The 10th Nikkei FT Communicable Diseases Conference

Tokyo Communicable Diseases Statement 2023

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0. Introduction—Marking the 10th Conference

The Nikkei FT Communicable Diseases Conference has marked its 10th year. Since its inception in 2014, the Conference has brought together key figures from a variety of sectors and countries to make recommendations to prepare for the unending fight between humans and communicable diseases and to propose public-private partnership (P3) projects to solve various problems related to communicable diseases every year. In addition, this year's conference featured the 10th anniversary lecture.

It has been four years since the outbreak of the novel coronavirus (COVID-19) pandemic. As the winter approaches, we cannot rule out the possibility of an outbreak of the ninth wave. However, judging that the disease is shifting from a pandemic to an endemic due to weakening of the virus through mutation and the deployment of vaccines and therapeutics, the government downgraded the classification level of COVID-19 from "Class 2 equivalent" to "Class 5" under the Infectious Diseases Control Law, effective May 8, 2023. This has forced a major shift in countermeasures for the communicable disease. On August 24, 2023, the government abolished the Subcommittee on Novel Coronavirus Disease Control and the Advisory Committee on the Basic Action Policy, which had served as the core organizations for countermeasures by the government and transferred the core role to the Cabinet Agency for Infectious Disease Crisis Management, which was launched on September 1 inside the Cabinet Office.

In the Conference, we reviewed the COVID-19 countermeasures taken to date and discussed key issues for ending the COVID-19 pandemic and preparing for the next pandemic. We also discussed the progress and development of the P3 projects launched during the ten meetings in the past.

For this meeting, we leveraged remote conferencing technologies, which have rapidly spread and developed amid the pandemic, and brought key figures from industry, academia, government bodies, and the public and private sectors from around the world to Chiyoda-ku, Tokyo. We extended the meeting period by one day, holding it from October 16 to 18, 2023. In addition to inviting participants to the venue, we widely live streamed the 10th conference on the Internet.

<COVID-19 and matters related to preparing for the next pandemic>

The key issues discussed at the Conference included: human resource development for communicable disease crisis management; building a drug discovery ecosystem to rapidly develop a vaccine for a new pandemic (100DM) and develop therapeutics for communicable diseases; ensuring incentives and economic predictability to sustain innovation to combat communicable diseases; proper risk communication, building a crisis-resistant civil society; and the command post function to be performed by the Cabinet Agency for Infectious Disease Crisis Management.

Please read the "Tokyo Communicable Disease Statement 2021" and "Tokyo Communicable Statement 2022" as well as the "Yokohama Communicable Disease Statement 2020" for more information on countermeasures for COVID-19.

<Other P3 related to communicable diseases>

We also discussed the progress and further development of P3 for malaria, TB, NTDs (Neglected

Tropical Diseases), and AIDS, which we have been repeatedly discussing and making recommendations on each year since 2014. Through open discussions involving a wide range of stakeholders from industry, academia, government bodies, and the public and private sectors, participants in the Communicable Diseases Conference once again confirmed the need and effectiveness of further promoting initiatives to address communicable diseases that threaten people's health and economic activities through P3.

We have also been continuing to discuss infections caused by bacteria with antimicrobial resistance (AMR), a topic that has been continuously addressed at the G7 major economies (G7) summits, including this year's G7 Hiroshima Summit, and specific proposals were made for pull incentives and economic predictability to support new drug development. The Conference was attended by multi-stakeholders from comprehensive sectors, including industry, academia, government bodies, and the public and private sectors and served as an opportunity to suggest P3 projects that involve specific actions, allowing us this year as well to steadily continue with the progress we have made.

(Releasing Tokyo Communicable Disease Statement 2023)

At the conclusion of the Conference, the participants agreed on the "Tokyo Communicable Disease Statement 2023," which includes proposals for training human resources for crisis management to combat communicable diseases, including pandemics. Going forward, in addition to releasing the results of the Conference online and through media, we will report them at relevant government meetings and in other occasions. Furthermore, we will release this statement not only to Japan, but also to the world at large, including Asia and Africa, and to international organizations. Japan is expected to further strengthen its commitment to efforts to control communicable diseases in the world, leveraging the international mutual understanding achieved through the release.

Please refer to the previous statements below for details of discussions at previous Nikkei FT Communicable Diseases Conferences.

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*Information including position titles in the statements reflect the latest version at that time

1. Learning from Pandemics to Build a Society Resilient to Communicable Diseases

1-1 Developing Human Resources and Establishing a Network to Combat Communicable Diseases

[Background—Why human resources skilled in communicable disease crisis management are needed]

It has been revealed that Japan failed to find and utilize sufficient human resources skilled in communicable disease crisis management during the COVID-19 pandemic. For example, one of the reasons why Japan frequently suffered strain in medical care during the pandemic despite the fact that the WHO regards the country's medical service quality as the best in the world is because although there are many excellent clinicians and basic medical researchers in Japan, the number of physicians capable of handling systemic diseases such as communicable diseases was limited. Furthermore, there were few human resources capable of crisis management or directly contributing to policy recommendations for the government.

The reason why our country failed to find and utilize sufficient human resources to address the communicable disease crisis is because even though various individual organizations have been implementing human resource development initiatives in Japan, there have not been sufficient cross-sectional and proactive initiatives to expand the base of human resources.

First of all, there is no single correct measure to combat communicable diseases, which is like solving complex equations based on the circumstances that change from day to day. Solving this equation requires mobilizing the knowledge and experience of people in various specialties, including not only medicine but also natural sciences, social sciences and humanities, as well as tacit knowledge in the frontline setting of each sector.

Our society has entered the era of VUCA (variability, uncertainty, complexity, and ambiguity). Natural disasters, pandemics, and other unpredictable events are occurring one after another, and technological innovation is accelerating. The risk of communicable disease crises may increase, but will not decrease, due to globalization and other factors. Therefore, human resources are needed who are not bound by existing thought patterns, but capable of proposing and implementing measures for communicable disease control by utilizing the latest scientific technologies, including digital technologies, while leveraging the perspectives of youth, etc.

[Issue—the reason for human resource shortages in measures for communicable disease control and crisis response]

Possible factors of human resource shortages in measures for communicable disease control and crisis response include the following:

(1) Failure to communicate the rewarding aspect and importance to society and the public

Planning and implementing countermeasures based on analysis of infection risks are extremely important not only during pandemics of communicable diseases or in geographical areas with pandemics, but are also essential for preventing spread of infection and maintaining the safety and security of society in general,

even when there is no pandemic or in areas not suffering pandemics. Therefore, careers in communicable disease control and crisis response are likely to be rewarding in a tangible way since they provide opportunities to contribute to society. However, this aspect is not being communicated to the public, including youth.

(2) Concerns about income and career development

Youth trying to pursue a career in communicable disease control or public health are likely to face obstacles to enjoying stable income and career development. Non-governmental organizations (NGOs) and non-profit organizations (NPOs) that work to control communicable diseases in developing countries and elsewhere may be viable options, but the income from such organizations is unstable and the career prospects are less certain than those for doctors working in hospitals or researchers at universities and other institutions. Meanwhile, it can be overwhelming to join international organizations such as the WHO (World Health Organization) and the UNICEF (United Nations Children's Fund).

(3) An inadequate system for developing human resources with a cross-sectional and broad perspective

Communicable disease control requires considering the broad impact of communicable diseases on society, including the economy, diplomacy, and people's lives, based on the knowledge of medicine, and therefore human resources with cross-sectional perspectives are required. In Japan, however, we have not always trained such human resources.

For example, medical schools have focused on individual clinical subjects and specialties, but since they have not emphasized public health education, students have had little incentive to become interested.

[Actions required]

<What is the profile of human resources skilled in communicable disease crisis management?>

First, it is essential to develop leaders through engaging in measures for communicable disease control in Japan and overseas. At the same time, leadership with a public health perspective alone would not be sufficient for implementing measures for communicable disease control. There is an urgent need for training basic researchers so that in the event of an outbreak of an unknown communicable disease, therapeutics and vaccines can be developed as soon as possible.

In order to respond effectively to communicable disease crises, it is important for all healthcare professionals, other professionals, and the general public to act proactively, with an overall social perspective and followership. Laying foundation for this requires each individual to have knowledge and insight of communicable diseases and pandemics, and to be able to utilize them in their own specialized areas, in other words, to broaden the base of human resources for communicable disease control and crisis response.

The human resources required for controlling communicable disease crises can be classified into the following three categories:

(1) Crisis-resistant leaders

(1) Human resources capable of analyzing information from a public health perspective and making recommendations to the government on what measures are required

(2) Human resources capable of coordinating and managing a variety of specialists

(3) Human resources capable of implementing the most appropriate measures for communicable disease control as needed by utilizing the capabilities of domestic industry, government, academia, and the public, while collaborating and coordinating with international organizations and people and organizations in other countries

(2) Basic researchers

Human resources that engage in basic research that leads to development of new therapeutics, vaccines, and diagnostics, as in the "100-days mission." Japan is weak in the foundation for developing such human resources.

(3) Human resources that address communicable disease crises in frontline settings

(1) Human resources that address communicable diseases in frontline settings, information analysis and countermeasures in and outside Japan. They are the starting point for all measures for communicable disease control, and are candidates for leadership roles for category (1).

(2) All healthcare professionals (doctors, nurses, etc.). In the COVID-19 pandemic, physicians often did not know how to perform PCR tests or how to wear PPE (personal protective equipment). In order to avoid recurrence of strained medical care during the next pandemic, it is essential that all healthcare professionals have basic knowledge and skills relating to medical response for communicable diseases, even if it is not their specialty, so that they can practice measures for communicable disease control in the event of a crisis.

(3) Experts in information science, engineering, agriculture, economics, law, political science, health communication, sociology, and other related fields. They share experiences, verified results, and findings from various fields related to this pandemic, and ensure planning and implementing more effective measures to control communicable diseases from various perspectives, such as utilization of digital technologies, effective ventilation, One Health, balance between socioeconomic activities and infection control, and co-creative communication with the public, in the event of the next pandemic.

It is also important to visualize where and what kind of human resources are available so various specialists can participate in policy recommendations and execution in the event of a pandemic or crisis and register them in a roster-like system to provide opportunities for exchanging information relating to measures for communicable disease control.

(4) The public's cooperation is essential for taking countermeasures during a pandemic. It is necessary to educate and enlighten the general public in advance so that they will gain basic knowledge of communicable diseases and countermeasures, and can make decisions and cooperate in infection control in

the event of crisis.

<Proposal of human resource development platform>

Traditionally in Japan, human resource development in communicable disease crisis response has been implemented by individual organizations, but going forward, a cross-sectional human resource development platform will be needed that transcends organizational boundaries.

(1) Basic philosophy for a human resource development platform for responding to communicable disease crises

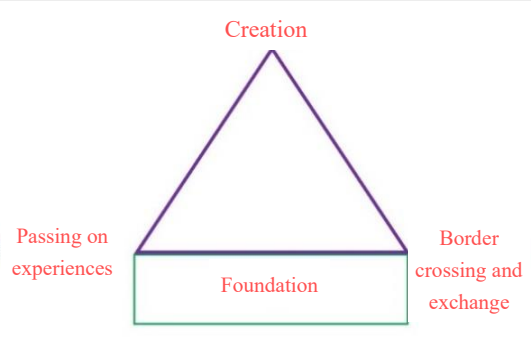
First, this platform is expected to enable us to pass on insight and experience related to past measures for communicable disease control, including the COVID-19 pandemic, to the next generation so we can prepare for the next pandemic.

However, it is anticipated that the next pandemic will present problems that we won't be able to solve using the norm of past countermeasures. It is quite possible that new technologies, including digital technologies, may be effective in solving such problems. Therefore, it is important to integrate across generational and professional boundaries.

It is hoped that this will help create flexible ideas that are not bound by stereotypes and experiences and more effective solutions.

The target for human resource development implemented through this platform is not limited to Japanese nationals, but it also includes international students coming to Japan and non-Japanese people studying in developing countries through technical cooperation of the Japanese government. The goal is to promote this platform worldwide as a human resource development platform originating from Japan and to establish an open network to cooperate with other countries.

1. Verify findings and experiences, including from this pandemic, and pass them on to the next generation <Passing on experiences>.
2. Integrate across generations and professional boundaries <Border crossing and exchange>
3. Generate new ideas without being bound to stereotypes or experiences<Create>
4. Allow the next generation to be optimistic, including about career prospects and income as well as to feel rewarded
5. The target is not limited to Japanese nationals, but it also includes non-Japanese students coming to Japan and non-Japanese people studying in developing countries through technical cooperation of the Japanese government



(2) Details of the human resource development platform for responding to communicable disease crises

For the content of the human resource development program, items 1 and 2 below are expected, and item 3 for financial resources. However, the working group as described in item 4 will carefully examine them and industry, academia, government bodies, and the public will develop concrete proposals.

1. Early exposure

(1) <Onsite experience> Learn to engage in onsite activities for communicable disease control in and outside Japan.

(2) <Policy advocacy> Enable youth to participate in government advisory organizations and the decision-making process.

(3) <School education> Incorporate curricula on communicable diseases suitable for each learning stage from elementary school to university. Incorporate infectious disease control in curricula at medical and nursing schools. Incorporate programs for students at non-medical schools to learn about pandemics.

Under these curricula, the schools should not only teach about what is known, but also introduce programs that allow students to learn independently and actively about problems that are not easy to solve, such as what is currently unknown and dilemmas that arise when dealing with communicable diseases.

2. Developing promising career paths

(1) The government will clarify career paths, including income, for human resources skilled in communicable disease crisis management. They will also introduce the personal histories of leaders in communicable disease crisis response to increase youth's interest in such career paths.

(2) Introduce domestic and international NGOs and other organizations where young people can build their careers.

(3) Create a "revolving door" mechanism among companies, local governments, other entities and first responders for communicable disease control.

(4) Companies should further promote the diversification of work styles, such as by lifting the ban on side jobs and implementing four-day work weeks, and help employees engage in measures for communicable disease control and crisis response, solving social issues, etc., while ensuring income and employment stability. It will help strengthen a company's human capital for its employees to have cross-boundary experiences and work with people in various positions to solve issues. This is likely to generate seeds of new businesses, in turn benefiting the company, and help our country in general to realize "Society 5.0."

3. Financial resources

(1) The government is expected to fund these initiatives. In addition, consider a system like the "GX Economy Transition Bonds" that enables refunding to the treasury in the future.

(2) Solicit funds from domestic and foreign companies, foundations, and other private sources.

4. Working groups to develop concrete proposals

Establish a working group (WG) as soon as possible in cooperation with the government to develop concrete proposals for a framework and specific initiatives, including financial resources and an operational

structure for the platform. The WG will include not only participants from industry, academia, government bodies, and the public of the Nikkei FT Communicable Diseases Conference, but also from the Cabinet Agency for Infectious Disease Crisis Management, the Ministry of Health, Labour and Welfare, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Foreign Affairs, the Ministry of Economy, Trade and Industry, and other relevant government agencies.

The roles of this platform could include, for example, developing educational programs such as intensive training for healthcare professionals, designating an observance period to promote practicing and knowledge of communicable disease control among the general public, and cross-disciplinary exchange study groups, as well as visualizing where human resources with certain skills are available and developing human resource development plans. Details will be discussed in the above-mentioned WG.

(3) Future impacts from establishing the human resource development platform

By establishing such a human resource development platform, the following future impacts can be expected:

1. Establish a system to prepare for the next pandemic
2. Develop human resources capable of helping solve complex problems that have never been experienced before not only during communicable disease crises but also in normal times
3. Achieve health innovation including for social systems
4. Help foster a mature civil society
5. Help achieve UHC and “human security” in the international community

1-2 Expectations for the Command Post Function following the Establishment of the Cabinet Agency for Infectious Disease Crisis Management

[Background]

(Strengthening the functions of the Cabinet Agency for Infectious Disease Crisis Management)

In September 2023, the Cabinet Agency for Infectious Disease Crisis Management was established in the Cabinet Secretariat to serve as the command post for communicable disease crisis response. In FY2025 and later, the National Institute of Infectious Diseases (NIID) and the National Center for Global Medical Research (NCGM) will be merged to establish the National Institute for Health Risk Management (Japanese version of the CDC). It is very welcome that the Cabinet Agency and the National Institute are expected to utilize reflections on COVID-19 to quickly formulate effective infection control measures and play a central role in the event of the next communicable disease crisis.

A communicable disease pandemic is not just a disease, but a disaster that has a major social, economic, and educational impact on many aspects. In order to minimize the impact of the next communicable disease crisis on Japan’s shrinking population, it is essential to have a diverse range of human resources with diverse knowledge and experience capable of solving “complex equations.” Therefore, the Nikkei FT Communicable Diseases Conference recommends that the government address items (1) through (4) so that

the Cabinet Agency and the National Institute can perform better, while taking into account experiences from the COVID-19 pandemic.

COVID-19 was a once-in-a-century crisis, with widespread and serious social, economic, and livelihood impacts. In order to build a society that is resistant to communicable diseases, we must look back on the wide range of sectors involved in response to COVID-19, and conduct solid review to prepare for the next pandemic. Some domestic local governments are already conducting review work. Also in the UK, an extensive third-party review work (The Covid-19 Inquiry) is underway with regard to response to and impact of COVID-19. Japan can better prepare for the next communicable disease crisis by reflecting on past experiences and reviewing not only its healthcare delivery system and R&D, but also decision-making and risk communication by the government.

(1) Risk assessment of communicable diseases

[Issues]

Traditionally in Japan, pandemic countermeasures have been formulated based on the risk of highly pathogenic avian influenza virus (H5N1) infecting humans and causing a pandemic. And in formulating these countermeasures, the risk of communicable diseases has been assessed based primarily on their severity.

However, according to the Pandemic Influenza Severity Assessment (PISA) published by the WHO in 2017, not only (1) the severity of the disease, but also (2) its transmissibility and (3) its impact on healthcare and society in general should be considered. In response to such concepts, the “Characteristics of COVID-19 and Medium- to Long-Term Risks” submitted to the 110th Novel Coronavirus Infection Control Advisory Board Meeting in December 2022 emphasized that risk assessment for COVID-19 should focus on (1) transmissibility, (2) severity of the disease, and (3) medical and social impacts.

[Actions required]

The risk of a new pandemic should not be assessed based solely on the severity of the disease as before. Based on the recommendations of the WHO and the Advisory Board, the risk should be determined based on the comprehensive criteria of (1) transmissibility, (2) severity of the disease, and (3) medical and social impacts (Table 1).

Table 1: Proposed risk assessment scale for communicable diseases

Transmissibility
High
Medium
Low

Severity
High
Medium
Low

Medical and social impact
High
Medium
Low

(2) Establishing a network of experts for policy making and research

[Issues]

In making policy recommendations that contribute to infection control, it is important to collect supporting information and conduct surveys and research on the infection situation. For COVID-19, this process involved many difficulties. Specifically, (1) there was not sufficient data to identify the infection situation in the first place, (2) there was no support available for public health experts to collect data or network with experts in other disciplines such as engineering, IT, risk communication and social marketing, which limited use of personalistic connection to collect information as well as opportunities to involve such experts and (3) there was a shortage of public health experts to help local governments and other entities to develop infection countermeasures or local communities to execute them. In addition, the limited number of public health and other experts available were not able to make policies, though they were highly specialized.

Furthermore, (4) in the first place, there was a shortage of experts in communicable diseases, health, public health, epidemiology, mental health care, disaster medicine, and crisis management, and not an established system in place to collaborate with experts in various areas such as data analysis, engineering, information technology (IT), artificial intelligence (AI), economics, laws and regulations, and ethics, (5) the government was unable to fully utilize experts in risk communication and social marketing to clearly communicate its decisions on infection control to the public, and (6) in formulating policies for infection control, there were no human resources familiar with the situations of local governments, such as prefectures and government-designated cities, and no foundation was in place for ensuring smooth execution of infection control measures.

[Actions required]

The new National Institute for Health Risk Management will house several centers to promote human resource development and R&D. It is a welcome development that the institute will promote human resource development. In the event of a new communicable disease crisis, it is expected that the Cabinet Agency and the National Institute will take the lead in formulating infection control measures. However, as mentioned earlier, given that there was a shortage of diverse researchers capable of policy making, surveying and researching during the COVID-19 pandemic, it may be difficult to respond flexibly and quickly to a communicable disease crisis only with experts in the Cabinet Agency and the National Institute. Therefore, it is necessary to form partnerships with multiple organizations and centers in Japan and to establish a network of diverse experts.

The WHO maintains a panel of experts called the “IHR Expert Roster” to prepare for crises. In the event of an international public health crisis, the WHO systematically appoints experts from the panel as appropriate to a committee to discuss recommendations. Therefore, Japan is expected to organize in advance an open network of experts in communicable diseases, health, public health, epidemiology, mental health care, disaster medicine, crisis management, data analysis, engineering, information technology (IT),

artificial intelligence (AI), economics, laws and regulations, ethics, risk communication and regional public health. In addition, in order to smoothly implement infection control measures nationwide, the government should establish a network with prefectures and government-designated cities, while involving governors and mayors, to leverage the network for policy making.

When the National Institute takes the lead in promoting policy making and surveying and research for policy making, the government should ensure that the Cabinet Agency and the National Institute can fully utilize external resources (the aforementioned open network and network with local governments) to help promote more effective infection control. Such networks are expected to play a role of providing full support for the Cabinet Agency and the National Institute.

(3) Establishing a nationwide system for rapid R&D

[Issues]

R&D of diagnostics, therapeutics, and vaccines is a risky market for companies to enter because outbreaks of communicable diseases are difficult to predict and they may not occur at all. For COVID-19, public research funds to promote R&D of vaccines and therapeutics were limited and there was not an established system in place to conduct research and clinical trials in Japan while the country was dealing with the pandemic. This prevented industry, academia and government from working together to develop diagnostics, vaccines or therapeutics.

[Actions required]

The G7 Summit advocates the "100-day mission" to rapidly develop diagnostics, vaccines, and therapeutics in the event of an outbreak of a new communicable disease and deploy them within 100 days. In order to realize the 100-day mission, it is essential that the Cabinet Agency provide large-scale, long-term public R&D funding to academia and companies, not only in the event of crisis but also in normal times. It is difficult for companies to enter the R&D market for vaccines and therapeutics for communicable diseases because the demand for such products only increases during pandemics, among other reasons. Therefore, it is important for the Cabinet Agency to provide public R&D funding and institutionalize market incentives (pull incentives) for therapeutics and vaccines for communicable diseases.

In addition, human resources capable of carrying out R&D should be identified and registered in advance in order to utilize them for domestic and international efforts to control communicable diseases. Furthermore, it is necessary to promote creating an environment that enables collaborating with Asian and other countries to implement non-clinical and clinical trials in Japan in the event of an outbreak of a communicable disease and establishing a system for seamless execution from research and clinical trials to manufacturing by utilizing domestic contract research organizations (CROs) and contract drug development and manufacturing organizations (CDMOs).

(4) Developing diverse human resources capable of addressing infection crises (human resources for policy making and R&D)

[Issues]

For COVID-19, experts in communicable diseases, health, public health, epidemiology, mental health care, disaster medicine, crisis management and other areas gathered as volunteers to develop policies. However, there is only a limited number of experts in communicable diseases, health and public health in Japan to begin with, and the specialty areas of communicable disease and public health are not widely recognized among young physicians and lack predictability of career paths and financial security. In addition, there is no mechanism in place for experts in epidemiology, mental health care, disaster medicine, crisis management, data analysis, engineering, information technology (IT), artificial intelligence (AI), economics, laws and regulations, ethics, risk communications or other areas to acquire expertise in communicable diseases and public health in addition to their own expertise. In creating promising seeds for communicable disease control, long-term basic research, rather than pursuing short-term results, is important. However, current public research funds tend to be provided in pursuit of short-term results. Therefore, Japan falls far short of human resources for research, leaving the foundation of basic research weak.

[Actions required]

Physicians and other medical professionals should be informed of what makes communicable disease control and international collaboration rewarding. At the same time, the career paths for experts in infectious diseases, health, public health, etc. should be visualized. It is also necessary to drive human resources development by making sure such experts are appointed to positions where they can leverage their expertise on communicable diseases, health, public health, etc. in medical institutions, local governments, academia and other places, thereby ensuring their economic stability. It is also required to enable experts in epidemiology, mental health care, disaster medicine, crisis management, data analysis, engineering, information technology (IT), artificial intelligence (AI), economics, laws and regulations, ethics, risk communication and other areas to acquire expertise for infection control, in addition to their own specialties. Such a broad base of human resources should form an open network and closely collaborate with the Cabinet Agency and the National Institute, thereby helping to formulate measures for communicable disease control in the event of a communicable disease crisis. Public research funds should be provided to support long-term basic research projects, rather than in pursuit of short-term results, thereby helping to develop human resources capable of carrying out R&D by thinking outside the box.

The Nikkei FT Communicable Diseases Conference will establish a working group (WG) to build a platform for human resources to formulate infection control measures and promote R&D. It is necessary to make sure that these human resources will feel rewarded, enjoy stable income and career development and brush up their skills in normal times. The WG will consider specific measures, including who will promote human resource development initiatives as well as how and with what financial resources. In addition,

through the WG, a system should be established to connect experts engaged in infection control nationwide and hubs promoting human resource development, forming a virtual platform to produce human resources to take on roles in infection control in the future.

1-3 Realizing the 100DM in Japan—Importance of P3 Projects

[Background]

<Realizing the 100DM in Japan>

For COVID-19, Japan was unable to rapidly develop diagnostics, therapeutics or vaccines or roll them out globally. Japanese diagnostic and pharmaceutical companies intent to develop diagnostics, therapeutics and vaccines for communicable diseases, and Japanese academia has promising basic research seeds. However, in Japan, for COVID-19, due to lack of an established system to quickly conduct clinical trials or manufacturing bases for vaccines and other products, or experience in clinical trials and manufacturing of new types of vaccines such as mRNA vaccines, we missed opportunities to deploy diagnostics, therapeutics or vaccines quickly enough to serve not only domestic but also international needs. There were not sufficient human resources for rapidly developing and manufacturing vaccines and the collaborative relationship among industry, academia and government was weak. Moreover, the leadership from the government, which should have taken initiative in R&D, was not adequate.

In response to the COVID-19 pandemic, the world has gotten on the 100-day mission, or 100DM, to deploy diagnostics, vaccines, therapeutics, etc. within 100 days from the outbreak of a new pandemic. For COVID-19, diagnostics, vaccines, and therapeutics were developed at an unprecedented speed. However, it is estimated that if they had been developed and supplied to the world within 100 days, the death toll from COVID-19 would have been 98% lower. This prompted the proposal of the 100DM at the G7 summit in the UK in June 2021.

The 100DM is an ambitious goal to deploy medical countermeasures (MCM), by having rapid diagnostics (Dx) and safe and effective vaccines (Vx) approved, establishing treatment methods (Tx), etc. within 100 days from the declaration by the World Health Organization (WHO) of “public health emergency of international concern.” The 100DM is also aimed at guaranteeing access to MCM, including for low-income countries, and access and delivery (A&D) to ensure equitable supply worldwide.

If we can realize the 100DM and quickly develop and supply MCM from Japan to the world in the next communicable disease crisis, it will not only contribute to global public health and social economy, but also help enhance Japan’s presence. At this year’s Nikkei FT Communicable Disease Conference, stakeholders from industry, academia, and government in Japan shared the view that “the 100DM is not a pipe dream, but a feasible goal.” The group then identified the current issues to achieve the 100DM and discussed actions to take with the government, the research community, and companies, as described in items (1) through (4).

In order to achieve the 100DM in Japan, it is important to promote R&D of diagnostics, vaccines, and therapeutics against bacteria with antimicrobial resistance (AMR), TB, malaria, HIV, neglected transmitted diseases (NTD), and other unresolved communicable diseases in many countries in advance, and to build basic strength. It is also required to provide children and adults with various routine vaccinations such as for respiratory infections and antimicrobial-resistant pneumococcus, and ensure operating the manufacturing and supply infrastructure in the country so we can prepare to activate emergency response if necessary.

[Issues and actions required]

(1) Government (including the MHLW and regulatory authorities)

- ✓ In the next communicable disease crisis, the government should take the lead in the event of an emergency and ask academia and industry to conduct R&D of MCM, as well as provide a large enough research fund to conduct R&D, including large-scale clinical trials.

- ✓ The economic prospect of R&D of MCM is uncertain since outbreaks of communicable diseases are difficult to predict and outbreaks may not occur at all, among other reasons. The MHLW introduced a market incentive (pull incentive) on a trial basis through the Antimicrobial Securement Project to promote R&D of antimicrobial drugs in FY2023, and will institutionalize the pull incentive to encourage R&D of MCM by companies in advance.

- ✓ For COVID-19, specimens from infected patients were difficult to obtain and requests to transport them were often rejected. It also took time to address compliance with the Cartagena Act. In order to quickly implement R&D of MCM in the event of an emergency, it is necessary to establish a mechanism to collect specimens from infected individuals as soon as possible and deliver them to academia and companies working on MCM, and prepare measures to address the Cartagena Act so that living modified organisms can be immediately utilized for R&D and manufacturing purposes. Since there was a shortage of BSL3 laboratories, which are required for R&D of MCM, more of them need to be established.

- ✓ In the case of COVID-19, it was difficult to conduct clinical trials of therapeutics and vaccines in the midst of the pandemic. In order to verify the efficacy of therapeutic drugs and vaccines, it is necessary to collect healthy subjects (adults and children) quickly and on a large scale. Since this will be impossible in the middle of an emergency, a large-scale panel of healthy subjects (adults and children) and a network of medical institutions nationwide that will participate in clinical trials need to be established in advance. It would also be difficult to get consent for assignment to placebo groups in the middle of a pandemic, which would also involve ethical issues. Therefore, the Pharmaceuticals and Medical Devices Agency (PMDA) and pharmaceutical companies should prepare in advance to share placebo groups among multiple clinical trials of MCM and promote clinical trials in such a way.

- ✓ To prepare for emergency situations, companies need to ensure surge capacity by maintaining manufacturing bases for MCM, securing human resources and materials for manufacturing in advance, etc. It is also important to secure a base capable of producing a variety of vaccines. It is necessary to provide long-term support for companies to maintain and secure manufacturing bases, human resources and materials so they can maintain the surge capacity for communicable diseases involving poor economic outlook. In addition, since Japan is short of human resources capable of manufacturing and formulating biologics (biopharmaceuticals) such as mRNA vaccines and viral vector vaccines, human resource development needs to be promoted over the long term.

- ✓ During the COVID-19 pandemic in the United States, many diagnostics, therapeutics, and various types of vaccines were approved under Emergency Use Authorization (EUA), including mRNA vaccines. Subsequently, the approval was canceled for diagnostics whose sensitivity and specificity could not be verified, and for therapeutics whose efficacy declined. Japan also established an emergency approval system under the Pharmaceutical Affairs Law in response to the COVID-19 crisis, but the Pharmaceuticals and Medical Devices Agency (PMDA) should be prepared by closely exchanging information and collaborating with academia and companies in advance so that the PMDA can quickly review new types of therapeutics and vaccines in the event of an emergency. At the same time, the regulatory process for MCM needs to be accelerated and proper measures should be taken to respond flexibly such as by canceling approval granted under emergency, if necessary.

- ✓ The Cabinet approved the "Strategy for Strengthening the Vaccine Development and Production System," based on which the government established the Strategic Center of Biomedical Advanced Vaccine R&D for Preparedness and Response (SCARDA) inside the Japan Agency for Medical R&D (AMED). SCARDA leads R&D of vaccines. Currently, however, there are no enhancement strategies for diagnostics or therapeutics, and SCARDA is not conducting any relevant R&D. As with vaccines, it is necessary work to develop strategies and provide support for R&D of diagnostics and therapeutics.

- ✓ Current public research funding is designed for short-sighted objectives and there is no established environment where researchers can take time for basic research. It is not an attractive research environment for young researchers, either. In order to generate promising seeds from excellent basic research, there should be a framework for public research funding that will allow researcher to sit down and engage in long-term research.

(2) Researcher community

- ✓ Promising seeds for future MCM are expected to be generated from long-lasting basic research and communicable disease research. In Japan, there are many entities engaging in development of research talent, including world-class R&D bases of SCARDA, Ohsumi Frontier Science Foundation and

Nirasaki Omura Foundation. These entities should be networked to establish a comprehensive human resource development platform.

✓ Following the example of Institut Pasteur in France and other entities, a framework should be established for sharing “information,” “research reagents,” and “data (research results)” among researchers in academia to promote speedy R&D in the event of a communicable disease crisis. It is also necessary to ensure that credits, including patents, will be shared to drive speedy R&D of MCM.

（3） Diagnostic and pharmaceutical companies, CROs, CMOs and CDMOs.

✓ During the COVID-19 infection crisis, there was not a system in place to produce and supply sufficient MCM, including new types of vaccines such as mRNA vaccines and viral vector vaccines. It is necessary to establish manufacturing bases to manufacture and supply sufficient MCM for Japan and the rest of the world during the next communicable disease crisis, as well as to manufacture and maintain agents for unresolved communicable diseases and biopharmaceuticals in normal times. Additional contract manufacturing organizations (CMOs) and contract drug development and manufacturing organizations (CDMOs) should be established to ensure sufficient capacity not only for active pharmaceutical ingredients for therapeutics and vaccines, but also for formulating injections. Strategies for global deployment should be implemented in normal times such as developing and distributing diagnostics, therapeutics and vaccines overseas.

✓ There is a serious shortage of human resources for manufacturing of biopharmaceuticals such as mRNA and viral vector vaccines. The industry in general should continuously develop human resources for biopharmaceutical manufacturing.

✓ In order to efficiently conduct clinical trials of diagnostics and vaccines during the next communicable disease crisis, pharmaceutical companies and contract research organizations (CROs) should prepare systems to utilize real world data (RWD). Work with the government to establish in advance a large panel of healthy subjects (adults and children) and a network of medical institutions nationwide to participate in clinical trials. Gear up to conduct clinical trials not only in Japan but also globally.

✓ It is expected that ingredients of MCM, reagents needed to manufacture MCM, parts, materials, etc. will run out in the event of a communicable disease crisis. Take steps in advance to ensure continuous manufacturing and supply of MCM in the event of a communicable disease crisis, such as diversifying their supply chains and enabling domestic supply.

1-4 Ensuring Economic Predictability of Communicable Diseases Making Unpredictable Communicable Disease Predictable by Economic Incentives and R&D

[Background and issues]

<Outcome of the G7 Nagasaki Health Ministers' Meeting>

At the Group of 7 (G7) Health Ministers' Meeting held in Nagasaki, Japan, in May 2023, the participants discussed promotion of health innovation as one of the main agenda items. From the perspective that health innovation will serve as a pillar for health crisis management and efforts to achieve "Universal Health Coverage (UHC)," i.e. ensuring that everyone can access appropriate medical care, the participants agreed on the need to establish a value chain from R&D to manufacturing and distribution of Medical Countermeasures (MCM) and ensure access to them. Japan particularly emphasized the need to address AMR. The statement included a call to further promote initiatives such as to implement "pull incentives," which ensure profitability through support after a drug is approved and provide continuous support for R&D.

<Economic predictability for AMR measures>

The annual number of deaths from communicable diseases caused by bacteria with antimicrobial resistance (AMR) (in 2019) was reported to be 1.27 million, more than that for AIDS and for malaria. In Japan as well, it is estimated that approximately 8,000 people have died from a mere two types of bacteria with AMR. Antimicrobial drugs to treat infections due to bacteria with AMR are essential for modern medical care, including advanced surgery and anticancer therapy, and antimicrobial resistance is also a growing problem of the three major communicable diseases. However, new development of antimicrobial drugs is significantly decreasing because of the difficulty in R&D, its high cost, and low profitability. Even if the drugs were to become available, use would be limited from the standpoint of it being discouraged to prevent bacterial resistance, with little promise of ensuring profit based on sales quantity and sufficient return on investment. Major pharmaceutical companies are continuing to exit the antimicrobial drug market or are selling the business.

Given this situation, the AMR consortium, which was established in 2020 as the fifth consortium for the Asia-Africa Medical Innovation Consortium (AMIC) of the Conference, released a document in March 2021 proposing to the government specific functions for the pull incentive program and initiated activities to recommend them.

The first pull incentive program for addressing AMR in Japan, the Antimicrobial Securement Project was included in the initial budget plan for FY2023, with a budget of 1.1 billion yen. While this is perceived as a groundbreaking move, there is a gap in budget size, compared to the recommendation by the AMR consortium. It has been brought to attention that although this budget is for a single year, it is important to continue this program for multiple fiscal years, at least three to five fiscal years, for the purpose of ensuring economic predictability.

Sweden, which holds the Presidency of the Council of the European Union (EU), hosted a high-level meeting on AMR in the beginning of this year and released a policy brief in cooperation with the WHO and other entities on how the EU can promote sustainable and speedy access to new antimicrobial drugs. The country is already piloting an incentive program based on a profit ensuring model. In the U.S., the PASTEUR Act has been submitted primarily to allow the government to purchase antimicrobial drugs at a

fixed price of up to $3 billion from drug discovery companies through a subscription model. The U.K. is leading the way in promoting a pull incentive program based on the subscription model. For the program, antimicrobial drugs of Shionogi & Co., Ltd. have been adopted among others. The company reported that this program enables it to separate the sales of and revenue from its antimicrobial drugs, making it easier to fulfill the accountability for shareholders and plan on production based on the expected maximum production volume.

<Economic predictability of vaccines and other non-antimicrobial drugs>

In the past, the AMR consortium of the Conference has been actively discussing financial support for R&D and innovation for communicable diseases. This year's conference included a session to broadly share concerns with companies involved in diagnosis, treatment, and prevention of communicable diseases, etc., drawing a wide range of opinions from companies and others involved in areas other than antimicrobial drugs. Like the antimicrobial drug sector, business continuity is a challenge for the vaccine sector, and it was brought to attention that ensuring economic predictability, such as by promoting routine vaccination, is essential. Relating to economic predictability, the concept of "capacity reservation," i.e., securing a system from procurement of active pharmaceutical ingredients to manufacturing in advance, is also attracting attention.

It is also necessary to consider this from a perspective of "ecosystem," the mechanism for continuously creating new drugs for communicable diseases. It is not easy to create a flow in which seeds of new drugs from academia and biotech start-ups are nurtured through support by venture capital, and institutional investors invest in the startups that have gone public or large pharmaceutical companies that have acquired such startups. The obstacle is, as noted during the session, that venture capitalists (VCs) cannot wait for a future pandemic and such startups would have to, for example, achieve an M&A known as "exit" or go public within 10 years or so. In addition to the ongoing project by the Ministry of Economy, Trade and Industry to strengthen the drug discovery startup ecosystem aimed at establishing a drug discovery ecosystem for communicable diseases in Japan, initiatives to establish an authentic drug discovery ecosystem for communicable diseases should be further promoted.

Participants also shared information on procurement by the United Nations, governments of emerging and developing countries, and other public agencies. Of the $29.587 billion (4 trillion yen) in goods and services procured by UN agencies from private companies and others around the world in 2022, approximately 1 trillion yen is from the medical and healthcare sector, a huge market where pharmaceutical and medical device companies may be able to find potential targets for exit. In some cases, UN agencies may solicit interested companies for goods and services that the agencies are considering purchasing in the future, rather than products and services that they need now. However, the procurement amount in 2022 was about $100 million (about 14 billion yen) in Japan, ranking 56th among the supplying countries and accounting for only 0.3% of the total.

<Economic predictability and human resource development>

Economic predictability is also an important factor for continuously attracting human resources to the

communicable disease sector. Even if you want to develop your career as a researcher on communicable diseases, most of the job positions are with fixed-term contracts, so you will need to achieve outcomes and secure research funding within a short period of time. The poor economic predictability is causing instability and uncertain future prospects in this sector, undermining its attractiveness.

[Actions required]

Ensuring economic predictability is essential for continued R&D and innovation. You never know when an outbreak of a communicable disease will occur and how prevalent it will be. This is a difficult business sector for companies involved in related pharmaceuticals and devices, as it is less likely to be affected by the market mechanism. With these concerns in mind, the AMR consortium of the Nikkei FT Communicable Disease Conference has been discussing and recommending to the government the pull incentive system for supporting development of antimicrobial drugs. Although the Antimicrobial Securement Project was included in the initial budget plan for FY2023 as a pull incentive program, there is a gap in budget size and its continuity from the proposal by the consortium.

Such systems that support continuous R&D and innovation is equally necessary not only for antimicrobial drugs but also for the diagnosis, treatment, and prevention of communicable diseases in general. The lack of economic predictability also makes uncertain the prospects for stability and the future, which are essential for planning careers in this area. This has an adverse impact on attracting next-generation human resources.

The following actions are required to improve economic predictability for the sector of communicable diseases and to support continuous R&D, innovation, and human resource development:

(1) Promote evaluation and improvement of the pull incentive program for AMR as a leading example of an initiative to ensure economic predictability
(2) Plan and promote systems to enhance economic predictability and support R&D and innovation of non-antimicrobial drugs, such as vaccines
(3) Establish a drug discovery ecosystem for communicable diseases
(4) Study and promote economic predictability needed to support development of next-generation human resources

1-5 Actions to Take in Normal Times to Prevent Division—Promoting a Resilient Civil Society

[Background and issues]

<Guidelines for convincing the public to continue to engage in infection control>

Since the outbreak of the COVID-19 pandemic, the Communicable Disease Conference has been focusing on social marketing through application of behavioral science and discussing how to convince the public to take actions and actively participate in infection control. The objective of this discussion is to

apply commercial marketing techniques to solve social issues so people will find value in infection control and other measures, thereby driving behavioral change, in a similar way that people purchase products they think are worth investing in. Referring to the guidelines developed in the UK in 2020 to promote vaccination, academia and other volunteers from the Conference formulated and published the Japanese version of the guidance document in February this year (Mitsubishi UFJ Research and Consulting Co. / Doshisha University Social Marketing Research Center, "Guidance Document on Countermeasures for COVID-19, and Engagement of and Behavioral Change in the Public," https://www.jsocialmarketing.org/research-achievements). Based on this guidance document, students are actively engaging in medical-ecological activities for promoting personal health management to optimally utilize limited medical resources in case of strained medical care amid a communicable disease crisis, among other ongoing pilot initiatives.

<Plan specific actions based on initiatives from the pandemic period>

At this year's conference, the "end" of the COVID-19 pandemic was declared, and there was reference to the ongoing comparison of Japan and the UK on infection control measures, in addition to the guidance document, as discussion on preparation for the next pandemic continues in and outside Japan. Based on reports from local governments and companies that have been engaging in initiatives related to communication with the public amid the pandemic about the results and identified issues of such initiatives, the participants discussed actions required in the event of a communicable disease crisis and actions to promote in advance.

Yamanashi Prefecture reported that they have assigned roles for the local government to provide information in a responsible manner based on evidence from experts to prevent potential "division" on, for example, balancing infection control and economic activities, under the policy that, in order for prefectural residents to take proactive actions, it is essential that prefectural residents can make informed decisions and information and messages from the local government must be reliable.

One takeaway from the Conference is that a key to success in communicating information about communicable diseases and calling for behavioral changes lies in delivering clear messages in a way fun and entertaining enough to motivate the public to cooperate. Examples were introduced of content designed to interest and entertain different targets, such as a fun certificate exam on COVID-19 that was developed for parents and their children by a university in collaboration with public figures as well as stylish posters for young audiences. An advertising company that made an animated YouTube video about division that emerged during the COVID-19 crisis revealed that when they widely distributed the video through social media, quite a few people reacted, saying "I don't want to give into the division," "I don't want to hurt others," etc. It was noted that weaknesses such as fear and anxiety about communicable diseases change differences in position and disagreements into distrust and conflicts among people and cause division while such weakness can also become a source of empathy. From this perspective, we can learn from how New Zealand communicated information. Through the narrative of blaming the virus rather than people, the country succeeded in developing an effective message that the nation as a whole will combat COVID-19,

rather than pushing the responsibility to either the government or individuals.

It was also pointed out that although social media can serve as a platform for the public to work together to take actions, as in the case where the animation about division resonated with a wide range of viewers, it can also cause division by stereotyping different positions and ways of thinking.

Some suggested consulting knowhow for disaster prevention to leverage it for communicable disease control, such as by positioning outbreaks of communicable diseases as a type of disaster comparable to earthquakes, etc. and preparing for them as part of companies' business continuity plans (BCPs), taking measures like fire drills to develop a habit of preparing for communicable diseases and developing a public education system for the next generation to learn about such diseases and significance of preparing for them. However, these suggestions were not substantial enough.

[Actions required]

The public's cooperation is essential for controlling the spread of communicable diseases. Since the outbreak of the COVID-19 pandemic, many people have cooperated with various policies of local governments, companies and schools, including on vaccinations, wearing face masks and staying at home, but challenges have emerged. In the early days of the pandemic, available information was limited, and many people paid attention to messages mainly from the government to take countermeasures. As the pandemic prolonged, information became more abundant and decision-making criteria became more diverse, generating so-called division due to differences between generations and positions, balancing economic activities with infection control, as well as different attitudes toward vaccination.

It is not easy to convey accurate information and messages to a "divided" society, making it difficult for the public to come together to engage in infection control. Excellent initiatives such as to providing information so that the public can continue to cooperate with infection control policies emerged as "dots," but they failed to spread sufficiently enough to form a "plane." Such measures include: developing a science communication and risk communication system based on clear roles of national and local governments, and experts; communicating information on communicable diseases and calling for behavioral changes by delivering more clear messages in a way fun and entertaining enough to motivate the public to cooperate; a citizen participation mechanism in a co-creative way that enables the public to participate in talks about measures for communicable disease control; and taking hints from natural and other disaster prevention initiatives based on accumulated knowhow. We are still halfway through the initiatives to organize and verify good examples of communication with the public that emerged amid the COVID-19 pandemic. Still, not enough is being done to leverage the outcomes, lessons for the future and other positive legacies from the above.

The following actions are required to establish a more resilient society that is less prone to division:

(1) Collect, organize, and verify good practices for communication to the public and calling for behavioral changes implemented by national and local governments, companies, universities and other research institutions, and NGO/NPOs amid the COVID-19 crisis. Plan on how to inherit and implement initiatives to prevent division on a large scale

(2) Plan systems for enabling the public to participate in a co-creative manner, such as by utilizing NGOs, NPOs and other civil society organizations (CSOs), which serve as bridges between the national and local governments and the public, to communicate information to and collect voices of the public about measures for communicable disease control.

(3) Pilot projects for communicating with the public by utilizing social marketing techniques, such as segmenting and targeting information and messaging according to the attributes and values of individual people, etc.

(4) Create practical manuals on item (3). The content should include educational information about basic infection control measures and address weakness that can manifest in anyone and insecurity and fear that we can't share with others, human reactions to these feelings, how to deal with infodemics, etc.

(5) Communicate information on communicable diseases and call for behavioral changes by delivering more clear messages in a way fun and entertaining enough to motivate the public to cooperate;

(6) Plan and promote initiatives for ensuring that measures for communicable disease control are practiced on a regular basis, consulting knowhow for natural disaster prevention such as the designation of "Disaster Prevention Day." Designate Disaster Prevention Week as "Communicable Disease Control Week," reflect measures for communicable disease control in BCPs, utilize evacuation drills, etc.

2. What Japan Should Do to Play a Central Role in Global Health

2-1 Tuberculosis, Malaria, Neglected Tropical Diseases and P3 Projects

The Nagasaki Health Ministers' Meeting of the G7 Summit held last May this year mainly discussed three agenda items: preparing for future health crises, achieving robust and sustainable universal health coverage (UHC), and promoting health innovation. The world as a whole has been overwhelmed over the past 3+ years in combat with COVID-19, setting back initiatives for a variety of health issues that had been going on until before. The most conspicuous among them are countermeasures for TB, malaria and NTDs (neglected tropical diseases). At the summit, it was emphasized that collaboration among stakeholders in industry, government and academia is vital for us to shift our focus back to achieving UHC in the post-COVID era and for Japan to contribute to the world by utilizing its experience and technologies.

[Discussion on malaria]

The consortium for malaria reported that the target for 2030 set by the WHO is not being met due to the COVID-19 crisis. The numbers of deaths and infection cases both increased compared to 2019. The consortium for malaria has positioned vector control, diagnosis, and vaccine/drug discovery as the "three arrows" required to achieve the goal.

This year, the consortium reported that the activities of Malaria No More Japan, Ehime University, Nagasaki University, Sumitomo Chemical, Eiken Chemical, and others were featured in a top international journal on integrated science.

Shionogi and Nagasaki University are jointly conducting research on therapeutics and vaccines. They received fund from the GHIT for developing an anti-malarial drug. For vaccines, the consortium presented an example of an mRNA vaccine whose efficacy was verified in a model mouse. This case exemplifies industry-academia collaboration.

The Asian task force reported that performance evaluation studies of two new in vitro diagnostic medical devices, utilizing Eiken Chemical's malaria LAMP method and Sysmex's flow cytometry method, respectively, are in progress at Mahidol University and other institutions. Eiken Chemical reported that they are working on the PMDA application and other steps to obtain WHO certification.

According to the African task force, vector mosquito control is urgently required. Serious issues include resistance to insecticides, emergence of mosquitoes biting people outdoors before they go to sleep, and use of mosquito nets for unintended purposes. Overhead mosquito nets effective against resistant vector mosquitoes have proven to be highly effective in cohort studies of locals, and neighboring countries are requesting for their deployment. The African business consortium reported on the cross-industry co-creation project by Ajinomoto Foundation, NEC, and Sysmex in Ghana. They are promoting an integrated approach to maternal and child health problems such as malnutrition, anemia, and malaria with the UN Food Programme team and the Ghana Ministry of Health.

Meanwhile, the consortium reaffirmed the importance of approaching global key players such as the WHO and local governments and medical institutions through industry-government-academia collaboration in further promoting this initiative to public medical institutions.

[Discussion on NTDs]

The NTD consortium explained ongoing initiatives targeted at 20 communicable diseases. At this year's health ministers' meeting, the participants shared the recognized global issue of access to and delivery of pharmaceuticals, along with the importance of research and development (R&D) and developed the "Nagasaki Statement" at the stakeholders' meeting on NTDs held on the previous day. In response to the results of the Health Ministers' Meeting and the stakeholders' meeting on NTDs at this year's G7 summit, Japan has pledged approximately $200 million to the GHIT Foundation, which supports R&D for NTDs, malaria and TB.

Gen Z youth who established a general incorporated association that supports initiatives for NTDs presented case studies of Japanese medical and veterinary students coming together to collaborate with partners in Japan and abroad. They said they will also focus on promotional activities by hosting contests for junior high and high school students, etc. on World NTD Day on January 30 next year, to educate them about NTDs. They will expand their activities to contribute to the world from Japan.

They also reported on examples of progress made in diagnostic techniques. Eiken Chemical deployed a prototype machine to diagnose Chagas disease in hospitals in Bolivia, Paraguay, Argentina, and other countries. The machine was proved effective in improving detection sensitivity and reducing diagnosis time, making progress towards commercialization.

[Discussion on TB]

The TB consortium reported that there is a global goal to reduce the number of people infected by 80% by 2030 compared to 2015. According to the consortium, however, the number is currently decreasing by approximately 2% annually, and it is expected to take 150 years to achieve the target. They said that innovations of diagnostic technologies, vaccines, etc. are essential for achieving the goal.

Nipro developed a technology to test for bacteria with AMR in a short period of time, subsequently gaining approval from the WHO. This technology has also been adopted in Indonesia with cooperation of JICA. Eiken Chemical is lobbying the WHO and other organizations to promote adoption of the highly sensitive testing method that you can use anywhere to detect every single infection case. Fujifilm's battery-powered ultra-compact X-ray device was introduced for its excellent ability to detect cases.

The consortium also noted challenges associated with research funding and collaboration. The trend of seeking short-term results is making it difficult to implement challenging research projects that may lead to innovative discoveries. In addition, bilateral cooperation is decreasing in Japan, resulting in fewer opportunities for researchers to identify frontline needs. The consortium identified the need for opportunities to match seeds of research with frontline needs in order to generate innovative research projects.

2-2 Expectations for Japan in Realizing UHC—Beyond G7 Hiroshima

[Background and issues]

Under the Sustainable Development Goals (SDGs), the UN aims to achieve universal health coverage (UHC) by 2030, which aims to ensure that all people have access to effective and quality health care

services at a cost they can afford.

In recent years, however, the progress toward the global goal of achieving UHC by 2030 has stalled. A major cause is the COVID-19 pandemic. According to the report by the World Bank, it will be difficult to break out of this delay without strong political commitment.

Chaired by Japan, the G7 Health Ministers' Meeting held in Nagasaki City on May 13, 2023 discussed, with the aim of promoting collaboration for more healthy future, the three pillars of (1) building and strengthening the global health architecture (GHA) to address future public health crises, (2) contributing to achieving more resilient, fair, and sustainable universal health coverage (UHC), and (3) promoting health innovation to support these efforts, and developed the G7 Nagasaki Health Ministers' Communiqué to indicate the policy of the G7. In addition, the participants agreed on the "G7 UHC Global Plan" for achieving UHC, which was released in the appendix.

On the same day, the G7 finance ministers' and central bank governors' meeting took place in Niigata City. The G7 finance and health ministers joined online from Nagasaki and Niigata, respectively, and discussed further collaboration between finance and health authorities and financing for pandemic PPR (prevention, preparedness, and response). They agreed to consider a surge financing framework that will enable providing necessary funds quickly and efficiently in the event of a pandemic.

At the G7 Hiroshima Summit, which took place from May 15 to 19, the participants, including those from eight guest countries such as India, engaged in discussion around the three pillars above. Prime Minister Kishida announced that the G7 will contribute at least $48 billion in public and private funds to initiatives to achieve UHC. In addition, he said he intends to promote initiatives to achieve UHC, such as utilizing private funds by promoting "impact fund investments" designed to solve social issues and executing the GH UHC Global Plan. Japan plans to make public and private contributions of $7.5 billion in total to international health from 2022 to 2025, including the $200 million pledge to the Global Health Technology Fund (GHIT Fund).

The G7 also agreed to launch a delivery partnership for Medical Countermeasures (MCM), based on the principles outlined in the G7 Hiroshima Vision for Equitable Access to Medical Countermeasures (MCM) issued by the G7.

In September 2023, a high-level UN General Assembly meeting on UHC took place. Prime Minister Kishida said, "Before forgetting the lessons learned from COVID-19, the international community should once again remind itself of the goal of achieving UHC and take action," and expressed his determination to lead the efforts of the international community to help the entire world, including developing countries, and achieve UHC by 2030.

[Actions required]

(1) The Japanese government will continue to lead discussions on what is needed for the world to achieve UHC and who should do what. The government will also continue to demonstrate leadership, especially in discussion of UHC financing.

(2) To achieve the philosophy of leaving no one behind, visualize as much as possible the infection situation in low- and middle-income countries where communicable and other diseases are prevalent,

and plan how services should be delivered by leveraging digital technologies, etc.

(3) As part of preparation for pandemics, plan contingency measures in advance for the surveillance system, medical care delivery system, and the R&D system including clinical trials, and make investments accordingly. Developed countries will help developing countries establish sustainable, effective systems for emergency situations, in addition to establishing such systems in their own countries.

(4) Address crises caused by bacteria with AMR that is being an obstacle to achieving UHC.

(5) Implement a tiered pricing model and other measures to facilitate access to treatments for patients in developing countries, while promoting innovation by private pharmaceutical companies to make therapeutics and vaccines affordable to everyone.

(6) Promote actions by the private sector, such as for prevention, health promotion, treatment, drug prescriptions, and medical insurance.

3. Conclusive Words

The Nikkei FT Communicable Diseases Conference, now in its 10th year, was attended by a wide range of experts from across disciplines, including medical institutions, companies, national and local governments, academia/research institutions, and overseas stakeholders that have experienced the COVID-19 pandemic over a period of approximately three years and identified lessons and issues to solve to address future pandemics. As initiatives to prepare for the next pandemic are in progress rapidly in Japan and abroad, it is necessary to communicate experiences of the participants of the Conference, measures for communicable disease control to take and even recommendations on how society resistant to communicable diseases should be actively and widely in and outside Japan, further contributing to measures for communicable disease control in Japan and in the international community. In particular, it takes medium to long term efforts to secure and train human resources to take charge of measures for communicable disease control in the future, which was the focus of this year's conference. We hope that the recommendations incorporated in this statement will be utilized to advance policy and social initiatives in the future.

At the end of the three-day conference, participants of the tenth round of the Nikkei FT Communicable Diseases Conference agreed to this statement.

End

The 10th Nikkei FT Communicable Disease Conference

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<Reference Material>

Summary of the 10th Nikkei FT Communicable Diseases Conference Special Sessions / Breakout Sessions / Special feature

■Special Session 1 (the Japan Pharmaceutical Manufacturers Association):
"Establishing a drug discovery ecosystem for communicable diseases—reflection on the past year and future initiatives."

The drug discovery ecosystem for communicable diseases requires push incentives provided by the Japan Agency for Medical R&D (AMED) and other organizations mainly for academia; revitalizing drug discovery through investment in drug discovery startups and accompanied support by venture capitals (VCs); pull incentives to pharmaceutical companies, which play the central role in deploying drugs, etc. Since initiatives of drug discovery startups in the Japanese ecosystem have been particularly weak compared to those in Europe and the U.S., the MHLW has been working to enhance them through various measures in recent years. One of them is MEDISO, a total support business for medical startups. As a one-stop consultation service connecting academia and companies, this business is currently growing at a steady pace.

In light of these current circumstances, the speakers in this session exchanged opinions on the drug discovery ecosystem from their respective standpoints. In the U.S., investment in the development of anti-tumor drugs is rapidly increasing, but the amount of investment is limited for communicable diseases, especially for development of antibacterial drug, which is barely making progress. Amid these difficulties for development of anti-microbial drugs, participants shared cases where members of academia were required to launch a company to receive funding and where researchers left academia to dedicate full time to launching a startup, etc., indicating once again the importance of business advice and venture capitals for academia engaged in drug discovery. In addition, it was noted that raising funds and forming business alliances are particularly difficult when launching a communicable disease drug discovery startup, and the number of Japanese drug discovery startups going public per year and their scale are limited. Furthermore, venture capitals pointed out that it is important for the seeds to serve as the foundation for establishing multiple development pipelines, for specialists to form internal and external global teams and establish relationships with potential future partners and to secure a massive funding source.

Since drug discovery for communicable diseases is difficult to predict scientifically and economically, the Japan Pharmaceutical Manufacturers Association (JPMA) stated that it is important to provide hands-on support to identify and launch startups for promising themes on communicable diseases with a focus on the community and commercialize them and that it is essential to enhance in advance the communicable disease drug discovery ecosystem, push or pull incentives, and the government's command post function to prepare for emergency. Regarding human resource development, they also indicated the importance of industry presenting a wide range of career plans to students who have studied communicable diseases and the importance of mobilizing and sharing diverse human resources with experience in the pharmaceutical industry.

■Special session 2 (SHIONOGI):

"The importance of new antimicrobial drugs and global collaboration to expand required pull incentives."

AMR (Antimicrobial Resistance) is a global threat. The number of resistant bacteria is steadily increasing, and resistant Gram-negative rods in particular are causing concern in many parts of the world since these therapy-resistant bacteria are highly fatal. It was warned in 2014 that without effective measures, the death toll will reach over 10 million by 2050. According to recent analysis, however, the reported death toll associated with AMR had reached 4.59 million and that directly attributed to AMR 1.27 million as of 2019. In addition, resistant deep-seated fungal infections as well as bacteria-caused infections is still significantly affecting life expectancy. Promptly administering effective antimicrobial drugs in the early stage is critical for reducing mortality.

However, there are significant barriers to quickly establishing infection control strategies by utilizing appropriate antimicrobial drugs. This is because it takes about 20 to 40 years from discovery research to approval of a new antimicrobial drugs, at an average cost of about $1.3 billion. In many cases, the annual sales of a new antimicrobial drug is 25 million yen or less, which makes it impossible to recover the cost from usage-based revenues. In the US, drug discovery companies have been experiencing bankruptcies, liquidations and sell-off in recent years. Antimicrobial drugs, like fire extinguishers used in the event of a fire, are worth preparing in advance in case of an emergency. It is necessary to expand pull incentives, which are paid whether the product has been used or not, and establish a system to ensure that compensation is commensurate with risk.

In this April, the Ministry of Health, Labour and Welfare revised the National Action Plan on Antimicrobial Resistance (AMR). The plan includes the Antimicrobial Securement Project, for which they have implemented a market incentive system for new antimicrobial agents and earmarked approximately 1.1 billion yen. Under this system, the government compensates for a certain amount of revenue loss due to cooperation with market incentive projects, while promoting the development of antimicrobial drugs. Although there is a discrepancy between the figure under the fair share policy to split the cost of antimicrobial drug development among developed countries according to the economic strength (e.g. GDP) of each country, and the budget for the Antimicrobial Securement Project, it is significant that the first step has been taken to promote the development of new antimicrobial agents and secure treatment options for resistant bacteria while maintaining appropriate use of antimicrobial agents.

Japan has made significant contributions to many global actions for push incentives, such as the GARDP (Global Antimicrobial R&D Partnership) and the CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator). The 2023 G7 Summit mentioned the possibility of international cooperation on pull incentives, and there are high expectations for the role the G7 will play as a global leader going forward.

■Special Session 3 (Daiichi Sankyo Co., Ltd.): Immediate challenges for the vaccine industry

Although several Japanese vaccines have been developed for the novel coronavirus infection (COVID-19), none were deployed in the early stages of the pandemic.

Unlike therapeutic drugs that treat diseases, a high level of safety is required for vaccines to prevent communicable diseases because they are administered to healthy people. Also, unlike common small-molecule drugs, vaccines require special manufacturing techniques and facilities. Furthermore, the predictability of the sector is poor since it is impossible to predict which communicable diseases will be prevalent and which vaccines will be used for routine immunization in Japan. Therefore, it is difficult for pharmaceutical companies to continue to invest in R&D and manufacturing of vaccines in advance.

In addition to the difficulties inherent in the vaccine industry, other reasons for the delay in the deployment of the Japanese COVID-19 vaccines include a failure to establish an environment for vaccine development to prepare for an emergency in advance and an absence of an adequate manufacturing system and an industry-academia-government ecosystem to enable private companies to develop and supply based on seeds from academia.

In order to prepare for the next pandemic, it is important for the vaccine industry and the government to further repeat dialogue, and for the public and private sectors to work together to strengthen the vaccine industry as a whole, with the aim of achieving a society that is resistant to communicable diseases.

- It is necessary to strengthen the foundation of R&D for vaccine discovery in advance through industry-academia-government and global collaboration, under the command of the national government. As part of this effort, a collaborative project between SCARDA and four vaccine organizations has started.
- Developing a production system to prepare for emergency situations requires measures to utilize relevant facilities even in normal times. Maintaining emergency response facilities, systems, etc. requires more than the companies' efforts, and therefore support from the government is essential.
- Since the vaccine industry is strongly influenced by government policies, the business predictability for normal times should be increased by promoting R&D of vaccines with high development priority, improving the decision-making process for routine vaccination, clarifying the target population for vaccination, etc.
- For evaluation indexes and methods for new modality drugs and regulatory science for manufacturing and quality control based on state-of-the-art scientific technologies, the private sector should discuss and collaborate with regulatory authorities from the planning phase of the development project in advance to realize speedy screening and approval in the event of an emergency situation.
- It is also necessary to establish a system for conducting large-scale validation studies of vaccines and promoting development of pediatric vaccines (clinical trial network of vaccines, pre-registration of clinical trial subjects, etc.).

In the future, the vaccine industry will continue to take on challenges as part of the pharmaceutical industry by collaborating with industry, government, academia, and the global community to promote the

development of biotechnology human resources, develop vaccines that contribute to the world, and supply vaccines overseas in advance.

■ Special Session 4 (Pfizer Japan Inc.):
"'With Japan' to bring about innovation—promoting revitalization of open innovation in Japan"

Looking at global trends, most drug discoveries in recent years have come from innovations originating in academia and biotech startups, which have played a major role especially in novel modalities (drug discovery method). We can no longer succeed in drug discovery in Japan only, such as under "All-Japan" and "Made-in-Japan" drug discovery programs. Japan, as a member of global community, needs to promote innovation through open collaboration among industry, government, and academia that transcends national borders for the purpose of saving the world.

Open innovation is not limited to research to find seeds, but also involves utilizing an ecosystem that leads from there to ultimately providing pharmaceuticals, including development, manufacturing, and supply. In order to fully utilize Japan's capabilities and make the seeds from Japanese academia and start-ups successful, it is important to roll out the research outcomes to the world and realize innovation by utilizing the global R&D ecosystem. This will also contribute to the Japanese people. We need to create such a virtuous cycle.

Under the direction of the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), established in March 2022 inside the Japan Agency for Medical Research and Develop (AMED), there are high expectations for establishing a world-class R&D center where industry, academia and government collaborate organically in vaccine development.

In addition, strong leadership will be needed for Japan to lead the world in the next pandemic. In September, the Cabinet Agency for Infectious Disease Crisis Management, which serves as the government's command post for measures for communicable disease control, came into force. In reviewing of the government action plan currently under discussion based on the lessons learned from COVID-19, expanding measures to support vaccines, therapeutics, and R&D and to encourage international collaboration are being considered as part of efforts to prepare for emergency. What's important is how we will develop the ecosystem in advance and activate emergency response if necessary. We may be able to utilize such discussions for action planning.

Collaboration between industry and academia also has its challenges, such as differences in concept of intellectual property (IP). However, academia and companies should work together toward the common goal of "creating innovative drugs and vaccines," taking into account their respective agenda items. One key lies in developing biotechnology startups in Japan and creating a mechanism for this purpose. It is also important to clearly separate areas to receive government support and for the private sector to take risks and promote. In addition, when incorporating promotion of open innovation into the government system, it will be necessary to discuss what form is appropriate and how the fruits will be distributed to the Japanese public.

■Special Session 5 (Gilead Sciences K.K.)

"A roadmap for ending the AIDS epidemic in Japan—Preparing for revision of the AIDS prevention guidelines"

Japan has long been contributing to the international countermeasures for AIDS, including investment in global funds and participation in the Joint United Nations Programme on HIV/AIDS (UNAIDS) Program Coordinating Board. Meanwhile, there are various unresolved institutional barriers for domestic policies. In particular, overcoming the three specific challenges, i.e., (1) developing a system for providing pre-exposure prophylaxis (PrEP), (2) diversifying testing opportunities, and (3) achieving early treatment, is a key to ending the AIDS epidemic in Japan.

PrEP is an antiretroviral drug taken orally before risky behavior and expected to be effective in preventing infection. Although the drug has been shown to be highly preventive overseas and is covered by insurance in many countries, it has not yet been approved by Japan's pharmaceutical authority. Meanwhile, private imports of generic drugs and prescriptions at clinics are also becoming more common. Given this situation, a research group of the Ministry of Health, Labour and Welfare (MHLW) has prepared and published guidelines for proper use of PrEP. It is necessary to establish the system for providing PrEP as soon as possible.

With regard to expanding opportunities for AIDS virus (HIV) testing, it is necessary to address various testing needs by diversifying the system for providing testing, including testing via mail, while maintaining the efficient testing system that has been developed to date. Specifically, this includes establishing a system for providing tests based on risks. It is also necessary to establish an educational and consultation system for encouraging high-risk groups to take the tests, as well as a collaborative relationship with medical institutions for referral of confirmed cases.

Early treatment is important not only for reducing the risk of infecting others, but also for treating individual patients. The World Health Organization (WHO) recommends starting antiretroviral therapy (ART) within seven days of HIV diagnosis, but under Japan's current system, in principle, patients must wait for four weeks before they become eligible to receive public funding under the Physical Disability Certificate system or System of Medical Payment for Services and Supports for Persons with Disabilities. It is necessary to reform the system so that all HIV-infected patients can start ART within the WHO's recommended time frame.

At the end of August 2023, GAP6, a consortium of citizen groups working to promote education on HIV/AIDS, submitted a request to the Minister of Health, Labour and Welfare, including for improvement of these three issues. The UNAIDS upholds the principle of involving patients and the public in the process of planning and implementing the government's AIDS control measures in each country. We hope that patients and the public will participate and guide efforts again to solve these issues for the next revision of HIV prevention guidelines.

■Special Session 6 (Moderna Japan Co., Ltd.):

"Impact on cancer and dementia of COVID-19's transition to the endemic phase"

In May, the World Health Organization (WHO) withdrew the emergency declaration for the novel coronavirus, and the world entered the transition phase from pandemic (infection is prevalent on a global scale) to endemic (infection becomes prevalent on a periodic basis). Research is underway to examine the effects of the infection on cancer patients and cognitive function.

In Japan, the number of COVID-19 infection cases has increased among cancer patients since the outbreak of the sixth wave of the Omicron strain. According to U.S. data, cancer patients have a 1.46 times higher risk of getting infected with COVID-19 and patients diagnosed with cancer within one year have a 7.14 times higher risk. In the UK, patients with cancers other than hematologic tumors were 1.72 times more likely to die in less than one year of diagnosis, and patients with hematologic tumors 2.82 times more likely.

Recently, the product line of antiviral drugs, including oral drugs, has been expanding, making it possible to diagnose at an early stage and administer antiviral drugs as soon as possible for confirmed cases. Since the immune system in cancer patients are weakened, the vaccine may not be fully effective for them. In such cases, prophylactic administration of neutralizing antibodies is an option.

Because COVID-19 are also a serious risk factor for dementia patients, it is necessary to continue to educate the public about protecting the brain and preventing infection. According to the U.S. Department of Veterans Affairs, getting infected with COVID-19 approximately doubles the risk of Alzheimer's disease, and even mild infections may affect higher brain function. In Norway, it has been reported that even patients with mild symptoms treated at home commonly experienced memory impairment six months later. The percentage increases with age, but memory impairment was also observed in 11% of patients aged 16 to 30.

Imaging studies show the orbitofrontal cortex becomes atrophied in the elderly after infection. The virus may be transmitted via the olfactory conduction pathway, and it has been confirmed that the virus is capable of replicating itself after infection. Antiviral drugs and drugs that restore the mitochondrial function are expected to treat this condition. It is desirable to establish prophylactics and therapeutics for neurological sequelae.

COVID-19 continues to gain momentum around the world, with more than 200 symptoms identified as sequelae. It is an important agenda item to figure out how vaccines should be routinely administered going forward to protect people with weakened immune system, such as cancer patients, as well as the elderly.

■ Breakout session A (KM Biologics):

"Industrial" efforts to prepare for the next pandemic based on the Strategy for Strengthening the Vaccine Development and Production System

KM Biologics, a company of the Meiji Group, is promoting integrated R&D from prevention to treatment of communicable diseases through collaboration with Meiji Seika Pharma, the group's pharmaceuticals segment.

In preparation for the next communicable disease crisis, the Strategy for Strengthening Vaccine Development and Production Systems, which was approved by the Cabinet in June 2021, emphasizes the need to strengthen the R&D and production systems for domestically produced vaccines. KM Biologics and Meiji Seika Pharma are vigorously working to strengthen the R&D and production systems for domestically produced vaccines through the following initiatives included in the strategy: (1) establishing a world-class R&D center, (2) enhancing strategic research funding capabilities, (3) developing and expanding clinical trial environments, (4) developing vaccine manufacturing bases, and (5) developing and manufacturing vaccines.

In particular, the two companies are working together to develop a domestically produced inactivated vaccine (development number: KD-414) against COVID-19.

COVID-19 is currently transitioning from a pandemic (global outbreak) to endemic (periodically recurring). For periodic outbreaks of COVID-19, the vaccine should be administered on a regular basis, like the seasonal influenza vaccine. However, since many people in Japan choose not to receive the vaccination due to concerns about the mRNA vaccine currently in use, a safer vaccine is needed. In particular, the COVID-19 vaccination rate among infants and children in Japan has not improved.

For the inactivated vaccine (KD-414) currently being developed by KM Biologics and Meiji Seika Pharma, the infectivity and toxicity of the virus or bacteria causing the communicable disease is eliminated (inactivated) and only the components that induce immunity are extracted. The KD-414 has been used in a wide variety of vaccines, including the seasonal influenza vaccine and DPT-IPV. In clinical trials of the vaccine (KD-414), it was confirmed that it boosts the immunogenicity (antibody level) higher in younger subjects and is as safe as the conventional inactivated vaccines.

Therefore, in December 2023, the two companies will begin the final stage of a clinical trial (Phase 3 study) of the inactivated vaccine (KD-414) for the Omicron strain (XBB strain) in pediatric patients. They will investigate whether the inactivated vaccine (KD-414) can prevent development of COVID-19 by administering it or a sham vaccine (placebo) in 5,000 healthy children from six months to less than 13 years of age. If all goes well, the inactivated COVID-19 vaccine that can be administered to children could be deployed as early as fall 2024.

■ Breakout session B (FUMAKILLA LIMITED):

"Issues surrounding insecticide resistance: highly resistant striped mosquitoes found in Southeast Asia."

Dengue fever is spreading widely in Southeast Asia, and the major factor is the increasing resistance to insecticides of yellow-fever mosquitoes, which carries the virus. There is no effective therapeutic or vaccine for dengue fever, and the main countermeasure is to exterminate mosquitoes that carry the virus by

using insecticides. However, in recent years, yellow-fever mosquitoes highly resistant to insecticides have been breeding throughout Southeast Asia. This has been causing epidemics because people, unaware of this trend, continue to use the same type of insecticide to control the population of the mosquitoes in a wide range of areas.
Continued use of the same type of insecticide results in a repeated cycle where mosquitoes that become resistant to the insecticide through genetic mutation, etc. produce offspring and only insecticide-resistant mosquitoes survive. We need to combine diverse insecticides or promptly study the resistance development and introduce new insecticides for vector control.

To detect resistant mosquitoes, we need to catch mosquitoes in each area and subject individual mosquitoes that have survived the insecticide to genetic testing and analysis. Research conducted by the National Institute of Infectious Diseases has found super-resistant mosquitoes at rates as high as 40% in Vietnam and 90% in Cambodia. Many existing insecticides sold in Southeast Asia are likely to lack efficacy, and development of new insecticides is being awaited. FUMAKILLA intends to develop pyrethroid-based products that are safer and more effective for humans, especially for personal care use.

Even if companies work hard to develop new pesticides, the response may be delayed if they are not approved soon. Some countries do not have an approval process, and if highly dangerous and less effective insecticides are mixed in, people may feel less confident in insecticides, which in turn results in fewer opportunities for personal care. In order to reduce the risk of dengue fever infection and save many lives, it is important that various organizations and private companies in each country cooperate to share information and promote initiatives.

■ Breakout session C (Takeda Pharmaceutical Company Limited):
Communicating information about immunization to promote accurate understanding and informed decisions—in an era of diversifying means of communication

As the National Immunization Plan is under review, communication about immunization has become one of the key agenda items. During the novel coronavirus (COVID-19) pandemic, vaccinating against the virus was recommended and the national and local governments have provided information on the vaccination through their websites, publicity materials, and social media. In the session, they discussed the challenges that emerged of providing information in a way that makes it easy for the recipients to understand, limitations of budgets of local governments for subsidizing voluntary vaccination, and difficulty of effectively verifying scientific evidence and fairness for subsidizing it, as national and local governments have strategically communicated information to the public.

Nudging and social marketing complement existing regulatory and policy approaches and require less financial commitment. It is necessary to consider intervention measures based on influencing factors for each stage of behavioral change, on the basis of evidence that better convinces the public on the vaccination, and the latter method makes it possible. Based on these findings from the COVID-19 experience, it is important to determine how to define evaluation indicators related to the public perception

and behavior as one way to prepare for a new pandemic, and to this end, it is vital to encourage broad public participation at the stage of policy planning and formulate policies in a co-creative manner in normal times.

Meanwhile, during the COVID-19 pandemic, inaccurate or weakly substantiated information and information that gave negative impressions were prevalent on social media, and it is possible that national and local governments failed to promote proper awareness and actions among the public. In addition, it is not clearly institutionalized who should provide the public with information on voluntary vaccination. Furthermore, when there are multiple vaccines, even for routine vaccination, with different characteristics in efficacy, safety, and route of vaccination, people without a family doctor may not be able to properly recognize and understand the differences among them. Therefore, in order to ensure the public proper decision-making opportunities regarding vaccination, it may be necessary to organize issues regarding various entities, including pharmaceutical companies that have detailed pharmaceutical information, playing the role of providing reliable information, rather than limiting the information providers for the public to national and local governments.

■Breakout session D (The Research Foundation for Microbial Diseases of Osaka University): "Rethinking what it means for companies to engage in control of communicable diseases and relevant issues"

In addition to childhood immunization and vaccine policies that have contributed to extending the life expectancy of Japanese people, it is important to prevent communicable diseases through immunization and other means so that the elderly can work longer amid the declining birthrate and aging population, and it is advisable that companies participate in the role as actors for new immunization policies going forward. The term "health and productivity management" has permeated society, and the recognition has grown that, in optimizing corporate management, it is important for the company to manage the employees' health more actively. The fact that many companies contributed through workplace vaccinations and other measures amid the pandemic was a symbolic achievement in Japan's vaccine history. However, there is still considerable room for improvement with regard to measures for communicable disease control in general that significantly affect the health of employees and corporate management.

While the actual screening rate of regular company medical checkups is almost 100%, only approximately two-thirds of companies are engaging in health management initiatives to prevent communicable diseases. More focus needs to be placed on preventing communicable diseases that cause cancer, which accounts for 50% of all deaths during employment, and communicable diseases other than COVID-19. As the Tokyo Metropolitan Government has been promoting the Communicable Disease Preparedness Improvement Project since 2015 for the purpose of encouraging companies to take additional measures for rubella in men who have not had an opportunity to receive routine vaccination, some companies are starting to plan measles-rubella vaccination or preparing for the next emerging communicable diseases as part of their business continuity plans (BCPs), prompted by the workplace

vaccinations for the novel coronavirus. Shingles, which can cause a decline in productivity, is now preventable through vaccination for those aged 50 or older, so companies are expected to proactively take actions.

The government included Infectious disease prevention measures in the selection criteria for the 2024 Certified Health & Productivity Management Outstanding Organizations Recognition Program. The highest priority of such measures is immunization. In addition, employee education on communicable diseases and the workplace environment are also important. It is desirable that companies strengthen efforts for health and productivity management, including prevention of communicable diseases, as collaborative management strategies for ensuring corporate sustainability among all ranks of employees, including senior management, management and staff-level employees, and as risk management measures.

■Breakout session E (Saraya Co., Ltd.): "The JAPAN Pamoja (Collaboration) Platform initiative for combating communicable diseases in East Africa"

Africa has many issues related to infection control, such as poor infrastructure for clinical examinations, lack of customary access to examinations and treatment at medical facilities, people not sufficiently washing and disinfecting hands due to lack of proper hygienic environment and education on infection control, etc. As a result, the rates of infection associated with pregnancy and childbirth and infant mortality from communicable diseases are high.

The breakout session introduced initiatives to address these issues. Connect Afya is working to establish an infrastructure for clinical examinations and treatment of communicable and other diseases in Kenya by providing test reagents and equipment, establishing clinics, as well as building clinical laboratories and making gene sequencers and other equipment available to local doctors and researchers. Shionogi is providing the antibacterial drug cefiderocol, which has antibacterial activity against Gram-negative bacteria, including multiantimicrobial-resistant bacteria, to approximately 130 countries, most of which are low- and middle-income countries, through NGOs, as well as promoting establishment of a system for providing the drug to many countries by licensing pharmaceutical companies in other countries. The company also aims to increase the percentage of deliveries at health facilities and reduce the incidence of diarrhea in infants by developing health facilities and water supply facilities for people to access, which is necessary for achieving UHC, and educating and enlightening local health care workers and residents in Kenya and Ghana. Dr. Tomohiko Sugishita, who has been dispatched to Africa by JICA, introduced the trend and significance of promoting adoption of the electronic maternal handbook, Kenya's initiatives to encourage health checkups using the handbook and other secondary impacts.

Saraya began locally manufacturing and marketing disinfectants in Uganda in 2014. In 2017, the company began distributing its products in Kenya, and during the COVID-19 lockdown, it obtained a permit for 24-hour operation to supply disinfectants throughout the country.

The company is also implementing the Safe Motherhood Project to reduce maternal deaths in Uganda. Since many expectant mothers die from sepsis and other causes after childbirth, the company uses part of

the product sales to provide infection control training for local clinics, including instruction on how to sanitize hands, and provides disinfectants. This has improved hand hygiene compliance, and clinics that received the instruction saw a decrease in number of cases of pregnancy- and childbirth-related sepsis, and unexpectedly, fewer deaths from COVID-19 compared to other medical facilities. The company is also promoting their next initiatives for cervical cancer, which has a high mortality rate among women in Uganda, such as to educate local residents on and encourage testing for cervical cancer and sexually transmitted diseases and procure medical equipment and materials to increase testing for cervical cancer and HIV.

In order to achieve a significant impact in prevention, testing, diagnosis, and treatment of communicable diseases in Africa, as well as education and enlightenment of local medical facilities and residents, it is desirable that more companies, organizations, and other players join the initiatives and to build a platform for collaboration where players can work together and discuss areas for operational improvement.

■Breakout session F (Fujita Health University): How to utilize Haneda, a National Strategic Special Zone, to globalize medical services

For Haneda, which has been designated as the National Strategic Special Zone, there is an aim to leverage its location as an international aviation hub to promote Japan's cutting-edge medical care to the world. Fujita Medical Innovation Center Tokyo was established to provide cutting-edge medical services such as regenerative medicine, genetic diagnosis, and precision medical examinations for patients in and outside Japan. They have introduced the state-of-the-art robots for reproductive medicine and rehabilitation to help realize advanced fertility treatment and active longevity for the elderly to live long and healthy lives.

They are also promoting collaboration with the private sector. For example, they established a laboratory for joint research on regenerative medicine with Rohto Pharmaceuticals. They are working with more than a dozen companies for industry-academia collaboration to promote development of new medical treatments.

So far, in National Strategic Special Zones, various special and deregulation measures have been leveraged to revitalize the regions. In the medical field, such measures include lifting restrictions on activities of non-Japanese doctors, new construction and expansion of hospital beds. Fujita Health University will also focus on actively leveraging these deregulation measures through the special zone program as a new hub for next-generation medical treatment and research.

Practicing advanced medicine also requires taking medical expenses into consideration. The medical expenses in Japan amount to more than 40 trillion yen, and there is little room to include advanced medical care cost in the medical reimbursement for the UHC system. A framework separate from the existing system will be essential for promoting state-of-the-art medical care. We must not forget that such a measure will enable practicing of advanced medical care that is not yet covered by insurance, and help determine its health economic value, in turn allowing it to be covered by insurance and enabling all people to enjoy its

benefits. It is desirable for Fujita Health University to work to pilot such new cases.

National Strategic Zones also play a role in realizing innovations that create social value. In one aspect, it will accelerate innovation for beneficiaries of cutting-edge medical care to pay for it themselves. If the scope of medical care not covered by insurance expands, the market is likely to expand and technological development to advance. It would be very significant if such a mechanism could be implemented in Haneda. In the first place, there is a large international demand for Japanese medical care and testing services. We look forward to practice of cutting-edge medicine that leverages the one and only location of Haneda.

■Special feature (PoliPoli Inc.):
"The role of youth in global health: addressing challenges and developments emerging from the Reach Out Project"

PoliPoli is a startup that operates a policy advocacy platform that brings public voices to politicians and government agencies. In January 2023, the company launched the Reach Out Project to support youth organizations tackling global health and other global issues. The project is unique in that it not only supports young people's social entrepreneurship, but also advocates policies at the same time.

PoliPoli feels that young people's role and presence for policy advocacy are growing. Meanwhile, the company has identified three issues.

The first is that issues about global health are harder to make feel personal than others, such as climate change, so it is difficult to get many young people onboard for relevant initiatives. Other issues include difficulty in building careers and unstable income. In addition, the members tend to be active only for a limited period time as students, because they are unable to overtly implement advocacy activities depending on organizations they belong to.

The second challenge is that it is difficult for youth or for-profit companies and organizations that emphasize the public interest to publicly collaborate. In addition, PoliPoli is unable to actively engage in advocacy due to its neutral position as a policy advocacy platform provider.

The third issue has to do with recipients of recommendations. Young people can't often participate in decision-making discussions. Due to the siloed ministries and government offices and conflicts of interest of international organizations, they may not be able to find any organization open to hearing their policy recommendations. Another obstacle is the limited number of politicians who agree with the youth.

In order to solve these issues, PoliPoli has been advocating the necessity and possibility of enhancing its programs as a human resource development platform, improving young people's ability to advocate policies and enhancing the reception system of governments and international organizations.

For example, for education through early exposure, the company is working with a university to plan on establishing an endowed course that includes on-site visits in policy advocacy and international cooperation. The company believes that working with young influencers and the media is also essential. They are also visualizing and quantifying impacts of projects and policies and establishing a support

system. In addition, they have ongoing negotiations to establish an advisory board for youth to speak at meetings of the government and international organizations.

For these initiatives, the company expects to receive funding and human resources from the government, domestic and international funds and private companies and give back by producing human resources and generating impact on policies.