POLICY BRIEF

Japan's Global Health Strategy in the Post-Covid-19 Era

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Essential Medical Products during a Public Health Emergency of International Concern (PHEIC): Public Funding for R&D and Internationally Equitable Access to Its Results

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"International Fairness" in the Response to COVID-19

On January 30, 2020, World Health Organization (WHO) Director-General Tedros Adhanom Ghebreyesus declared the novel coronavirus disease (COVID-19) to be a public health emergency of international concern (PHEIC), as stipulated by the International Health Regulations. Since that time, WHO member nations have been cooperating on the response to the COVID-19 pandemic.

However, issues regarding "international fairness" have emerged when it comes to access to essential medical products. It has therefore become necessary to consider such questions as why the global disparity in access has occurred, whether international efforts to close those gaps have been successful, and what is needed for a fundamental solution to the problem. These matters are also vital from the standpoint of "Leaving no one behind," a basic principle of the United Nations (UN) Sustainable Development Goals (SDGs).

Essential Medical Products in the Battle against COVID-19

Medical products can be classified into three areas: diagnostics, therapeutics, and vaccines. In the first area, diagnostics, attention was paid initially to the shortage of rapid antigen testing and PCR (polymerase chain reaction) test kits, and the lack of systems for administering the testing.

In the second area, therapeutics, there were moves to divert existing medicines developed for other diseases and use them for seriously ill COVID patients. After that, the use of so-called antibody cocktail therapy, combining different virus-neutralizing antibodies, became widespread as a medical product for use at the early, non-severe stage of infection. At the same time, efforts are in full swing to develop new oral drugs and bring them to practical application.

In the third area, vaccines, these are developed through three phases, basic research, nonclinical testing, and clinical trials. Normally, it takes several years before they reach final approval for use. This time, however, large sums of public funds have been invested in research and development (R&D) efforts by universities, research institutes, and corporations, thanks to which they have reached the stage of practical usage at a faster pace than usual. After COVID-19 vaccines became available in late 2020, expectations rose for the role of pharmaceutical interventions. The reason is that while the vaccines do not completely prevent infection, they are seen as being able to reduce the risk of severe illness in case of infection.

One unique feature of COVID-19 vaccine development is the diverse types of vaccines that have been worked on, including inactivated vaccines, recombinant protein vaccines, peptide vaccines, messenger RNA (mRNA) vaccines, DNA vaccines, and viral vector vaccines. As of December 2021, WHO had authorized nine vaccines for emergency use. These consisted of five vaccines manufactured in high-income nations by the AstraZeneca/Oxford University group, the Pfizer/BioNTech group, Janssen (a pharmaceutical company that is a subsidiary of Johnson & Johnson), Moderna, and Novavax, as well as two Indian vaccines developed by the Serum Institute of India and Bharat Biotech, and two Chinese vaccines made by Sinopharm and Sinovac. In addition, companies in Russia, Cuba, and China are conducting clinical trials. This vaccine R&D is being undertaken by a few high-income nations and newly emerging nations that have active pharmaceutical industries.

COVAX Facility

In April 2020, the Access to COVID-19 Tools (ACT) Accelerator was launched to deliver essential medical products so that “no one is left behind” in the battle against COVID-19. The objective is to promote global collaboration in four areas: vaccines, therapeutics, diagnostics, and health system strengthening. Led by the UN and other UN specialized agencies, including UNICEF, the WHO and the World Bank, it is a global scheme for collaboration across the public and private sectors and academia. The roles of developing, manufacturing, procuring, and distributing vaccines are assigned to Gavi, the Vaccine Alliance, and to the Coalition for Epidemic Preparedness Innovations (CEPI); therapeutics is handled by the Wellcome Trust

and the Unitaid; and diagnostics is covered by the Foundation for Innovative New Diagnostics (FIND) and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

The COVAX Facility is a new initiative being undertaken in the area of vaccines. Countries are working together with the goal of achieving vaccination rates of at least 40 percent in all countries by the end of 2021 and 70 percent by mid-2022. In reality, however, there is a large disparity in vaccination rates among nations based on their levels of economic development.

High-income nations and upper-middle-income nations are able to reserve and purchase vaccines for 20 percent of their populations with their own funds. Specifically, 58 individual nations and team Europe (29 nations), as well as eight regions that are not UN members, are official participants. Russia, on the other hand, is not yet taking part.

A total of 92 lower-middle-income and low-income countries and economies are able to obtain vaccines for 30 percent of their populations at no cost through Gavi's COVAX Advance Market Commitment (AMC). The AMC is funded mainly through contributions from wealthy nations, international foundations, and so on. In April 2021, One World Protected was launched, and in June 2021, Japan co-hosted the COVAX AMC Summit to raise additional funds for the vaccines. As a result, funding was secured well in excess of the amount needed to reach US$8.3 billion, the amount seen as necessary to provide 1.8 billion doses of vaccines for developing economies (approximately 30 percent of the populations of 92 lower-middle-income and low-income nations).

Vaccine Nationalism

In some cases, high-income nations attempting to acquire enough vaccines for their own citizens have been accused of "vaccine nationalism." While it was difficult to predict which pharmaceutical company was going to be able to supply safe and effective vaccines, Canada, as one example, faced international criticism after it negotiated with multiple companies to purchase more vaccines than needed for its own people. The United States and European Union faced similar complaints.

Then, once the Omicron variant began to emerge in November 2021 and the need for a booster shot was indicated, countries began administering third shots, which had not been sufficiently anticipated. It is highly likely that this situation will result in low-income nations having their access to vaccines further restricted.

Meanwhile, since low-income nations lack adequate funds, they are unable to negotiate directly with pharmaceutical companies, making it difficult for them to secure vaccines on their own. All they can do is wait for distribution from the COVAX Facility.

Due to vaccine nationalism among high-income nations, however, pharmaceutical companies tend to prefer two-party negotiations with wealthy nations, given their ability to pay. This could potentially result in delays in supplying vaccines to the COVAX Facility. When high-income nations engage in two-party negotiations with pharmaceutical companies, they should keep in mind the potential ripple effects it may have on the COVAX Facility.

Ironically, the failure to promote vaccinations in low-income nations will hasten the emergence of new strains like the Omicron variant, which could eventually spread throughout the world, including in high-income nations.

Vaccine Tourism

Disparities have arisen even among those living in the same low-income nations. The wealthy people living in such countries have resorted to "vaccine tourism," traveling to places like the United States, UAE (e.g., Abu Dhabi), Maldives, Indonesia (Bali), Russia, and Serbia to get vaccinated. By offering vaccinations in airports or other convenient places, such destinations have attracted tourists from overseas as a way of boosting their own economic recoveries. Note that this no longer applies to the United States, which has since made proof of vaccination a requirement for entry into the country.

The current reality is that people living in high-income nations and wealthy people living in low-income nations have enjoyed preferential access to vaccines, which are still in short supply. There are concerns that in low-income nations, many people—including healthcare personnel —are being left behind when it comes to access to medical products.

Vaccine Diplomacy

Vaccine diplomacy is being carried out, targeting developing nations. Whereas the COVAX Facility is a multilateral cooperation framework, vaccine diplomacy is conducted bilaterally. Countries like the United States and Canada, for example, which bought up more vaccines than necessary for their own use, in some cases have supplied them at no cost to low-income nations.

There are also reports of emerging nations like Russia and China engaging in a form of vaccine diplomacy by selling to lower-middle-income nations or giving away to low-income nations the vaccines developed in their own national laboratories or state-owned companies. Russia, which as noted above does not participate in the COVAX Facility, uses its domestically produced vaccines for its own needs and also supplies them to "friendly nations." It should be noted that as of December 2021, Russian-made vaccines have not been approved by the WHO for emergency use due to a lack of data.

China is a COVAX Facility participant but is also enthusiastic about two-party vaccine diplomacy, and there have been reports that it has discussed conditionality in the supply of its vaccines to "friendly nations." For some time, China has been pursuing the Belt and Road Initiative as a framework for international cooperation, and in that context, it proposed a "Health Silk Road" initiative in 2015 to promote more systematic provision of support to partner nations in the healthcare field.

When the COVID-19 pandemic struck, China began providing its domestically produced vaccines to the Belt and Road Initiative partner nations. It also conducted vaccine diplomacy with countries outside the initiative. Given the supply shortages, the fact that Chinese vaccines

approved by the WHO for emergency use have contributed to raising the vaccination rates in lower-middle-income and low-income nations is deserving of praise. On the other hand, according to Taipei authorities, Beijing is said to have asked Paraguay to sever its diplomatic relations with Taiwan as a condition of receiving vaccines. The Beijing administration denies this, and the truth of the matter is unclear.

In any case, the appropriateness of using vaccines as a diplomatic card is a matter that will need to be discussed further. In the future, it may be necessary for the WHO to draw up ethical guidelines that would be agreed upon by WHO members.

Toward Internationally Equitable Access to Medical Products

Access to essential medical products including vaccines is important in the battle against COVID-19, but in an oligopoly market, high prices and supply shortages have become issues. The supply shortage of vaccines is particularly remarkable. In this regard, I would like to offer a few notable points.

The first is that many of the international infectious disease measures up to now have involved high-income nations providing assistance to developing economies. In the case of COVID-19, infections have been spreading worldwide on many fronts at the same time, without regard to a nation's or individual's income level. As a result, from a short-term perspective, high-income nations appear to have fallen into vaccine nationalism. Yet even if wealthy nations boast high vaccination rates, if new variants emerge one after another as the virus surges through under-vaccinated low-income nations, the effectiveness of the vaccines could eventually wane, causing problems also for high-income nations. In other words, from a medium- to long-term perspective, it is a case of "No one is safe until everyone is safe." What is needed, then, is to formulate international public policies that take into account both short-term and medium- to long-term perspectives at the same time.

Second, the establishment of the ACT-Accelerator and launch of the COVAX Facility just three months after the declaration of a PHEIC has won high praise. Vaccine distribution by the AMC to lower-middle-income and low-income nations, however, seemed to be largely dependent on the procurement of vaccines from India, which manufactures viral vector vaccines for which temperature control is relatively easy. In fact, however, this scenario collapsed due to the imposition of lockdowns in India as the virus spread there as well as for other reasons, such as the difficulty of obtaining raw materials in light of export restrictions in leading industrial nations. Chinese vaccines, meanwhile, can be seen as making up for much of this gap. It will be important for developing economies that vaccines with easy cold chain management requirements be procured from multiple sources in order to diversify risk.

Third, given the international protections on intellectual property (IP) obtained through R&D, when pharmaceutical companies seek to increase the supply of vaccines in response to rising global demand, one conceivable approach is to voluntarily license the rights to companies in other countries. In reality, however, there has been little progress on the voluntary granting of licenses. Under such circumstances, compulsory licensing has been

permitted in the past, particularly in the case of HIV/AIDS, but the objections of countries where pharmaceutical companies are located, and other obstacles have made it difficult to implement in practice. A framework is needed that will encourage licensing by pharmaceutical companies and expand supply to meet demand.

Fourth, the COVID-19 Technology Access Pool (C-TAP) was launched by the WHO and partners as a scheme for the global sharing of COVID-19-related IP. While it seems ideal, the reality once again is that pharmaceutical companies have been reluctant to participate in the scheme. When large amounts of public funds are devoted to an initiative like this, it may be best for governments and international organizations to negotiate such matters in advance.

Fifth, 62 member nations of the World Trade Organization (WTO) jointly submitted a proposal to the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Council, which administers the WTO Agreement on TRIPS, for a temporary waiver of COVID-19-related IP protection obligations. More than 100 member nations consented to the proposal. While many high-income nations objected, the United States and France are in favor now. For organizations conducting R&D, IP protection is an important means for recovery of investment. It is also an indispensable premise when making public the results of the R&D. At the same time, however, there is the argument that, since the R&D of each organization is supported by public funds from national governments and international organizations, or by research grants from foundations and others, and the medical products are being purchased, the results can be seen as global public goods. Achieving the necessary agreement among WTO member nations, however, is not easy.

And finally, sixth, while this is not limited to COVID-19 use, the WHO is proceeding with a plan to establish bases for the transfer of mRNA technology to middle-income nations. If this plan goes forward with the cooperation of pharmaceutical companies, it should give real impetus to the development of medical care technologies for diagnostics, therapeutics, and vaccinations for neglected tropical and other diseases.

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