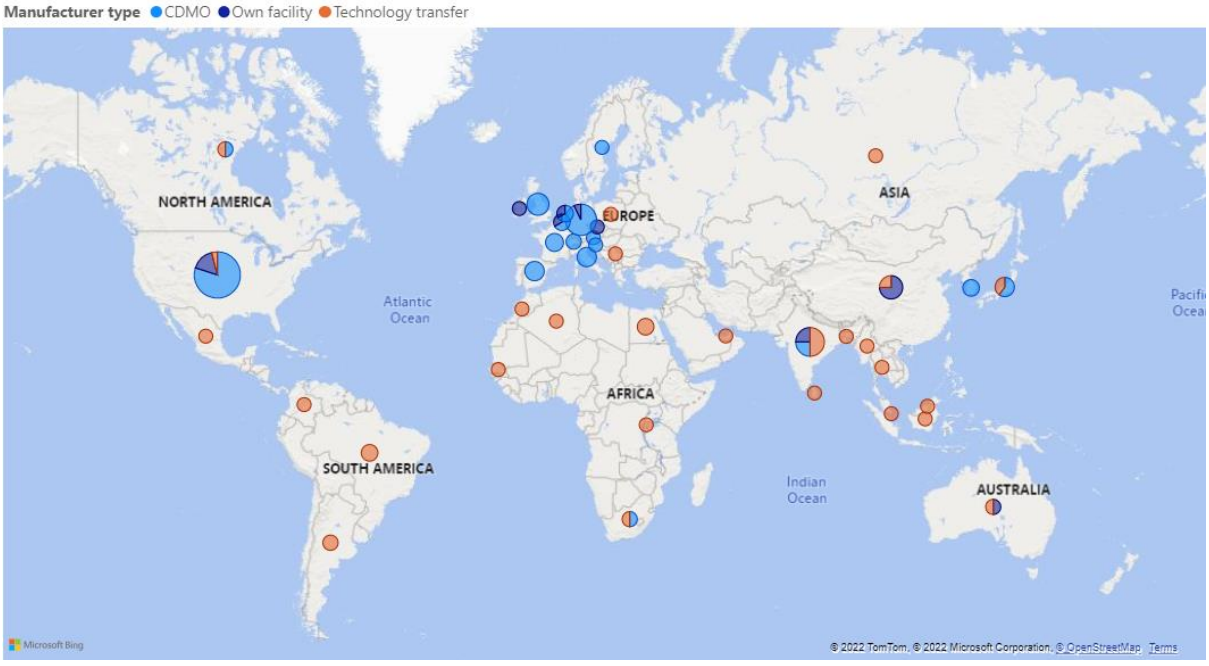
[6] Discussion of the survey can be accessed here: https://cepi.net/news_cepi/cepi-survey-assesses-potential-covid-19-vaccine-manufacturing-capacity/

Figure 4: Geographical locations of vaccine production by type of activity, February 2022



Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.
Disclaimer: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

Figure 5: Geographical locations of vaccine production by type of manufacturer, February 2022

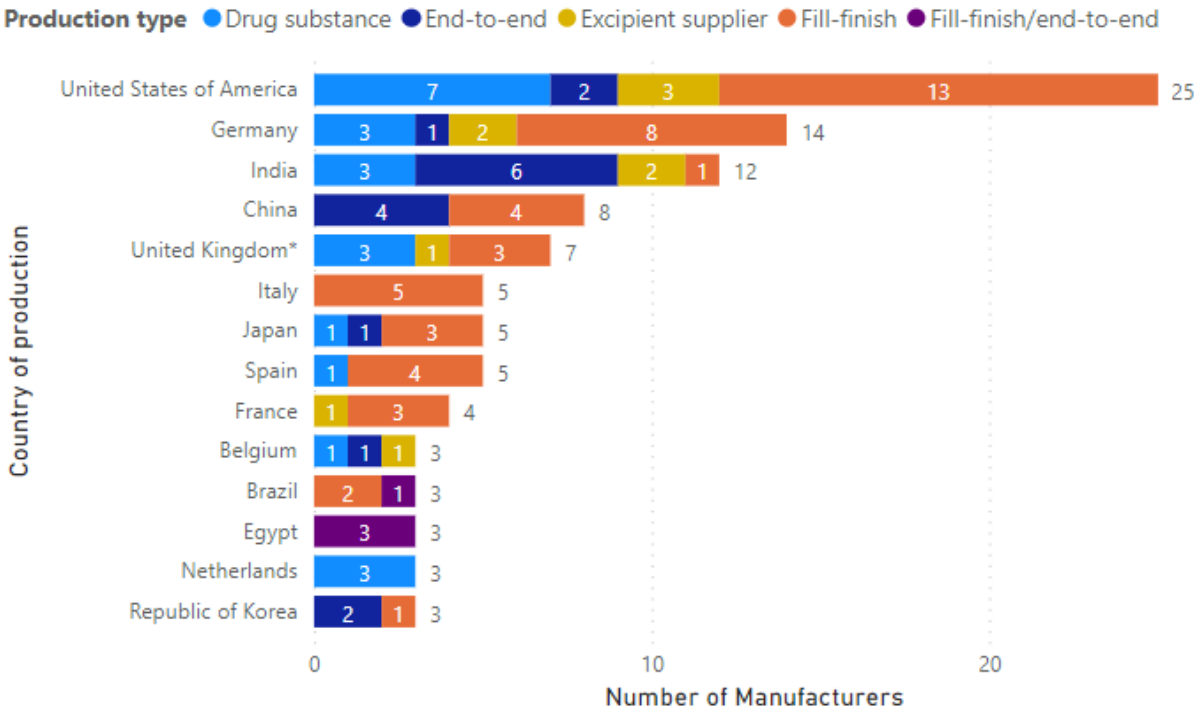


Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.
Disclaimer: The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations

The results are similar to earlier findings. Vaccine production is not evenly distributed across regions. The maps in figures 4 and 5 show that vaccine production activities are more concentrated in Europe, North America and Asia, while Africa and Latin

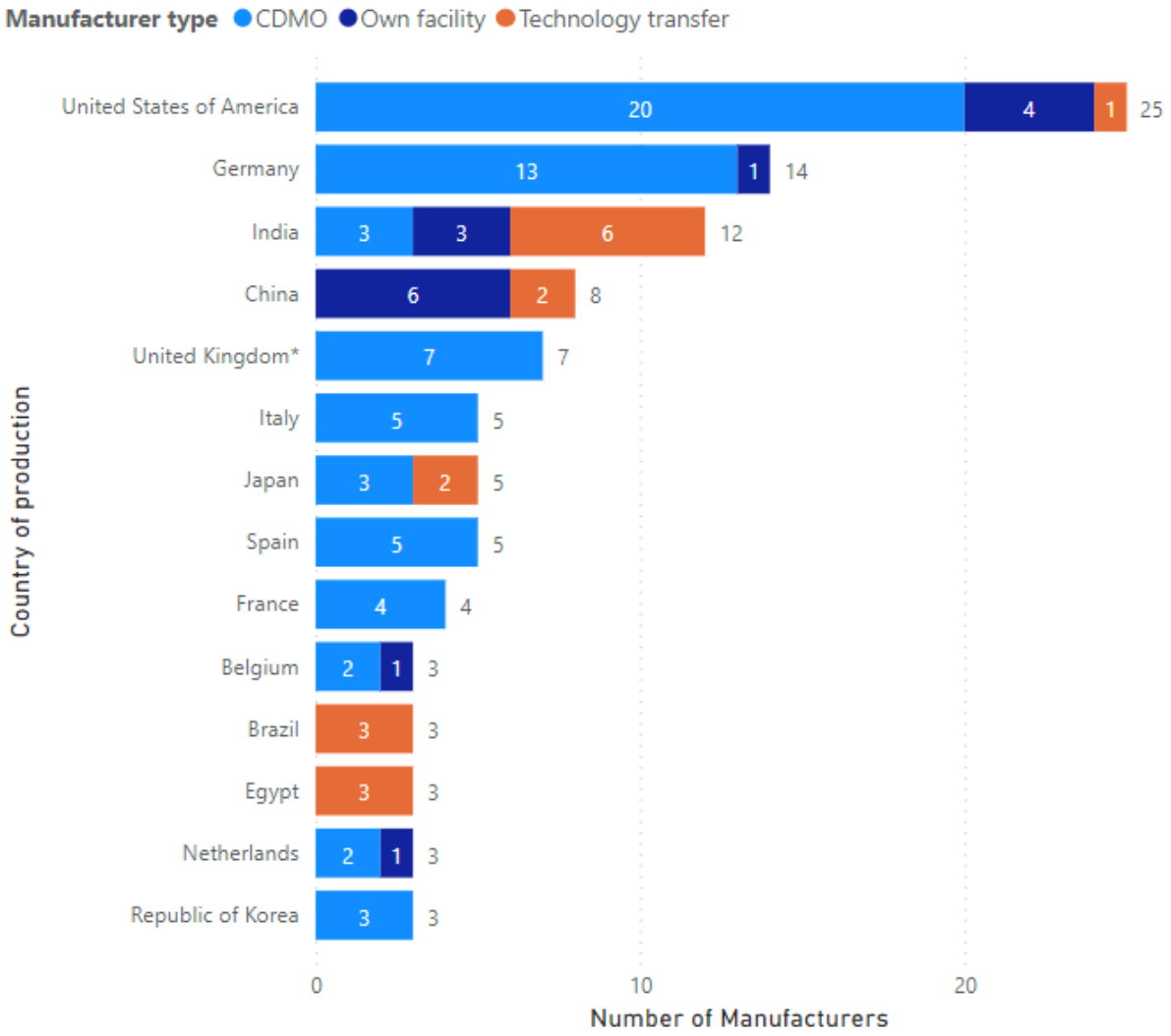
America are sparsely represented in the vaccine production value chain. The Coalition for Epidemic Preparedness Innovations (2021) estimated that around 55 per cent of capacity was in East Asia, 40 per cent in Europe and North America, and less than 5 per cent in Africa and South America. Vaccine production networks are, in general, global and have been built by collaborations through CDMOs and technology transfers. Figure 6 and 7 show the top 10 locations with the highest number of vaccine manufacturers. What is evident from these two figures is that manufacturing activities in key locations are diverse, covering all stages of vaccine production and comprising a broad range of organizational forms – from own facilities to externalized contracts. The United States, for example, is the single most important country for vaccine production activities, from active ingredient production to fill-finish activities. The same is true for major vaccine-producing countries such as China, Germany, India and the United Kingdom, confirming the geographically concentrated nature of vaccine production.

Figure 6: Top 10 vaccine production locations, number of facilities and type of activity, February 2022



Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.
United Kingdom* includes United Kingdom of Great Britain and Northern Ireland

Figure 7: Top 10 vaccine production locations, type and number of manufacturers, February 2022



Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.
Abbreviations: CDMO: Contract development and manufacturing organizations.
United Kingdom* includes United Kingdom of Great Britain and Northern Ireland

Fourth, while demand for global production capacity has been heightened because of the pandemic, vaccine production activities reflect firm-level strategies of vaccine developers more than government policies. Vaccine production strategies vary between the two opposite approaches of fully internalized end-to-end production and the globally outsourced and fragmented one. Pfizer-BioNTech, Moderna, Janssen (Johnson & Johnson), and Sinopharm-Beijing lean more toward a centralized approach. These firms have kept manufacturing largely in-house while working with one or two big partners. Their manufacturing tends to be concentrated in one or two regions globally (Taylor et al., 2021).

Pfizer-BioNTech may not control all the production activities internally but rely heavily on existing plants and facilities of Pfizer and BioNTech to undertake drug substance

production, resulting in their concentrated production facilities in the United States and the European Union (Bown and Bollyky, 2022: 477–479). The decisions to expand production capacity outside of the United States and the European Union only came in 2021 when BioNTech decided to set up a new manufacturing facility in Singapore and forge more partnerships in China and South Africa. Although BioNTech has unveiled plans to establish turnkey modular production facilities in shipping containers that could be transported to other regions, in particular to Africa, with the production capacity of 50 million doses, this is a fraction of the capacity of its unit in Marburg, Germany, in 2021 (1.2 billion doses) (*Aljazeera*, 2022).

Similarly, Moderna relied heavily on contract partners to ramp up their production facility. Moderna teamed up with global CDMO partners to benefit from their capacity in the United States and Europe. Moderna also partnered with Samsung Biologics in the Republic of Korea for fill-finish activities to increase their coverage in Asia (Bown and Bollyky, 2022: 480–482; Taylor et al., 2021). The production strategy of these two mRNA vaccine makers remains concentrated geographically, with most activities located in North America and Europe. Factors that contribute to the geographical concentration of production include the lack of sufficient capabilities to support a new vaccine technology platform and the need for mRNA vaccines to be kept and transported in ultra-cold temperatures.

Vaccines based on more traditional technology platforms, such as viral vector, protein subunits, and inactivated virus, face fewer challenges in engaging external partners across geographical locations. Oxford-AstraZeneca typifies the distributed approach, with many technology transfer deals and manufacturing distributed across several regions globally. With a strategy that focuses more on creating different regional supply chains, Oxford-AstraZeneca stands out as the vaccine with the most geographically diverse locations, extending beyond the United States and Europe to Australia, India, Latin America, and South-East Asia (Bown and Bollyky, 2022: 482–488). The geographical diversification also reflects Oxford-AstraZeneca's distribution strategy of supplying vaccines to a wider range of countries, particularly middle-income ones. Based on data from the Duke Global Health Innovations Center on total purchase classification by country income level,[7] Oxford-AstraZeneca puts the strongest emphasis on supplying middle-income countries and Covax, the United Nations-backed global alliance, which together account for more than 75 per cent of Oxford-AstraZeneca's total production. The ratio for Pfizer-BioNTech, however, is only about 23 per cent, as most of their doses procured are supplied to high-income countries. To understand how vaccine supply chains are established, these firm-level strategic differences also need to be considered. Table 3 shows how different vaccine developers organize their production chains regarding types of contracts and geographical locations.

[7] See https://launchandscalefaster.org/covid-19/vaccinemanufacturing (accessed on 13 April 2022).

Table 3: Vaccine production strategy

Vaccine developer	Africa	Asia and the Pacific	Europe	Middle East	North America	South/Latin America	Unknown	Total
Pfizer BioNTech	**3**	**2**	**20**		**4**	**1**		**30**
Fill-finish	1		11			1		13
Excipient supplier		1	4		2			7
Drug substance			4		1			5
End-to-end	2	1	1		1			5
AstraZeneca		**9**	**11**		**4**	**3**		**27**
Fill-finish		3	5		3			11
Drug substance		1	4		1	1		7
End-to-end		4	1					5
Fill-finish/end-to-end		1				2		3
Excipient supplier			1					1
Moderna		**3**	**6**		**8**			**17**
Fill-finish		1	2		4			7
Drug substance			3		3			6
Excipient supplier		1	1		1			3
End-to-end		1						1
Novavax		**3**	**8**		**4**		**1**	**16**
Fill-finish			4		2			6
End-to-end		3			1			4
Drug substance			2		1			3
Adjuvant							1	1
Excipient supplier			1					1
Fill-finish/end-to-end			1					1
Janssen Pharmaceuticals	**1**	**1**	**5**		**5**			**12**
Fill-finish	1		4		3			8
Drug substance			1		2			3
End-to-end		1						1
Sinopharm (Beijing)	**1**	**8**	**1**	**1**		**1**		**12**
Fill-finish	1	7		1				9
Fill-finish/end-to-end			1			1		2
End-to-end		1						1
Sinovac	**1**	**4**		**3**		**2**		**10**
Fill-finish	1	3				2		6
Fill-finish/end-to-end				3				3
End-to-end		1						1
Bharat Biotech		**7**			**2**			**9**
End-to-end		3			1			4
Drug substance		3						3
Fill-finish		1			1			2
Total	**6**	**37**	**51**	**4**	**27**	**7**	**1**	**133**

Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.

4.3 Asia-Pacific region in vaccine value chains

Countries in the Asia-Pacific region are faced with the ‘triple challenge’ of pursuing equitable distribution of vaccines, ensuring successful vaccination roll-outs and developing agile manufacturing capacity to produce essential drugs and vaccines (Reform for Resilience Commission, 2021). Although the region is relatively well-represented in vaccine value chains, especially when compared to other developing regions such as Latin America and Africa, its presence is largely dominated by India and China. Both countries ranked among the top four producers of COVID-19 vaccines in January 2022, with China’s total production capacity (locally administered and exported) approaching 5 billion doses, followed by the European Union (approximately 2.5 billion doses), India (approximately 1.8 billion doses), and the United States (1.1 billion doses), according to Airfinity data cited in a report on vaccine production

presented by the Global Commission for Post-pandemic Policy.[8] Non-Chinese vaccines are taking more market share from the less effective Chinese vaccines, and the growth of new contracts is much slower for Chinese vaccines. The growth rate of new contracts for non-Chinese vaccines from October 2021 to March 2022 averaged over 10 per cent, whereas the rate for Chinese vaccines was 1 per cent (Airfinity, 2022). This slowdown reduced Chinese monthly output in January 2022, dropping to 45 million doses against 665.8 million in December 2021, according to data from the Global Commission for Post-pandemic Policy. The increase in production capacity in many countries in the region has been instrumental in responding to global vaccination demand.

Table 4: Geographical locations of vaccine production activities

Regions	Adjuvant	Drug substance	End-to-end	Excipient supplier	Fill-finish	Fill-finish/end-to-end	Grand total
Europe		14	2	7	26	2	51
Asia and the Pacific		4	15	2	15	1	37
North America		8	3	3	13		27
South/Latin America		1			3	3	7
Africa			2		4		6
Middle East					1	3	4
Unknown	1						1

Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.

[8] See https://globalcommissionforpostpandemicpolicy.org/covid-19-vaccine-production-to-january-31st-2022/ (accessed on 13 April 2022).

Table 5: Type of partnerships across geographical locations

Regions	Contract development and manufacturing organization	Own facility	Technology transfer	Grand total
Europe	43	5	3	**51**
Asia and the Pacific	9	10	18	**37**
North America	21	4	2	**27**
South/Latin America			7	**7**
Africa	1		5	**6**
Middle East			4	**4**
Unknown	1			**1**

Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.

Table 6: COVID-19 vaccine production activities in Asia-Pacific

Vaccine developer	Vaccine name	Manufacturer	Country of production	Manufacturer type	Production type
AstraZeneca	AstraZeneca - Vaxzevria	BioKangtai	China	Technology transfer	End-to-end
		CSL	Australia	Technology transfer	End-to-end
		Daiichi Sankyo	Japan	CDMO	Fill-finish
		JCR Pharmaceuticals	Japan	Technology transfer	Drug substance
		KM Biologics	Japan	CDMO	Fill-finish
		Nipro Corp	Japan	CDMO	Fill-finish
		Serum Institute of India	India	Technology transfer	End-to-end
		Siam Bioscience	Thailand	Technology transfer	Fill-finish/end-to-end
		SK Bioscience	Korea	CDMO	End-to-end
Bharat Biotech	BBIL - Covaxin	Bharat Biotech	India	Own facility	End-to-end
		Bharat Biotech	India	Own facility	Fill-finish
		Bharat Immunologicals and Biologicals Corporation Limited	India	Technology transfer	Drug substance
		Haffkine	India	Technology transfer	End-to-end
		Hester Biosciences	India	CDMO	Drug substance
		Indian Immunologicals	India	Technology transfer	Drug substance
Janssen Pharmaceuticals	Janssen - Ad26.COV 2.S	Biological E	India	Technology transfer	End-to-end
Moderna	Moderna - Spikevax	Moderna	Australia	Own facility	End-to-end

		Samsung Biologics	Korea	CDMO	Fill-finish
		VAV Lifesciences	India	CDMO	Excipient supplier
Novavax	Novavax - Nuvaxovid	Serum Institute of India	India	Technology transfer	End-to-end
		SK Bioscience	Korea	CDMO	End-to-end
		Takeda	Japan	Technology transfer	End-to-end
Pfizer-BioNTech	Pfizer-BioNTech - Comirnaty	Fosun Pharma	China	Technology transfer	End-to-end
		VAV Lifesciences	India	CDMO	Excipient supplier
Sinopharm (Beijing)	Sinopharm (Beijing) - BBIBP-CorV	China National Biotec Group Beijing	China	Own facility	End-to-end
		CNBG Changchun	China	Own facility	Fill-finish
		CNBG Chengdu	China	Own facility	Fill-finish
		CNBG Lanzhou	China	Own facility	Fill-finish
		CNBG Shanghai	China	Own facility	Fill-finish
		Incepta	Bangladesh	Technology transfer	Fill-finish
		Ministry of Industry	Myanmar	Technology transfer	Fill-finish
		Sino-Innovax Biotech	Singapore	Technology transfer	Fill-finish
Sinovac	Sinovac - CoronaVac	Bio Farma	Indonesia	Technology transfer	Fill-finish
		Pharmaniaga	Malaysia	Technology transfer	Fill-finish
		Sinovac	China	Own facility	End-to-end
		State Pharmaceutical Corporation	Sri Lanka	Technology transfer	Fill-finish

Source: Created using data from UNICEF COVID-19 Vaccine Market Dashboard.
Abbreviations: CDMO: Contract development and manufacturing organizations.

Tables 4, 5 and 6 show more details on COVID-19 vaccine manufacturing activities. While Table 4 provides an overall picture of the regions where different parts of vaccine production are located, Table 5 shows the types of partnerships adopted in those production across geographical regions. Table 6 presents vaccine-specific details on production activities in the Asia-Pacific. The region's participation in vaccine value chains can be broadly classified into two approaches depending on the role domestic companies undertake. Through CDMO and technology transfer contracts, larger and more experienced local companies may join hands with established pharmaceutical multinationals from developed economies to be part of their global vaccine production. For example, Oxford-AstraZeneca has engaged several pharmaceutical and biotechnology companies in Australia, China, India, Japan, the Republic of Korea and Thailand to scale up their production capacity. The Swedish-British pharmaceutical multinational is probably the vaccine producer with the most extensive networks of companies in the Asia-Pacific region, covering long-established contract manufacturers such as Samsung Biologics or SK Bioscience in the Republic of Korea, as well as relatively newer companies such as Siam Bioscience in Thailand. Pfizer-BioNTech, Moderna and Janssen have also established contract partners in the

region. Limited details are available on the precise nature of many of the manufacturing arrangements, but they range from arrangements covering purely bulk substance production or fill-finish to full process manufacturing (see Table 4). Some, but still a small proportion, are also reported to include licensing and distribution rights.[9]

The most notable example of a contract company in the region is Serum Institute of India. Considered to be the world's largest vaccine manufacturer by volume, the Serum Institute of India produces 1.5 billion doses of WHO-approved vaccines a year for diseases such as polio, diphtheria, measles, mumps and rubella for use by the public immunization programs of some 170 countries (Kazmin, 2021). The Serum Institute of India has been granted the right to manufacture the Oxford-AstraZeneca vaccine for developing countries through Covax under the name Covishield. Given its production capacity, the Serum Institute of India has also been granted the right to manufacture the Novavax vaccine starting in June 2021. However, the devastating wave of infections in India in March 2021 prompted the Government of India to ban exports from the Serum Institute of India and to divert all of its production to domestic use, causing the company to miss its export commitment from March to late November that year (*Aljazeera*, 2021).

In addition to serving as contract manufacturers for leading pharmaceutical multinationals, Asia-Pacific institutes and companies, particularly those in India and China, have also developed their own COVID-19 vaccines. Covaxin, developed by Bharat Biotech (India), Sinovac and Sinopharm are among the ten vaccines approved by WHO for emergency use. While Bharat Biotech limits its production facilities only in India,[10] Sinovac and Sinopharm also contract out part of their manufacturing activities to other middle- and low-income countries in the region. Sinopharm has set up fill-finish operations in Bangladesh, Myanmar and Singapore, while Sinovac has contract partners in Indonesia, Malaysia, and Sri Lanka (see table 4). The practice of contracting with other manufacturers in similar income-level countries is common for vaccine developers from middle-income countries, such as China, Cuba, India, Kazakhstan, the Russian Federation, and Viet Nam. This pattern is different for vaccine developers from high-income countries, which primarily select manufacturing partners in other high-income economies (Global Health Centre, 2022). Although increasing vaccine manufacturing capacity through regional participation in vaccine value chains is one way to ensure access to vaccines, it may not solve issues of

[9] Data on COVID-19 vaccine manufacturing are presented by the Global Health Centre at the Graduate Institute, Geneva, available at www.knowledgeportalia.org/covid19-vaccine-manufacturing (accessed on 14 April 2022).

[10] On 2 April 2022, WHO confirmed the suspension of supply of Covaxin (Bharat Biotech) through United Nations procurement agencies and recommended that countries using the vaccine take action as appropriate. The suspension followed an inspection by WHO on 14–22 March 2022, which revealed the need to conduct process and facility upgrades to address deficiencies in good manufacturing practices. See www.who.int/news/item/02-04-2022-suspension-of-supply-of-covid-19-vaccine covaxin#:~:text=The%20suspension%20is%20in%20response,good%20manufacturing%20practices%20(GMP) (accessed on 14 April 2022).

equitable vaccine distribution. The next part explores bottlenecks and challenges in vaccine production and discusses policy directions in further detail.

4.4 Challenges in vaccine production and policy recommendations

We now address the scope of vaccine production challenges and propose policy recommendations on how to address them to improve preparedness and resilience. Since the first cases of pneumonia were reported in Wuhan, China, in December 2019, the world has seen unprecedented progress in vaccine development, manufacturing scale-up, and vaccine deployment and distribution. As of 16 April 2022, 11.45 billion doses of COVID-19 vaccines have been administered globally, with 65 per cent of the world population having received at least one dose, according to Our World in Data.[11] Vaccine manufacturers and their suppliers have been scaling up production, and accumulated supply is forecasted to exceed 18 billion doses by the end of 2022.[12] This represents three to four times the pre-pandemic annual demand for all vaccines of 5 billion doses (Airfinity, 2021). Nonetheless, the vaccine production process is far from smooth, and there are still too many bottlenecks that can prevent vaccine manufacturers from achieving their targets. These challenges and obstacles are classified into three broad categories: those related to vaccine supply inputs; those inhibiting the vaccine production processes; and policy and regulatory issues.

First, the scale-up of manufacturing capacity is subject to mitigating upstream supply challenges in securing critical inputs in raw materials, consumables, and equipment across vaccine value chains (Taylor et al., 2021). While some inputs are specific to each vaccine technology platform, for example, lipid nanoparticles for mRNA vaccines, other inputs are common across all types of vaccines, for example, glass vials. Many of these inputs are provided by a limited number of suppliers that also face significant demand peaks from the pandemic outbreak. The limited data to forecast manufacturing needs, on top of the lack of visibility on the supplier base, increases potential supply constraints on these crucial inputs. Long-term demand uncertainties for these inputs also add to the challenges of investment decisions and capacity expansions.

Second, scaling up COVID-19 vaccine production capacity faces challenges in both establishing new facilities and repurposing existing ones. Vaccine production processes can suffer from bottlenecks. Each vaccine technology platform faces its own challenges in scaling up quickly. Hence, manufacturing capacity needs to be assessed from the technology platform perspective. The traditional way of growing cell cultures in bioreactors requires time and careful management to grow and keep live cells healthy and thriving. Vaccine makers who rely on live cultures also struggle with yields, making it harder to make vaccines fast and in large quantities. Scaling up this production stage in newly established facilities makes it even more challenging, as

[11] See https://ourworldindata.org/covid-vaccinations (accessed on 16 April 2022).
[12] UNICEF forecasted the 2022 low case total supply at 16.8 billion doses, base case at 18.7 billion and high case at 20.9 billion. See www.unicef.org/supply/covid-19-vaccine-market-dashboard (accessed on 16 April 2022).

seen in AstraZeneca's struggle to meet its production targets in early 2021. The company said it could take six to nine months to start a production site from scratch, and that timetable was possible only by working with experienced partners at an accelerated pace (The Economist, 2021).

Ramping up the production of mRNA vaccines has particular challenges. There are limited supplies of raw materials needed for vaccine production, such as nucleotides, or the fatty bubbles that are required to protect the mRNA molecules. Before using mRNA technology for COVID-19 vaccines, these materials were used in niche cancer treatment. Setting up new production capacity to meet the demand for COVID-19 vaccines presents an additional challenge. Networks of contract manufacturers had to be established for several of the leading vaccines that feature novel technologies, including those relying on mRNA (Wouters et al., 2021).

On top of setting up new facilities or repurposing existing ones, another crucial constraint to rapid capacity expansion is the requirement for widespread technology transfer. Few countries have the domestic capacity to produce COVID-19 vaccines rapidly and independently. Therefore, a successful global production capacity expansion will require intensive and active knowledge sharing, technology transfer, and data visibility along vaccine value chains. Doing all of this would be time-consuming even if circumstances were ideal, but having to manage intensive technology transfer during the period when many countries impose travel restrictions adds another layer of challenges to the scaling up of COVID-19 vaccine production. Setting up vaccine production facilities is also costly. The United States Department of Defense estimated the 25-year life-cycle cost of a three-product facility to be $1.56 billion and that seven years are needed to design, build, validate, and commence commercial manufacturing (Plotkin et al., 2017). Although these costs are estimated for high-resource countries and could be lower in low-resource ones, they are still exorbitant. They pose a crucial barrier to vaccine production expansion in emerging economies.

Successful technology transfer also requires technical competence and a skilled workforce. The ability to hire, train and develop quality personnel is a challenge even for highly experienced manufacturers. A strong base of scientific and technical workforce with vaccine-specific manufacturing know-how and quality control systems is crucial in sustaining vaccine production. This requirement may not be a challenge in advanced economies or large middle-income countries such as China and India that have sound technical and scientific education systems, but smaller economies that are new entrants to vaccine production may need to build the scientific ecosystem that can ensure sufficient development of the knowledge base (Plotkin et al., 2017). The need to rapidly scale up COVID-19 vaccine production across different geographical regions in a short period of time would pose challenges not just to vaccine developers, but also to contract partners in different parts of the world.

Beyond production-specific requirements, policy and regulatory issues can also cause bottlenecks in vaccine production. Five key areas that need to be considered to enable vaccine capacity expansion are: measures to ensure free flows of essential supplies; regulatory requirements on quality controls and manufacturing standards; agreements on collaborations; measures to increase financing; and initiatives to increase data visibility along vaccine value chains (Taylor et al., 2021). Vaccine manufacturing is an expensive, complex process, in which even subtle changes may affect the quality, safety, and ultimate efficacy of the final vaccine. That is why the process is tightly regulated, not just for the finished product but for each stage of production and each facility where manufacturing occurs (Bollyky and Bown, 2020). Not many companies in the world have the capacity to produce vaccines in billions of doses. Vaccines also need to meet national regulatory requirements in the markets to be administered. Complying with all these requirements could slow down the vaccine production process, and efforts need to be made to reduce these bottlenecks without jeopardizing the quality of the vaccines.

The globalized nature of vaccine value chains and production makes it even more necessary that regulatory requirements are enforced multilaterally and collaboratively. Imposing unilateral requirements or export bans can lead to disruptions in the supply chains of critical vaccine inputs as well as of vaccines. For example, the United States invoked the Defense Production Act, a Korean War-era law that enables the Government to require companies to prioritize federal contracts over other ones, in early 2021 to guarantee inputs of key medical supplies, which inevitably led to disruptions in the production of many medical products as overseas manufacturers cannot get access to those supplies (Bollyky and Bown, 2021). This has fueled critiques that the United States restricted sales of key medical supplies when others desperately need them, and this may have triggered the wave of export bans from other countries, including India, where vaccine exports were suspended in March 2021. Regulatory restrictions like export bans may help those countries in stockpiling supplies in the short-term, but unintentionally lead to adverse consequences in the longer-term. For example, after the six-month vaccine export ban imposed in India in March 2021, the Serum Institute of India has already announced plans to temporarily halve its production of the AstraZeneca vaccine until more orders come in. Not only did the procurement from the Government of India slow down as the country has reached its vaccination target, the company's main buyer, Covax, has also been looking to get supplies from elsewhere after the company failed to honor its earlier purchase agreement (Das, 2021).

4.5 Policy recommendations for vaccine production preparedness

Now that the challenge of finding vaccines for the COVID-19 pandemic has been met, the most urgent task is scaling up production capacity to meet global demand. Because access to vaccines has become a source of national security, governments worldwide are faced with the challenge of coping with the pandemic while preparing for the next pandemic, if and when it comes. Understanding the vaccine value chain

and the production process is crucial as stakeholders are still adjusting to this unforeseen challenge.

Regardless of the vaccine technology platform, achieving the complex vaccine manufacturing process without compromising on quality poses a wide range of operational challenges, including: the need for highly specialized equipment and personnel; manufacturing consistency and control to guarantee the quality and safety of each vaccine; lengthy capacity ramp-up and technology transfer timelines; complex global manufacturing networks of contract partners at different production stages; lengthy manufacturing times; and on-time input supply delivery for more than one hundred components (Coalition for Epidemic Preparedness Innovation, 2021). Regulatory and policy issues for these challenges need to address input supply challenges, manufacturing capacity, and interdependencies beyond COVID-19 vaccine stakeholders. Policy discussion can be classified into two broad topics: scaling up supply inputs and manufacturing capacity, and enabling an efficient and effective ecosystem of vaccine production. The first area of policy issues is operation-specific, addressing key questions like how to increase the efficiency of existing capacity and how to repurpose other existing capacity and add new capacity to handle the sudden demand spike. The second set of policy issues covers a wider range of issues that are crucial in enabling and strengthening longer-term supply capacity, including: guaranteeing the free flow of goods, technical capacity, and production capacity; creating a regulatory system that can help improve the fungibility of supplies and the capacity of supply chains; encouraging collaborations across public and private stakeholders; implementing financing solutions that contribute to expanding and enhancing the vaccine and scientific ecosystem; and increasing value chain visibility to help various market participants and stakeholders to make timely and effective decisions.

5. Conclusions

The COVID-19 pandemic provides the basis for reconsidering the production of vaccines in the Asia-Pacific region in preparation for the next pandemic. Most countries in the region seem well served with existing systems to administer vaccines to prevent the most common diseases. However, COVID-19 is an outlier event unlike previous outbreaks that were contained in location and space (e.g. Sars-CoV-1 in 2002–2004, H1N1 in 2009–2010, Mers-CoV in 2012–2015), and its relatively high transmission and mortality rates made access to vaccines a national security issue. Wealthier countries invested in helping pharmaceutical firms develop vaccines in exchange for being first to receive the vaccines, and the subsequent race to scale up production in which some countries paused the export of vaccines produced in their domestic markets, are dangerous precedents for health policy going forward.

As vaccines were developed, wealthier countries had faster access to better but more expensive vaccines while poorer economies waited to gain access to vaccines through global initiatives or donations, which was ineffective for creating global herd immunity. The vast difference in vaccination rates among developed and developing countries despite the increasing supply of vaccines reveals a stark truth of global inequality that has been made worse by vaccine nationalism. Stockpiling vaccines may help a country in the early phases of a pandemic, but it could lead to unsold products that cause financial burdens to vaccine manufacturers, as seen in the case of the Serum Institute of India. However, relying only on domestically produced vaccines that may not be the most effective has also proved costly, as evidenced by lockdowns in China in early 2022 driven by the Omicron variant when the rest of the world was slowly reopening. Lessons need to be derived from these public interventions before policymakers rush into prioritizing domestic vaccine production in pandemic management.

Nevertheless, there are important lessons to use to understand how countries in the Asia-Pacific region may be better prepared when the next pandemic comes. Appendix A provides a decision tree for the actions that can be considered to prepare for the next pandemic. The challenge of such preparedness, as shown by the COVID-19 pandemic, is that it is impossible to establish a production facility for a vaccine before it is discovered or its efficacy is known. Moreover, the complex production and distribution requirements, which varied considerably between different COVID-19 vaccines, are also not known and cannot be easily anticipated. Among the many alternatives governments supported at the beginning of the pandemic, only a few proved to be both effective and safe enough to administer to the population.

The rapid emergence and diversity of COVID-19 vaccine value chains reflect the dynamic interaction of factors at different levels. The broader context of the pandemic should not be overlooked. The early phase of vaccine shortage and disruption was characterized by several unprecedented incidents that could hardly be anticipated. The sudden global demand hike for vaccines and related products such as personal protection equipment led to a mismatch of demand and supply that would disrupt any industry. The concentrated nature and technological complexity of the vaccine industry and the severity of the disease added to the challenge of developing a vaccine.

Differences in the vaccine value chains reflect contributing factors at different levels (Gereffi, Pananond, and Pedersen, 2022). Firm-level considerations such as the vaccine technology platform and the marketing strategy on pricing and distribution channels all play a part in the vaccine value chain. In addition, global value chain governance also reflects factors specific to the vaccine value chain. How each developer wants to organize their value chain, as well as the availability of CDMO partners, are all relevant to global value chain governance decisions. Last but certainly not least are country-level factors such as trade policy and the extent and direction of government subsidies. Given the complex nature and the interaction of these factors, it is risky to make generalized conclusions about vaccine manufacturing.

Policymakers, therefore, are reminded that the most important factor that determines a country's readiness and ability to take part in vaccine value chains is its technological capacity. Where technological capacity is limited, Governments should focus first on ensuring effective and quick procurement and distribution of vaccines, either through their own purchasing agreement or through an international alliance such as Covax. Where there is higher technological capacity, Governments may consider entering into collaborations with companies to take part in vaccine value chains in addition to building effective procurement and distribution of vaccines. The more complex the stage of vaccine production, the higher the need for technological capacity. Vaccine production comprises a chain of technologically advanced steps, each requiring high technological capacity and skilled personnel. A country's readiness for vaccine production depends on an interaction of factors related to firms, value chains, and national capacity. Taking part in vaccine production should not be considered a goal in itself to achieve at all costs. Instead, national vaccine policy should focus first and foremost on full and rapid vaccination of the population with an effective system of vaccine production and distribution. Ensuring access to vaccines, regardless of where they are made, is the first step towards the quick vaccination of the population to save lives and livelihoods.

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Appendix: Decision tree for pandemic preparedness vaccine manufacturing

Step 1. Is there a new transmissible disease?
No: No action on production, invest in strengthening distribution channels for current treatments and vaccines
Yes: Go to step 2

Step 2. Does the new transmissible disease spread easily from person to person?
No: Isolate and treat sick people, contain cases (identify cases, limit exposure and travel), purchase additional personal protective equipment for health-care workers
Yes: Go to step 3

Step 3. Do existing treatments work well to treat the new easily transmissible disease?
No: Go to step 4
Yes: Use existing treatments and order more from manufacturers and go to Step 6

Step 4. Are there untested treatments that could work to treat the new easily transmissible disease?
No: Go to step 5
Yes: Collaborate with pharmaceutical firms to analyse efficacy of untested treatments. Go to step 6

Step 5. Could pharmaceutical firms develop new treatments to treat the new easily transmissible disease?
No: Isolate individuals to limit transmission and wait for the pandemic to run its course quickly
Yes: Collaborate with pharmaceutical firms to analyse efficacy of untested treatments. Go to step 6

Step 6. Can pharmaceutical firms produce enough treatment quickly?
No: Go to step 7
Yes: Contract with firms for the provision of treatment, negotiate price based on cost benefit analysis, invest in strengthening the distribution channels while treatment is being manufactured

Step 7. Do pharmaceutical firms need a sophisticated manufacturing base in place to produce the treatment?
No: Negotiate with pharmaceutical firms to set up local production to scale up to the needs of the country and invest in strengthening the distribution channels while treatment is being manufactured
Yes: Go to step 8

Step 8. Does the country have an established and sophisticated production capacity for the new treatment?
No: Contract with pharmaceutical firms for the provision of treatment, negotiate price based on cost benefit analysis, invest in strengthening the distribution channels while treatment is being manufactured

Yes: Negotiate with pharmaceutical firms to set up local production to scale up to the needs of the country and invest in strengthening the distribution channels while treatment is being manufactured

Meanwhile, consider these initiatives as generic guidelines:

- Assess the global value chains of vaccines to identify gaps and shortages and to understand where participation is possible. A plan to manufacture can also consider the supply chains of key ingredients such as lipid particles, proteins, syringes, and vials.
- Consider bilateral, regional, or multilateral collaborations and contracts across the public and the private sectors to scale up production. For example, explore regional initiatives such as those launched by the Pan American Health Organization (PAHO) to boost vaccine production in Latin America, or other collaborations agreed under the Quad Vaccine Partnership.
- Consider bilateral, regional, or multilateral regulatory agreements on standards and controls over vaccine production and distribution to help facilitate and speed up the possibility of new regional manufacturing activities.
- Consider access to financing and financial support to accelerate public and private investment across the vaccine manufacturing and distribution ecosystem.
- Invest in the education to enhance the overall skill levels in science and technology.

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