

SOUTH KOREA AS A GLOBAL VACCINE HUB

By Thomas Byrne, Claire Callahan, Irene Kyoung, Salomé Da Silva Duarte Lepez

ABSTRACT

South Korea aspires to achieve the status of global vaccine hub as a national strategic policy priority. South Korea's biomanufacturing industry has ramped up development and production of therapeutic treatments and vaccines to meet the public health demands of the pandemic. The government has responded by promoting public-private partnerships to expand vaccine production capacity to meet current and future needs domestically and abroad in LMICs. To bolster this strategy, the government has entered into partnerships with international organizations, namely the WHO, ADB and IVI, by establishing training hub programs for a global biomanufacturing workforce in 2022. This paper examines South Korea's mechanisms and strategy towards becoming a vaccine hub, the origins of which predate the Covid-19 pandemic but were again spurred by vaccine nationalism and challenges to access early in the pandemic. The paper first outlines the characteristics of a global vaccine hub and a WHO biotechnology hub, touches on collaborative vaccine

efforts in Asia, and then discusses the institutional structure of South Korea's global vaccine hub and the country's Covid-19 partnerships. The paper provides an overview of global vaccines, including Covid-19 vaccine production, showing where South Korea fits into that ecosystem, and summarizes global vaccine diplomacy efforts. The paper concludes that shortcomings of national and bilateral vaccine diplomacy, and multilateral mechanisms during the Covid-19 pandemic hindered global vaccine access and equity. It argues that South Korea's demonstrated capabilities to rise as a global vaccine development, manufacturing, and training hub will help bolster global public health capacities in the future. This report is largely based on information obtained in mid-2022 on the multinational and national institutions related to global WHO vaccine hubs. The authors attempted to synthesize these new, complex, and continuously evolving conditions to the best of their ability at the time of writing.

Key Words: Covid-19, World Health Organization, Vaccine Diplomacy, Vaccine Equity, South Korea, vaccine hub

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INTRODUCTION

In April 2021, more than a year into the Covid-19 pandemic, South Korea's Foreign Minister, Chung Eui-yong, approached the United States for a vaccine swap,¹ an idea that then-Representative Park Jin, who is now Korea's foreign minister, had raised months earlier. At that time, Korea faced a public health challenge that became a political liability for the government—the country did not produce any Covid-19 vaccines and could not acquire enough supply to roll out an effective nationwide vaccination campaign. At the end of April 2021 only 0.3 percent² of South Korea's population had received a full, primary series of doses in contrast to 30 percent in the United States.

At the onset of the pandemic in early 2020, Korea was a global leader in its public health response with highly effective testing, contact tracing, and quarantining. Such methods successfully contained the initial spread in February 2020 and the rate of infection dwindled rapidly immediately afterward. But as the pandemic ground on, such measures alone could not suppress recurrent surges as new variants made the coronavirus more transmissible. In this regard, Korea had become a laggard in its public health response to the pandemic in comparison with those countries that had early access to vaccines—namely, the United States, whose national vaccination program was rolled out on December 14, 2020, in Queens, New York City.

Although a U.S.-Korea swap of highly efficacious mRNA vaccines never took place, the Biden administration did eventually provide 1000,000 doses of Johnson & Johnson's one-shot Covid-19 vaccine to South Korea in June 2021,³ after having provided 550,000 vaccine doses for South Korean soldiers,⁴ as vaccine supply and demand in the United States had moved into a position of surplus.⁵ But needing more doses, Korea entered into a swap with Israel, which loaned it 700,000 doses of Pfizer-BioNTech's mRNA vaccine in early July 2021.⁶ In turn, South Korea agreed to repay Israel with the same number of shots already on order from Pfizer, but not scheduled for delivery to Korea until months later in September and October.

The predicament Korea found itself in catalyzed the government's decision to enhance self-reliance as much as possible in the national interest. In August 2021, just one month after the Covid-19 vaccine swap with Israel, the Korean government announced its "K-Global Vaccine Hub Policy" and set up a promotion committee.⁷ Korea's pandemic-induced aspirations dovetail well with its broader

developmental policy—to move up the ranks as one of the leading global manufacturers of all vaccines, to fifth place by 2025 from its position of ninth place in 2020, and to more than quadruple its pharmaceutical exports to \$36.4 billion over the same period.⁸ Indeed, the development of Korea's pharmaceutical industry is akin to the country's historical development of globally competitive industries in automobiles, shipbuilding, steel, consumer electronics and semiconductors.

However, there is another salient aspect of Korea's developing global vaccine capacity: enhancing worldwide equity in accessing vaccines and therapeutics. Historically, the United States and Europe have dominated both production and supply in this industry. More recently, they have been joined by one manufacturer in India. While relative newcomers such as China and India have expanded the scale and scope of vaccine production and supply, the problem of access to safe and effective vaccines for people in low and middle income countries (LMIC) became glaring during the Covid-19 pandemic. Korea is well-positioned to help address the issue.

In February 2022, the World Health Organization (WHO) nominated Korea as the "Global Training Hub for Biomanufacturing" for the vaccine and biologics workforces in LMICs.⁹ Korea was selected by the WHO because of its advanced private and public-sector capacities in biologics manufacturing processes, and its training infrastructure. Utilizing its pharmaceutical prowess, and embracing its role as a global vaccine force, South Korea is eager to enhance its own production while concurrently becoming a global force for good in public health.

WHAT IS A VACCINE HUB?

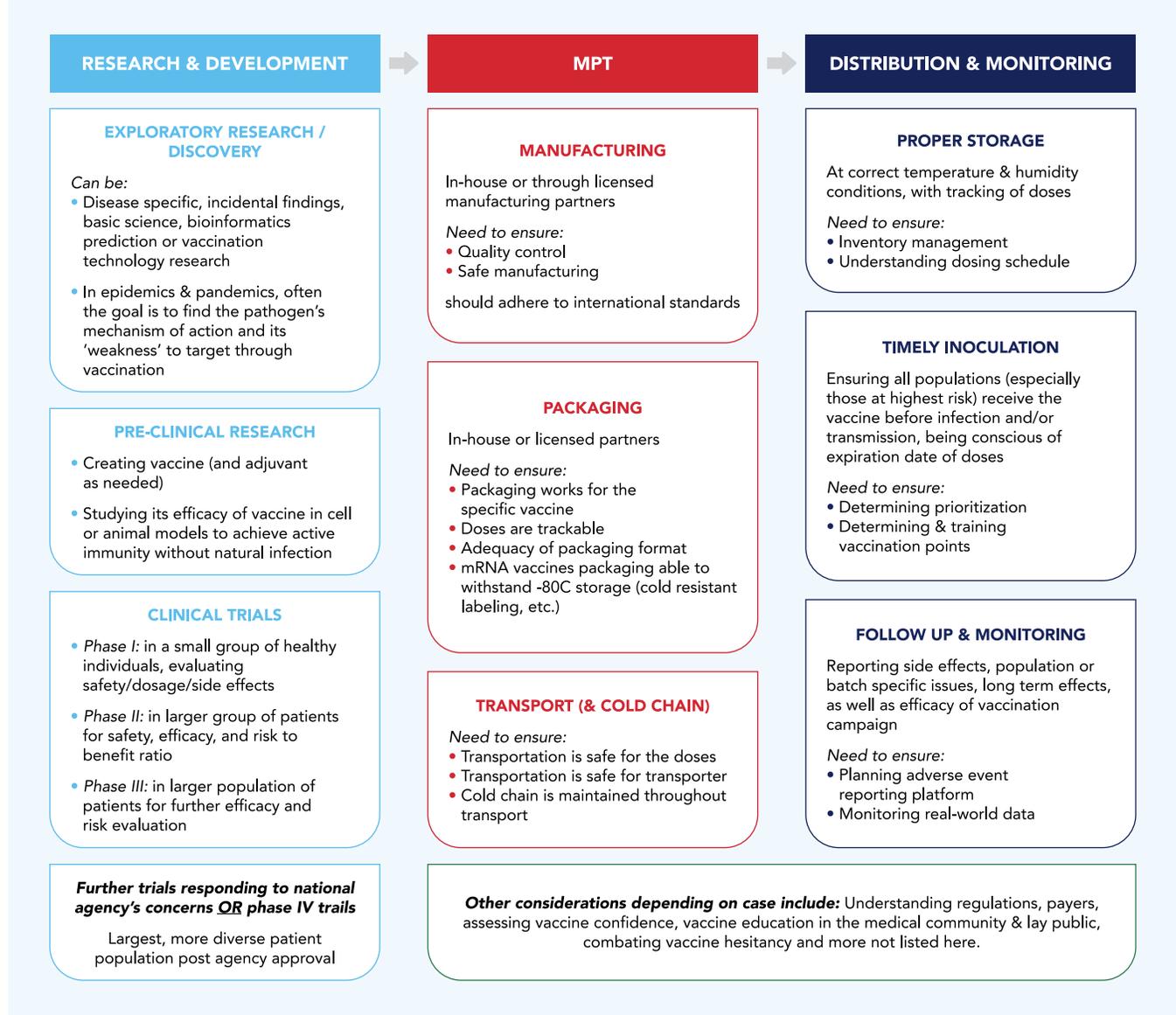
Types and Key Characteristics

The term "vaccine hub" has become a buzzword in the media and academic publications. The term is often used to mean vaccine production leader, center of international vaccine research, country making large vaccine industry related profits, and local large vaccination center. The use of "vaccine hub" as a blanket term leads laypeople and policymakers to conflate the vaccination process as one streamlined course. However, the process is multifaceted and is often divided between several countries, organizations, and steps (Figure 1). Furthermore, it is important to differentiate between a WHO vaccine hub and a global vaccine hub.

A WHO vaccine hub is a consortium of scientific, national, and non-profit bodies coordinated by the WHO, which aims to spread knowledge relating to the vaccination process. The WHO vaccine hub nominations aim to change the current imbalances in scientific and medical capacity worldwide. In comparison, we define that a global vaccine hub is a country that has the capabilities to complete and efficiently

manage the three major steps of the vaccination process, on a national level, which include Research & Development (R&D), Manufacturing, Packaging & Transport (MPT), and Distribution & Monitoring (D&M). Furthermore, it is able to export these practices or products internationally and plays an important role in vaccine diplomacy (Figure 1).

Figure 1. The vaccine production process, simplified into three phases



The WHO Technology Transfer Hub

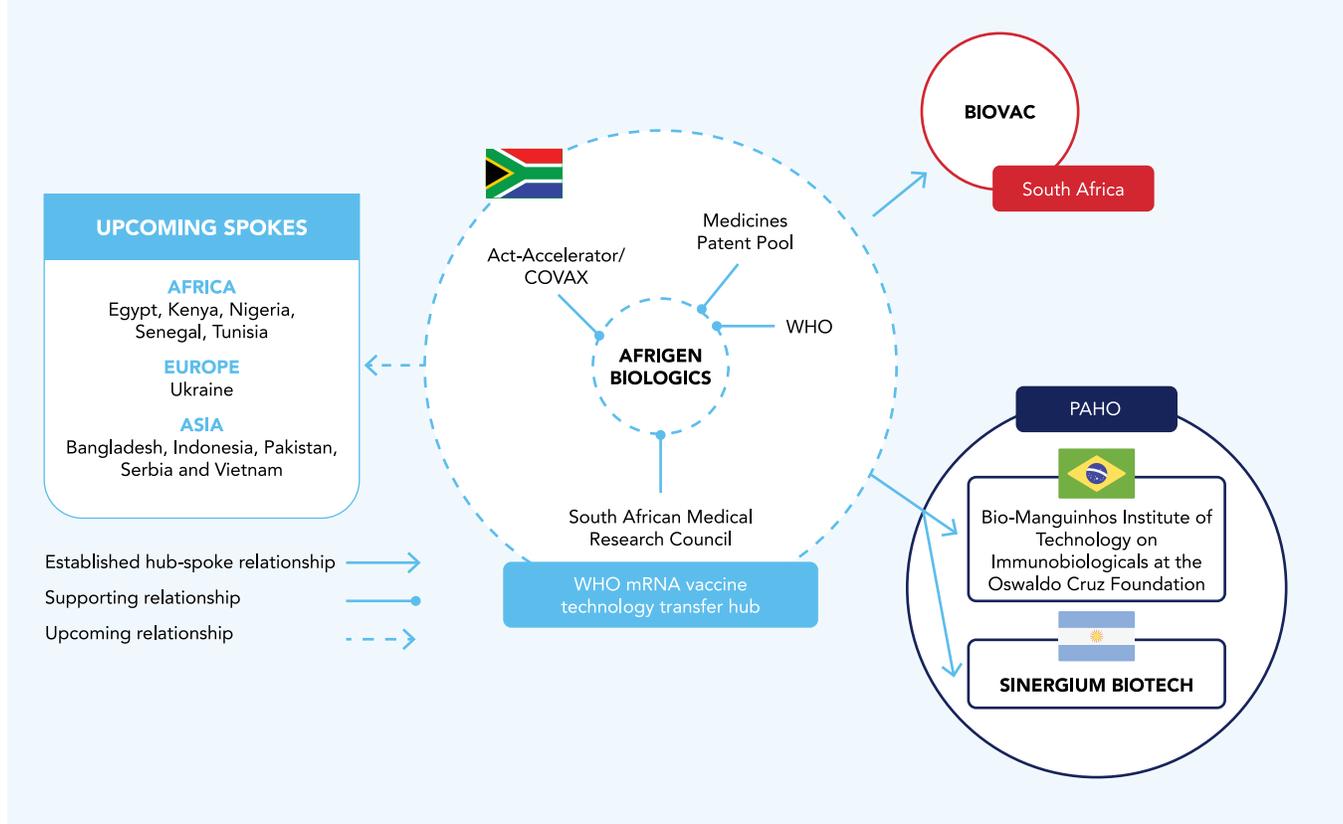
The first step towards equity is equal access to knowledge and system building for the long term. Since 2020, WHO Director-General Dr. Tedros Adhanom Ghebreyesus has made vaccine equity a priority in the WHO’s response to Covid-19, particularly through the Access to Covid-19 Tools Accelerator (ACT-A),¹⁰ which includes the vaccine distribution entity Covid-19 Vaccines Global Access (COVAX). However, this operation was created to address the Covid-19 pandemic in particular and does not address the long-term health inequities such as those seen in Covid-19 vaccination delays in some countries. The WHO hub system was designed to address these gaps in system capacity building, as well as scientific capacity building, through education. Adopting the hub and spoke model, WHO hubs are designated to become a learning center of a specific aspect of health technology, while spokes can apply

to attend the Hub and receive knowledge in a given area. This is akin to the airline hub and spoke network model, which increases the capacity and distribution of passengers.

The South African WHO mRNA vaccine technology transfer hub model

In July 2021, the WHO established the mRNA vaccine technology transfer hub in Cape Town, South Africa. Through the hub, the WHO and industry partners collaborated to establish a network of support for low- and middle-income vaccine manufacturers focusing on mRNA vaccines, with support from the Medicines Patent Pool, the ACT-A/COVAX, the Africa Centres for Disease Control and Prevention, and a network of universities.¹¹ Afrigen Biologics acts as host to establish the mRNA vaccine production technology hub, with the South African Medical Research Council providing the research (Figure 2).

Figure 2. Simplified diagram of the WHO South African mRNA technology transfer hub, as of August 2022



The first manufacturing spoke to receive mRNA vaccine technology was Biovac, a South African vaccine producer.¹² The next two manufacturing spokes, announced in September 2021, were members of the Pan-American Health Organization: the Bio-Manguinhos Institute of Technology on Immunobiologicals at the Oswaldo Cruz Foundation in Brazil, and Sinergium Biotech in Argentina. Future recipients will include Egypt, Kenya, Nigeria,¹³ Senegal, Tunisia, Bangladesh, Indonesia, India, Pakistan, Serbia, Ukraine, and Vietnam.¹⁴

The role and debate over the mode of vaccine decentralization

Apparently, mRNA technology transfer to the WHO South African hub is taking place, but in a limited mode so far, to increase production and access to LMICs. Moderna allowed the French government, after a request from the U.N. Medicines Patent Pool, to provide its Covid-19 vaccine to Afrigen Biologics & Vaccines, which is using the Moderna vaccine in comparison studies in mice to test the effectiveness of its own shots.¹⁵

After much debate, World Trade Organization (WTO) trade ministers adopted the Ministerial Decision on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement on June 17 2022, which gives members greater scope to take direct action to diversify production of Covid-19 vaccines and to override the exclusive effect of patents through a targeted waiver over the next five years. It also calls on members to decide on its possible extension to cover the production and supply of Covid-19 diagnostics and therapeutics by the end of 2023.¹⁶ This is supported by many LMIC members.

However, some WTO members take the position that there is “no evidence that intellectual property did indeed constitute a barrier to accessing COVID-19 vaccines.”¹⁷ This position is supported by the International Federation of Pharmaceutical Manufacturers and Associations, which issued a statement saying that weakening the intellectual property framework would undermine the ability to address the current and future pandemics.¹⁸ Indeed, a different tack to the patent waiver approach is a focus on intellectual property (IP) licensing opportunities as a way to facilitate owners of IP assets broadening the reach for their products and services. This is supported by Australia, Canada, the European Union (EU), Hong Kong SAR, Japan, Singapore, Switzerland, Taiwan, the United Kingdom, and the United States.¹⁹

Collaborative Vaccine Efforts in Asia

As the world emerges from the Covid-19 pandemic, the vaccine landscape evolves along with efforts to improve vaccine equity and access. This is evident in new diplomatic partnerships, active non-profit groups, and several countries which have taken the lead in vaccine campaigns.

Such diplomatic partnerships include the Quad Vaccine Partnership, including India, Japan, Australia, and the United States; ACT-A/COVAX; and bilateral agreements between various Asian countries, particularly related to the Covid-19 vaccine. However, critics have pointed to the fact that the Quad’s vaccine partnership has thus far seen limited success,²⁰ with first doses only being delivered in early 2022 primarily in LMICs such as Cambodia.²¹

Although numerous organizations have had an impact in vaccinations in Asia, namely the Asian Development Bank (ADB), the Association of Southeast Asian Nations (ASEAN), the Coalition for Epidemic Preparedness Innovations (CEPI), the Swedish International Development Cooperation Agency (Sida), the GAVI Vaccine Alliance, and the Gates Foundation, the WHO is focusing on the establishment of hubs to achieve more widespread vaccine development and training.

SOUTH KOREA’S VACCINE HUB STRATEGY

Origins and Institutional Landscape

South Korea’s ambitions to develop its vaccine capacities were catalyzed during the H1N1 influenza pandemic of 2009-2010. At that time, the South Korean government had difficulty accessing U.S.-made vaccines, an early case of vaccine nationalism. This prompted the South Korean government to collaborate with private and non-profit organizations on major initiatives to improve Korea’s vaccine production and manufacturing capacity. The first was Vaccine 3.0 in 2016, a project to build infrastructure to move towards vaccine self-sufficiency,²² followed by the Right Fund in 2018, focused on global vaccine research and development, including the International Vaccine Institute’s (IVI) cholera conjugate vaccine.²³

The onset of the Covid-19 pandemic further motivated South Korean public health policymakers to establish a comprehensive strategy not only to manage the immediate pandemic, but also to prepare for future pandemics or national health emergencies. In April 2020, Korea launched the Vaccine Innovative Technology Alliance Korea (VITAL-Korea), an initiative geared towards achieving vaccine sovereignty.²⁴

The national strategy crystallized in August 2021, when then South Korean President Moon Jae-in announced South Korea's intention to become a global hub for the production and distribution of Covid-19 vaccines and other vaccines.²⁵ In July 2022, the current South Korean President Yoon Suk-yeol took a notable step forward when he vowed to turn the bio-health industry into a key national strategic industry.²⁶

South Korea's capabilities and strategy fit quite well with the three defining features of a global vaccine hub, namely, R&D, MPT, and D&M. The country already has one of the largest pharmaceutical and biotechnology manufacturing capacities.²⁷ Furthermore, it is a global leader in contract development and manufacturing organization (CDMO) capabilities, through which Korean companies partner with global pharmaceutical companies.²⁸

In order to augment its home-grown R&D capacity, South Korea sought to attract investments from and form partnerships with countries with advanced technologies and international agencies with advanced R&D capabilities. South Korea also has highly efficient distribution capabilities throughout Asia and beyond thanks to its world-class airport, airlines, and ports. Moreover, South Korea's highly competent public health agencies possess the institutional capacity for monitoring vaccine trials and distribution. These include the Korea Disease Control and Prevention Agency, the Ministry of Food and Drug Safety, and the Ministry of Health and Welfare (KMHW), which executed a highly effective response to the pandemic.

Moreover, the South Korean government under the direction of the prime minister has set up an inter-ministerial, pan-government Global Vaccine Hub Office and Committee involving 10 related institutes and domestic biopharmaceutical manufacturers.²⁹ This office will also coordinate ongoing collaboration with international organizations such as the WHO and CEPI, and nascent collaboration with the United States under the KORUS Vaccine Partnership initiative.³⁰

The K-Bio Vaccine Fund was established to help Korean pharmaceutical companies become more competitive globally and advance vaccine sovereignty. Jointly created by the KMHW, Korea Development Bank, Export-Import Bank of Korea, and the Industrial Bank of Korea, it will complement public funds with funds raised from the private market. Two Korean private investment companies, Mirae Asset Venture Investment Co. and Yuanta Investment Co., will jointly manage a fund of ₩500 billion (\$346 million) and hope to raise up to ₩1 trillion (approximately \$700 million) to support innovation in drug and vaccine development.³¹

South Korea's Global Bio Training Hub Initiative

South Korea has made notable progress in its global vaccine hub strategy by adopting the global bio training hub model. The government has spurred success in this area by promoting the participation of leading domestic and foreign biotech and pharmaceutical firms. As of mid-2022, the KMHW has identified eight corporations that are integral to the strategy, five of which are Korean. The Korean firms include Samsung Biologics, SK bioscience, Celltrion, Hanmi Pharmaceuticals, and GC Pharma. GC Pharma is the second largest pharmaceutical company in Korea, with revenues of more than \$1 billion in 2021.³² Established in 1973, Hanmi is one of the country's top five pharmaceutical companies, with more than \$1 billion in total revenue in 2021.³³ Celltrion, founded in 2002, is a pioneering biopharmaceutical company that specializes in producing "antibody biosimilars," which also had over \$1 billion in revenue in 2021.³⁴ Though established recently, Samsung Biologics is a world class CDMO. Since 2015, it has garnered 154 global regulatory approvals, including from the Food and Drug Administration (FDA) and European Medicines Agency (EMA).³⁵ It, too, pulled in more than \$1 billion in revenue in 2021.³⁶ SK bioscience is also relatively new, specializing in vaccine R&D and manufacturing, while also engaging in CDMO and Contract Manufacturing Organization (CMO) commercial partnerships.³⁷ Its 2021 sales rose sharply to about \$0.8 billion and it developed South Korea's first domestic Covid-19 vaccine.³⁸

One of the two foreign companies currently participating in Korea's global bio training hub is Cytiva, a Massachusetts-based research and biopharma manufacturing firm. It is investing \$52.5 million in South Korea to build disposal cell-culture bags used in vaccine production, which had run into supply chain bottlenecks during the pandemic.³⁹ The other is Sartorius, a venerable company headquartered in Germany,

which is investing €270 million (when announced, about \$300 million) through 2024 to expand its cell-culture media production as well as an application center with laboratories and logistics.⁴⁰ These firms will help boost South Korea's vaccine industry, both in a domestic capacity as well as in the global market.

The training plan for Korea's global hubs in 2022 consists of two collaborative efforts. The largest one is the KOR-WHO global training hub for a biomanufacturing workforce.⁴¹ IVI was designated by KMHW in February 2022 as operator of the 2022 Global Bio-Intensive Training Courses to "provide workforce training in vaccine and biologics R&D and manufacturing for students from LMICs and Korea."⁴² A week later the WHO announced the establishment of a global biomanufacturing training hub in South Korea that "will serve all low- and middle-income countries wishing to produce biologics, such as vaccines, insulin, monoclonal antibodies and cancer treatments."⁴³ South Korea is the second country to be chosen by the WHO for this type of initiative.

The training program intends to train at least 310 participants annually from 33 LMICs in South America, Africa, the Middle East, and Asia.⁴⁴ Training consists of courses in biologics development and manufacturing process, and global biologics quality control.⁴⁵ While the basic structure of the hub is similar to that of South Africa, with the host government, WHO, and non-governmental organizations (NGOs) supporting the operating organization, the training structure in South Korea differs slightly.⁴⁶ The pilot efforts for the KOR-WHO global training hub mirror several other global programs put on by the South Korean Ministry of Education, such as the Global Korea Scholarship, which also selects participants from LMICs. As such, a certain number of participation seats are allocated for each country, and participants are selected to all participate at the same time. This is different from having one representative company from one country go through the training at one time like in South Africa.

The second collaborative effort, the Korea-Asian Development Bank (KOR-ADB) program, targets nationals from developing member countries of the ADB and focuses on training for the entire vaccine manufacturing process.⁴⁷ This training is operated by the Korean National Institute for Bioprocessing Research and Training (K-NIBRT) for a total of 60 participants this year in an eight-week course.⁴⁸ The K-NIBRT project is also developing a world class biopharma

manufacturing and training and research center in Incheon, South Korea, with the goal of establishing industry leading training in the Asia-Pacific region. It is scheduled to open in 2024.⁴⁹

Public Financial Support

The South Korean government provides financial support for vaccine research and development, manufacturing, and distribution. Less than one month after the country's first Covid-19 death, on March 17, 2020, the South Korean National Assembly passed a supplementary budget of ₩11.7 trillion (\$10.1 billion), of which ₩3.7 trillion (\$3.2 billion) was allocated to the KMHW which brought its annual expenditures for 2020 to ₩86.2 trillion (\$74.5 billion).⁵⁰ The South Korean government and national health insurance program shouldered the full cost of coronavirus testing, quarantine, and treatment for Korean citizens and noncitizens.⁵¹

President Yoon plans to expand financial support to drug and vaccine businesses through investments and by modifying regulations to establish a "K-bio vaccine hub."⁵² The South Korean government will provide \$1.8 billion to help finance investments related to the K-Global Vaccine Hub Strategy and also \$420 million for the Global Bio Training Hub between 2022 and 2026.⁵³

GLOBAL VACCINE PRODUCTION

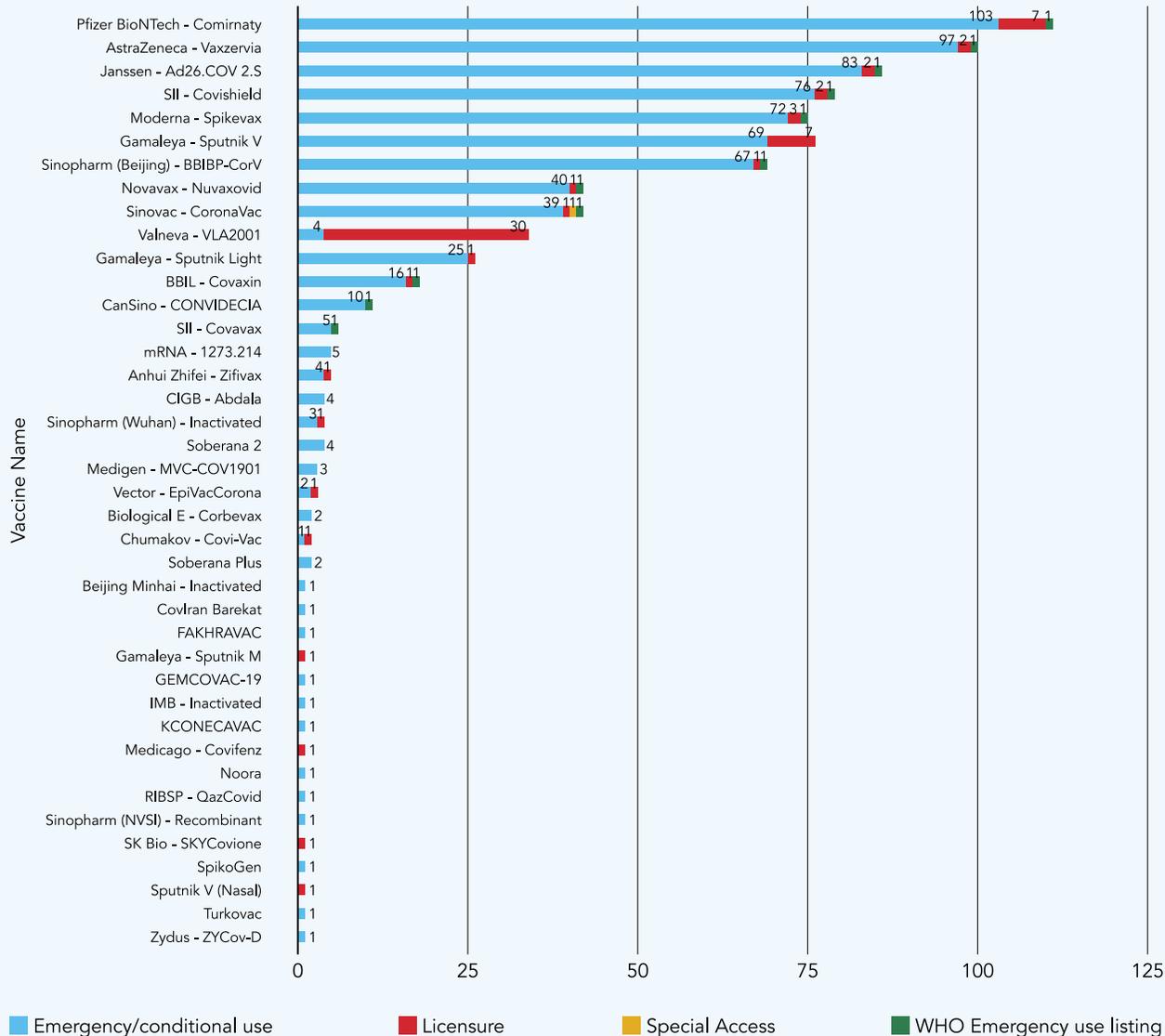
Global Covid-19 Vaccine Production

The overwhelming global demand for Covid-19 vaccines caused a large number of vaccine production candidates to emerge. Recurring waves of infection have further propelled demand for vaccines that are effective against new variants of the virus. However, only relatively few countries had the capacity to marshal an effective vaccine production response.

Forty-one vaccines have been developed and approved by at least one national regulatory body, as of September 2022 (Figure 3). Eleven of them have been approved for emergency use by the WHO, with Pfizer-BioNTech, AstraZeneca, and Janssen (Johnson & Johnson) as the top three most widely approved vaccines, attesting to their safety and efficacy. These three were produced in multinational partnerships between wealthy Western nations; the U.S.-based company Pfizer joined forces with Germany's BioNTech, Oxford University in the United

Figure 3. Chart of Vaccines, Number of National Regulatory Approvals

Number of Vaccine Approvals
As of 9/29/2022



Source: UNICEF COVID-19 Market Dashboard.⁵⁴

Kingdom developed the vaccine in concert with the British-Swedish company AstraZeneca, and the Netherlands-based Janssen Vaccines partnered with its Belgian-based parent company, Janssen Pharmaceuticals, respectively. The next vaccines with the most approvals were manufactured by the Serum Institute of India, Moderna (U.S.-based), Gamaleya (Russia), Sinopharm (China), Novavax (U.S.-based), Sinovac (China), and Valneva (Austria). Figure 3 tracks each type of vaccine and the number and type of approvals received.

Worldwide vaccine distribution has been very uneven. Around 17.76 billion doses have been produced, with 1.58 billion shipped to 146 countries. As of early October 2022, more than 5.39 billion people (around 70.3 percent of the world population) have received a dose of a Covid-19 vaccine.⁵⁵ However, the vaccination rates differ starkly around the globe.

South Korea Covid-19 Vaccine Production

Of the 41 vaccines in Figure 3, only one was produced in Korea. In late June 2022, SK bioscience's Covid-19 SKYCovione vaccine received approval for use from the Ministry of Food and Drug Safety.⁵⁶ Because the vaccine does not require ultra-cold chain facilities, the company intends to apply for emergency use by the WHO for distribution to developing countries.⁵⁷ For its global outreach, SK bioscience has also submitted applications for conditional approval to the EMA.⁵⁸ Once authorized, SK bioscience will supply the new vaccines to the COVAX distribution system.⁵⁹ The South Korean government has also pledged to buy 10 million doses worth ₩200 billion (about \$160 million) of the new SKYCovione vaccine.⁶⁰

South Korean firms have also partnered in manufacturing vaccines developed by some of the leading global vaccine companies. For example, Moderna, a biotechnology company pioneering in mRNA therapeutics and vaccines, entered into a fill-finish manufacturing contract in May 2021 with Samsung Biologics to produce its Spikevax® Covid-19 vaccine at Samsung's Songdo production facilities.⁶¹ The first batch was speedily finished in five-months' time. Shortly after in December 2021, Moderna received marketing authorization approval from South Korea's Ministry of Food and Drug Safety. This allowed the vaccine to be distributed within Korea and exported to other countries. At around the same time, The Philippines and Colombia authorized emergency use of the vaccine manufactured by Samsung Biologics in November and December 2021, respectively.⁶²

In November 2020, SK bioscience and AstraZeneca struck a deal to manufacture AstraZeneca's vaccines in South Korea.⁶³ In February 2021, Hankook Korus Pharm created a consortium to produce 500 million doses of the Sputnik vaccine, albeit not for domestic use in South Korea.⁶⁴ However, around the same time, SK bioscience signed an agreement to manufacture 40 million doses of the Novavax vaccine for domestic use.⁶⁵ South Korea's previous and ongoing efforts in producing and jointly manufacturing vaccines puts the country in a good position to take the next steps in becoming a vaccine hub.

Major Vaccine Producing Countries

South Korea's aforementioned efforts join with the existing global vaccine structure. The United States remains at the forefront of basic and clinical research, both in terms of funding and capacity. Historically, the United States has led global vaccine development, with government agencies

overseeing vaccine development and clinical trials, while funding vaccine studies and research since 2000.⁶⁶ Vaccine giants such as Novavax, Moderna, and Johnson & Johnson are all based in the United States.⁶⁷ The FDA, considered the gold standard of drug safety review,⁶⁸ oversees the regulatory approval process of vaccines and coordinates the scaling up of manufacturing.

In response to the Covid-19 pandemic, Operation Warp Speed (OWS) was set up in May 2020 as an initiative of the Trump Administration. It caught headlines by funding the two groundbreaking mRNA vaccines. It was an interagency partnership between the Department of Health and Human Services (HHS) and the Department of Defense that coordinated federal efforts to accelerate the development, acquisition, and distribution of Covid-19 diagnostics, therapeutics and vaccines, although most of the funding went to vaccines. Collaborating HHS components include the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, and the Biomedical Advanced Research and Development Authority (BARDA).⁶⁹

OWS's origins, however, go back to the 2001 anthrax attacks through the postal system, which prompted the federal government to create BARDA, which has since become a leading government public health funding agency.⁷⁰ The U.S. government used contracts with industry partners to facilitate government and industry cooperation through measures including funding clinical trials, granting companies usage of government clinical trial sites and FDA staff, and covering the costs of vaccine doses produced.

Four vaccine producing candidates received federal funds for development (Moderna, Janssen Pharmaceuticals, Sanofi/GSK, and Merck/IAVI) and three others (Pfizer/BioNTech, Janssen, and Novavax) participated in OWS through federal purchases of doses only. In addition, OWS funded 15 companies that produced ancillary supplies, such as syringes and vials, so as to mitigate supply chain deficiencies. This public-private partnership enabled the government to expedite vaccine trials and development that delivered safe and highly effective vaccines in record times, in a matter of months rather than years. Its total budget was \$18 billion.⁷¹

The European Union (EU) released its vaccines strategy in June 2020, one month after OWS.⁷² The twenty-seven member states acted as a unitary group in order to increase their bargaining power in the purchase of vaccines. This group sought to procure vaccines through contracts with

pharmaceutical companies and distribute them to each nation based on its population size. One drawback of this system was that the centralization of this approach came at the expense of speed, since 27 national health authorities needed to coordinate with each other. Additionally, the EU focused more on the purchase, rather than the production of the vaccine, which impacted the vaccine rollout process due to pharmaceutical companies' inability to scale up production when needed, as was the case with AstraZeneca.⁷³ Another factor that hindered the speed of vaccine rollout was the EU's mandate for vaccines to obtain full approval from the EMA, rather than granting emergency use authorization as U.S. health authorities did.

Known as the "Pharmacy of the World," India has developed tremendous capabilities as a mass producer of low-cost vaccines, an important capacity given its population of 1.3 billion people.⁷⁴ These capabilities also made India a global exporter. From 2017 to 2019, the country exported 80 percent of their vaccines to low-income countries.⁷⁵ India also exports pharmaceutical products to high-income nations. In the last three years alone, India's exports to the United States have risen by over 15 percent,⁷⁶ solidifying it as India's top destination for pharma exports.⁷⁷

The Serum Institute of India (SII), founded in 1966 in order to address critical vaccine shortages and high vaccine import costs, is the largest vaccine manufacturer in the world by doses produced.⁷⁸ SII produces 1.5 billion doses a year of vaccines, including those for Covid-19.⁷⁹ In 2012, the company acquired Bilthoven Biologicals from the Netherlands government,⁸⁰ leading SII towards global expansion. SII has also partnered with Oxford/AstraZeneca to manufacture its Covid-19 vaccine candidate,⁸¹ as well as with Russia's Gamaleya Research Institute of Epidemiology and Microbiology to produce the Sputnik vaccine.⁸² Bharat Biotech is another India-based biotech company that produced the first local Covid-19 vaccine, Covaxin,⁸³ as well as an intranasal Covid-19 vaccine.⁸⁴

Japan has recently invested heavily in vaccine production⁸⁵ to improve its domestic capabilities.⁸⁶ In June 2021, the Japanese government pushed for the creation of new biopharmaceutical facilities that could also double as

vaccine manufacturing centers in emergencies.⁸⁷ The government will also support formulation facilities to create equipment necessary for vaccine production.⁸⁸ In March 2022, a new governmental body known as the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) was created to aid in vaccine research and development as well as the export of vaccines abroad.⁸⁹ SCARDA is intended to function like BARDA, which, as noted, played an integral role in OWS in the United States.

During the pandemic, China became the world's largest supplier of Covid-19 vaccines.⁹⁰ It sold close to two billion vaccine doses to over 100 countries.⁹¹ About half of the world's Covid-19 vaccine jabs were produced by the China National Pharmaceutical Group Corporation (Sinopharm) and SinoVac.⁹² China's Covid-19 vaccines were composed of inactivated virus compounds, though the country has recently begun to conduct trials on mRNA vaccines.⁹³

In recent years, China has built up its pharmaceutical capabilities in line with President Xi Jinping's "Heath Silk Road" goal to expand the country's role as a major player in global public health.⁹⁴ China has traditionally been known as the leading producer of pharmaceutical ingredients, with the pharmaceutical industry reaching around \$2 billion in investment in 2021;⁹⁵ its pharmaceutical market is second in size to that of the United States.⁹⁶

Russia's Sputnik V vaccine was produced early in the pandemic and it has received regulatory approval in fifty countries. In 2021 the Russian Direct Investment Fund (RDIF), the government-funded entity behind the Sputnik V vaccine, planned to produce 700 million doses of Sputnik V internationally, enough to vaccinate one out of ten people on Earth,⁹⁷ although they later struggled to deliver vaccine doses due to supply shortages.⁹⁸ Russia has partnered with the SII to produce 300 million doses of Sputnik V annually,⁹⁹ though supply chain disruptions hindered its initial rollout. Moreover, companies in India have been wary of working with RDIF after the United States and EU imposed sanctions on Russia for its invasion of Ukraine.¹⁰⁰

VACCINE DIPLOMACY

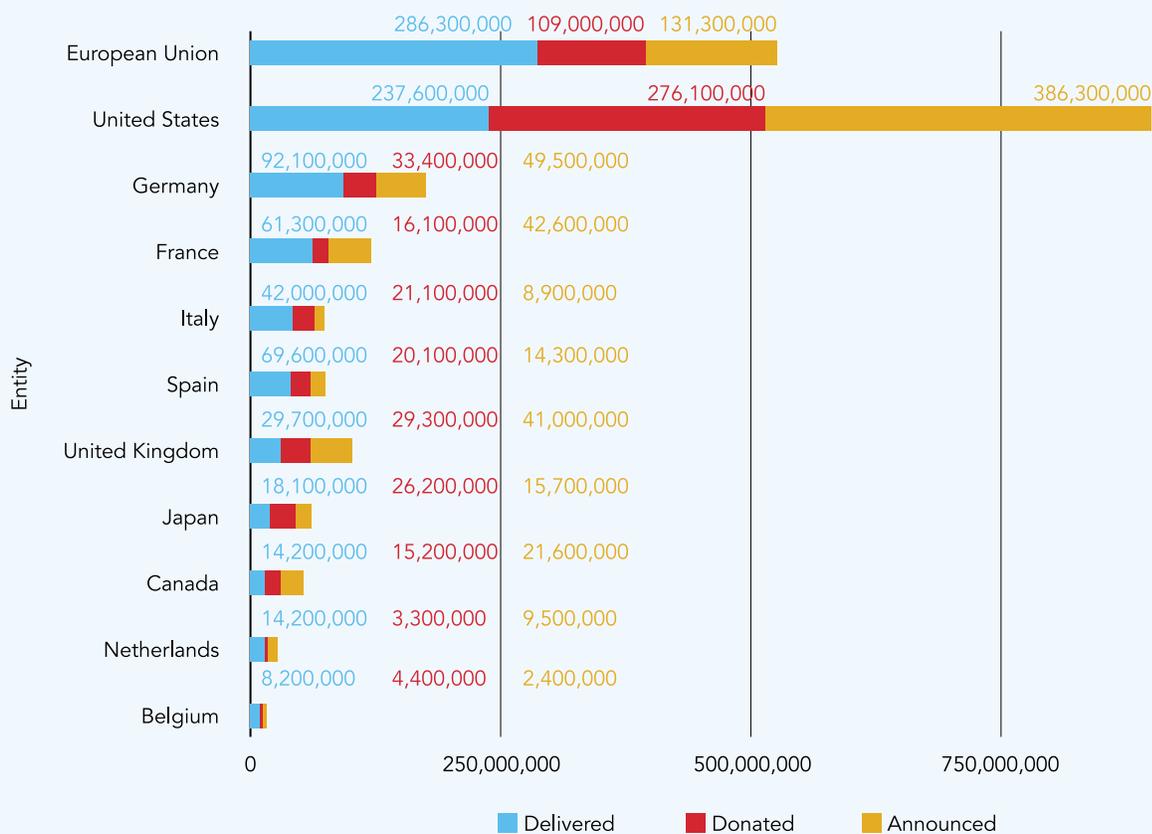
Global Diplomacy

Some countries have approached Covid-19 vaccine diplomacy on a multilateral basis, using the WHO-backed COVAX initiative to distribute vaccines. The United States has been the largest contributor to COVAX (Figure 4), shipping over 623 million Covid-19 vaccines globally as part of its pledge to donate 1.2 billion doses.¹⁰¹

In contrast, China’s vaccine diplomacy has operated bilaterally, outside the COVAX system. However, Chinese vaccines have received far fewer national regulatory approvals than the top three Western vaccines: Pfizer-Biotech, AstraZeneca, and Jansen & Jansen (Figure 3).

Figure 4. Covid-19 vaccine doses donated to COVAX

Top 11 Countries: COVID-19 Vaccine Doses Donated to COVAX
(Data from 3/23/22)



Source: COVAX, ACT-Accelerator Hub, March 23, 2022, OurWorldInData.org/coronavirus.¹⁰²

South Korean Vaccine Diplomacy

Even though former President Moon emphasized the need to provide equitable access to vaccines, it is one of the minor contributors to COVAX. In December, South Korea pledged \$15 million to help ensure equitable Covid-19 vaccine access to African countries, in cooperation with the African Union and COVAX.¹⁰³ The Ministry of Foreign Affairs pledged to donate 3.4 million Covid-19 vaccine doses to Africa in March 2022.¹⁰⁴

The KORUS Global Vaccine Partnership was first announced in May 2021 between President Biden and Moon. Building on this partnership, during a joint press conference with President Biden in May 2022, South Korean President Yoon Suk-yeol announced the formation of the Global Health Security coordinating office in Seoul.¹⁰⁵ However, progress on this front has been relatively slow to create action plans for vaccine development, manufacturing, and distribution.

Finally, the South Korean government's offer to provide Covid-19 aid, including vaccines, to North Korea remains on the table.¹⁰⁶ It seems that North Korea will continue to ignore these requests, as the country has been reported to have conducted a national campaign using vaccines from China, thus making it one of the last countries on Earth to have a national Covid-19 vaccination program.¹⁰⁷

CONCLUSION

Among the risks facing humanity, pandemics are a real existential threat to prosperity and well-being. Covid-19 has killed 6.9 million people according to official reports as of May 2022 and likely many more, up to 17.2 million in total, according to estimates by the Institute for Health Metrics Evaluation at the University of Washington—in a two and one-half year period alone.¹⁰⁸ Furthermore, the recent frequency of global disease outbreaks is alarming, having occurred in 2002 with the original Severe Acute Respiratory Syndrome (SARS), in 2009 with H1N1, in 2015 with Middle Eastern Respiratory Syndrome (MERS) and in 2019 with Covid-19. There is great urgency for pandemic preparedness.

However, the Covid-19 pandemic revealed “a massive global (institutional) failure at multiple levels,” according to The Lancet Commission's Covid-19 report recently released in September.¹⁰⁹ The report enumerated 10 failures, including multiple shortcomings not only within the WHO itself, but also more broadly in the “lack of a multilateral

and coordinated approach by governments” to manage IP rights, technology transfer, international financing and vaccine access and production in LMICs.¹¹⁰ Korea's global hub initiatives are part of the solution to such deficiencies. On one track, Korea will ramp up its national vaccine capacity and expand its CDMO and CMO production. On the other track, its global training programs will decentralize vaccine development, production, and distribution in LMICs. The combination of both tracks is a big step towards improving global health preparedness for future pandemics. This strategy is akin to efforts needed to build more balanced, resilient global trade supply chains.

Korea's holistic KOR-WHO and KOR-ADB training hubs have the potential to decentralize educational expertise so that LMIC hubs and spokes could more rapidly identify locally emerging pathogens and also produce new vaccine formulations in a timelier way. This would improve global health policy by better meeting demands for equitable access to vaccines in LMICs. The reality is that pathogens are less likely to cross borders if they are controlled at the source, and less likely to spread from outside in an immunized population. Equitable vaccine access in LMIC locales also means effective public health campaigns to ensure preventative vaccination and health educational campaigns. In the context of the scheme sketched above, local complete vaccine hubs would have all three pillars: R&D, MPT, and D&M capabilities. This will require a steadier commitment and funding from advanced country governments as well as from the WHO and other multilateral organizations, even as the Covid-19 pandemic ebbs.

A major factor that undermined COVAX's distribution efforts early in the pandemic was the difficulty LMICs and even South Korea had in accessing safe and effective vaccines approved by developed country regulators. Global demand outpaced supply, and vaccines were allocated to those who had the financial resources and the foresight to place early bids. This reflects the phenomenon of vaccine nationalism and inequity in global distribution. Yet, WTO Director General Ngozi Okonjo-Iweala noted early in 2021, “because every national government has a first-order duty to protect its own citizens, it is no surprise that some 35 countries have already concluded bilateral deals with pharmaceutical manufacturers for COVID-19 vaccines.”¹¹¹ It will be difficult for multilateral initiatives to overcome political realities at the national level, especially in the absence of a well-funded and highly responsive global scientific emergency center.

While the existing multilateral organizations and facilities, namely COVAX, eventually played a decisive role (once supply outpaced demand in developed countries) in distributing Covid-19 vaccines to LMICs, they have had negligible effects on decentralizing the global production of vaccines. For that, the WHO vaccine training hub offers promise in disseminating know-how on vaccine development, manufacturing, and distribution processes to LMICs. South Korea is stepping up to this task, as it is rapidly developing the multi-phased capabilities required for the decentralization of vaccine hubs: R&D, MPT, and D&M (Figure 1).

South Korea's global vaccine access strategy does not depend on the WTO TRIPS patent waiver scheme, which has come very late in the pandemic. And even the WTO recognized an opposing view that there is "no evidence that intellectual property did indeed constitute a barrier to accessing COVID-19 vaccines."¹¹² Moreover, patent waivers would need to avoid the unintended consequence of undermining incentives for pharmaceutical and biotech firms to take on risks to develop new therapeutics and vaccines for future global disease outbreaks.¹¹³

South Korea has an advantage over other aspiring countries by being a close partner with the IVI. Headquartered on the campus of Seoul National University, IVI has more than three decades of experience in developing vaccines and running trials within its LMIC member countries. Although South Korea's partnership with the WHO on the global training hub for biomanufacturing is a sound first step towards global institutional capacity building, it will not likely

increase manufacturing capacity to any significant degree in LMICs in the near term. This requires long-term investment in capacity building in terms of time, education, and funding needs.

The expansion of global vaccine hubs, as well as strengthening WHO hub curricula to include long-term follow-up and advising, could play a key role in meeting future demand for vaccines. Yet to increase overall supply capacity in the near term, the world will need to rely on those countries that have already established vaccine production capacity. Augmenting the vaccine sovereignty of nations, perhaps counterintuitively, will enhance vaccine equity—as long as these countries act as responsible stakeholders in the network of global public health institutions. We can count South Korea as one such country.

President Yoon designated the vaccine industry as strategic. South Korea has a laudable track record in developing world-class strategic industries. The semiconductor industry is a close analogy to South Korea's potential role in the global vaccine industry. South Korea is a dominant global leader in chip manufacturing, while it is also linked into the global supply chain for design as well as for production equipment. South Korea's vaccine industry will likely develop along similar lines, combining its manufacturing prowess with innovative technology of biopharmaceutical firms from other advanced countries. The sooner South Korea develops its national vaccine capacity and disseminates such knowledge to LMICs the better, before another global disease outbreak occurs.

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