

Tokyo Communicable Diseases Statement 2022

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0. Introduction

The ninth round of the annual Nikkei FT Communicable Diseases Conference, which started in 2014, was recently held. Each year, the conference brings together key players from different sectors and countries to discuss the never-ending battle between humanity and communicable diseases and to propose public-private partnership (P3) projects to address the issues.

Japan faced the peak of COVID-19 during the seventh wave in August 2022, and the recent conference was held amid concerns about an eighth wave. Using remote access technology developed during the pandemic, key players in the fight against communicable diseases from industry, academia, government and the private sector gathered for the conference in Tokyo's Meguro Ward on 15 and 16 November 2022. Some were invited to attend as audience members, and the event was streamed online.

<Issues related to COVID-19>

It has been almost three years since COVID-19 began ravaging the world in early 2020. The cumulative number of people infected worldwide since October 2021 has increased by about 400 million to a total of 642 million, and the number of deaths has increased by about 1.6 million to a total of 6.6 million (as of 29 November 2022). In Japan, the cumulative number of infections is 24.68 million (as of 29 November 2022), and the cumulative number of deaths is approximately 49,600 (same period), an increase of approximately 22.9 million and 30,000, respectively, since October 2021. Although COVID-19 posed a serious threat to the lives of citizens around the world, including Japan, and to socio-economic activities, information sharing about the disease, advances in medical technology, and weakened variants have contributed to the lifting of restrictions on activities and containment in Japan and countries around the world.

During the fifth wave in August 2021 (Delta variant), Japan faced a crisis with the collapse of its healthcare system. The seventh wave in August 2022 (Omicron BA.5 variant) shamefully caused the largest number of infections worldwide, and medical crises continued to occur. Participants at this latest conference, following a renewed and thorough investigation of the response to COVID-19 in Japan, strongly recognised that the lack of a command post function was at the root of the problem. As a result, an emergency recommendation on the ideal command post for communicable disease control was developed as an essential and effective measure against the pandemic and communicable diseases. Achieving the contents of this recommendation through the joint efforts of industry, academia, government and the private sector would ensure the safety of citizens. The creation of strong medical and social systems should also contribute to the global fight against communicable diseases for future pandemics. We encourage you to read last year's Tokyo Communicable Diseases Statement 2021, Measures Against COVID-19 in Japan, and the Yokohama Communicable Diseases Statement 2020 (see 7th Nikkei FT Communicable Diseases Conference Statement).

<Other P3 related to communicable diseases>

Along with the measures against COVID-19, progress and further development of other P3 projects that

had been discussed and recommended by this conference since 2014 were addressed. Through discussions on equal footing for the wide range of stakeholders from industry, academia, government, and private sectors, participants of the conference reaffirmed the need and effectiveness of P3 projects to better tackle communicable diseases that threaten human health and economic activities.

AIDS issues were also newly raised and discussed at the conference. This elevated the conference as a forum to discuss three of the world's major communicable diseases, namely tuberculosis and malaria, both of which had been discussed at previous Nikkei FT Communicable Diseases Conferences, and now AIDS. Communicable diseases caused by bacteria with antimicrobial resistance (AMR), which are being continually addressed by the Group of Seven (G7), were also discussed and concrete proposals for pull incentives for the development of new drugs were made. This conference in 2022 was a major step forward as a place to make P3 project proposals to take concrete action in a comprehensive way against the communicable diseases facing humanity, with the participation of a wide range of stakeholders from industry, academia, government and the private sector.

<The Tokyo Communicable Diseases Statement 2022>

At the end of the conference, participants agreed on the Tokyo Communicable Diseases Declaration 2022, which included a proposal to establish a command post to combat pandemics and communicable diseases. The results of this conference will be reported at government meetings, disseminated online and communicated through the media. The statement will be released not only in Japan, but widely around the world, including Asia, Africa and international institutions. It is hoped that the mutual understanding that will result will encourage Japan to become even more involved in the global fight against communicable diseases in the future.

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

https://cdc.nikkei.com/pdf/archive/statement/ja/8thnfc_statement2021_ja.pdf

https://cdc.nikkei.com/pdf/archive/statement/ja/7thnfc_statement2020_ja.pdf

https://cdc.nikkei.com/pdf/archive/statement/ja/statement2019_ja.pdf

https://cdc.nikkei.com/pdf/archive/statement/ja/statement2018_ja.pdf

https://cdc.nikkei.com/pdf/archive/statement/ja/okinawastatement2017_ja.pdf

https://cdc.nikkei.com/pdf/archive/statement/ja/3rdnac_tokyo2016_statement_jp.pdf

<https://cdc.nikkei.com/pdf/archive/statement/ja/OkinawaCommunicableDiseasesStatement2015.pdf>

<https://cdc.nikkei.com/pdf/archive/statement/ja/OkinawaCommunicableDiseasesStatement2014.pdf>

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

An Emergency Recommendation - Ideal Command Post for the Fight Against Communicable Diseases

[Background of the emergency recommendation]

<Issues revealed by COVID-19>

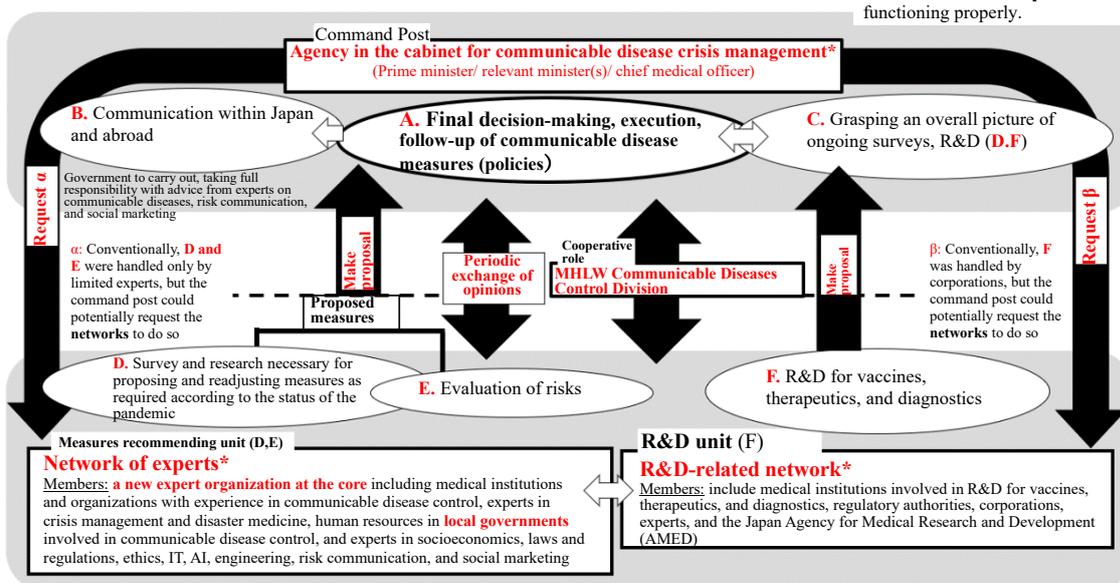
- Roles and authority of government and experts were not clearly defined. **The expert advisory group made over 80 recommendations along with supporting evidence, in spite of many restrictions.** However, there is room for improvement over quality and timing of recommendations due to **constraints on human resources and time.** Roles and authority of the expert advisory group including with regard to exemption of liabilities were also unclear.
- Development of diagnostics, vaccines, and therapeutics as a concerted effort by government, industry and academia was delayed because the **overall status** of R&D underway in Japan **was hard to see** and there was **no structure to conduct researches and clinical trials** while handling the pandemic.
- Issues included insufficient planning and proposing of measures (policies) against communicable diseases, **not enough experts available** for crisis management, and **no structure in place for cooperation among experts in many areas** including epidemiology, engineering, IT, AI, economics, laws and regulations, and ethics. There was also **an inability to use experts in risk communication and social marketing** to convey to the public any policies decided by the government.

<Background of the emergency recommendation made by the conference>

- Amidst the issues above and others, the government is expected to establish **an agency in the cabinet for communicable disease crisis management in FY2023** as a command post, followed by establishment of a **new expert organization.** Over the past three years, participants of the Nikkei FT Communicable Diseases Conference have contributed in various ways regarding COVID-19 both in Japan and abroad. Based on such experience, an **emergency recommendation is made for an ideal command post in both emergency situations and normal times** so that the government can create the best command post.

[Ideal command post: In emergency situations (proposed)]

*Create a system to enable **inspection based on records** on a periodic basis to see whether the **three parties** have been functioning properly.

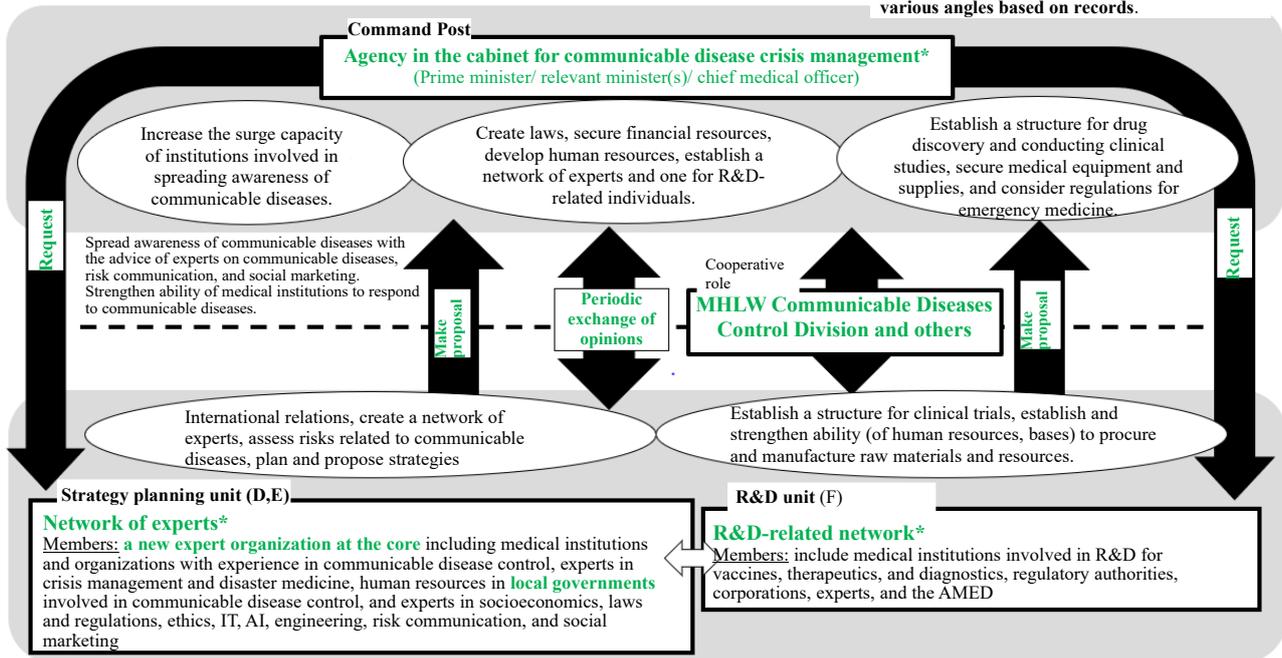


[Details of the ideal command post: In emergency situations (proposed)]

- **Government side above the dotted line, experts side below.** The ideal state in an emergency involves **three parties**: the **agency in the cabinet for communicable disease crisis management** that is the command post made up of the prime minister, relevant ministers, and the chief medical officer who is the head of the medical field; **network of experts and the R&D-related network** comprised of various experts and corporations; and the **MHLW Communicable Diseases Control Division**.
- **Measures recommending unit (network of experts)**: consists of various experts, conducting **D. survey and research necessary to propose and readjust measures as required according to the status of the pandemic**, and with **E. evaluation of risks, propose measures for communicable disease control** to the command post. With D in particular, although the expert advisory group were compelled to revise measures according to the status of the COVID-19 pandemic, for which surveying and researching was essential, they could not afford such surveys and researches at all.
- **R&D unit (R&D-related network)**: made up of medical institutions involved in R&D for vaccines, therapeutics, and diagnostics, regulatory authorities, corporations, experts, and relevant institutions, promoting **F. R&D for vaccines, therapeutics, and diagnostics**.
- **Command post (agency in the cabinet for communicable disease crisis management)**: the most important role is **A. final decision-making, execution, follow-up of communicable disease control**, including whether or not to adopt the measures proposed by the network of experts. They will also receive advice based on data analysis by experts on communicable diseases, risk communication, and social marketing regarding measures adopted, and **encourage citizens to participate** with **B. communication** after dutifully gaining consent of society. With regard to survey and R&D conducted during D and F, they will also need to **C. grasp the overall picture of ongoing survey and R&D. R&D of companies** developing diagnostics, vaccines, and therapeutics and **R&D of Japan Agency for Medical Research and Development (AMED)** needs to be understood in a centralized way.
- **Cooperative role (the MHLW Communicable Diseases Control Division)**: **coordinate** collaboration between the government and experts.
- Up until now, only limited experts dealt with **D and E** at their own expense, and experts and companies handled **F** on their own accord. Going forward, the government may **request them to do certain surveys or researches** depending on the situation of the pandemic that Japan faces at any given moment. For R&D as well, the government could also **request certain diagnostics or therapeutics to be developed**.
- Up until now, decisions regarding communicable disease control tended to be made centering on Tokyo. But in rural areas, **status of the pandemic and available structures for medical and nursing care provision vary among local governments**. Network of experts must include people involved in communicable disease control in local governments so that the situation in rural areas can be known. This ideal state for emergency situations **should be required both on a prefectural and municipality level**.
- A system should be created for **inspection based on records** from time to time to **ensure legitimacy** of the ideal state during emergency situations by checking if the **three parties** were functioning properly.

[Ideal command post: In normal times (proposed)]

*Put a **third-party review committee** in place to **inspect** whether the management agency, networks, and the ideal state are functioning properly **from various angles based on records**.



[Details of the ideal command post: In normal times (proposed)]

<Establish the structure>

- **Prepare for the next pandemic**, with relevant parties agreeing in advance upon **the ideal state in emergency situations**.
- Set up the same type of command post on both a **prefectural and municipality level** as well.
- Establish a structure to support the network of experts and the R&D-related network.

<Train and secure human resources to play an active role both in Japan and abroad>

- Foster individuals in communicable diseases, public health and hygiene, epidemiology, disaster medicine, crisis management, data analysis, R&D, laws and regulations, ethics, risk communication, and social marketing. Register them in a database.
- Strengthen the foundation for research, and also train researchers to contribute to planning and proposing measures during communicable diseases crises.
- Training human resources generally occurred individually among organizations, but organizations with experience in human resource development should handle it comprehensively for crisis management and communicable disease control in a cross-sectional way throughout Japan.

<Strengthen surge capacity>

- Surge capacity should be strengthened for elevated states in emergency situations, **for medical institutions, health centers, related organizations, and supply chains for medical equipment and supplies, fully using public funding, private funds, and other sources**.

<Ensure legitimacy>

- After the crisis is contained, a **third-party review committee** should be set up to assess **the three parties and their proper functioning based on records**, with a high level of transparency through adequate discussions among various stakeholders.

<Contribute globally>

- Commit to antimicrobial resistance (AMR), communicable disease control against tuberculosis and sexually transmitted diseases, and strengthen UHC to support such measures in advance during opportunities on a global scale such as G7 gatherings.

[Conditions for the success of command post functions]

So as not to end up like the proverbial phrase, “have the form but not the spirit,” the following conditions should be met for success:

- **Secure financial resources and place appropriate human resources in the command post** so that it functions both in emergency situations and in normal times.
- So that the command post and network of experts fulfill their function, **train and secure human resources in industry, government, and academia.**

[What is anticipated with the establishment of a command post]

By setting up a **functioning, ideal command post in emergency situations and in normal times** as declared in the emergency recommendation:

- (1) **Communicable disease control can be practically and resourcefully implemented, minimizing the effects communicable diseases have on Japan’s socioeconomic activities and leading to economic growth in Japan.**
- (2) **The 100 Days Mission announced at the G7 Summit and speedy deployment of vaccines, therapeutics, and diagnostics made in Japan become achievable.** This would allow socioeconomic activities to resume soonest, further strengthen Japan’s position in a prominent state internationally, and contribute to global society.
- (3) Make use of Japan’s limited resources, use **tax funds efficiently and resourcefully**, leading to **consent** among citizens.
- (4) First establish the crisis management structure for communicable disease crises that will help in the medium term to create **an all-hazards crisis management structure** to respond to all types of emergencies, including natural disasters, nuclear accidents, transport accidents, crime, terrorism, conflict, and war.

[The 100 Days Mission and Japan’s contribution]

<The 100 Days Mission>

The 100 Days Mission was announced in June 2021 at the Group of Seven (G7) industrialized nations summit. The 100 Days Mission is an initiative to make diagnostics, vaccine approval, and treatment methods available within 100 days of the World Health Organization (WHO) declaring a public health emergency of international concern. With the 100 Days Mission, access to and delivery of such diagnostics, vaccines, and therapeutics throughout the world, including to low-income countries, is also a goal.

<Issues faced by Japan>

In Japan, even with promising seeds in basic research, a shortage of human resources to use them came to light, and cooperation among government, industry, and academia was insufficient. Industry input had a hard time reaching the government. Leadership of the country to pull various sectors together was also lacking. Japan therefore lost its chance to deploy diagnostics, vaccines, and therapeutics for COVID-19 in a timely manner to its own people, not to mention contribute globally.

<Actions required>

- (1) Efforts in the past were separated for different diseases such as tuberculosis and malaria, but COVID-19 became an incentive to reaffirm gravity of communicable diseases, showing the need for collective initiatives against them.
- (2) To achieve the 100 Days Mission and for Japan to take the lead in communicable diseases crises, handle human resource development across organizations throughout Japan collectively, instead of companies and organizations training human resources individually. It is important to develop human resources both comprehensively throughout Japan and in cooperation with other countries so that Japan can dispatch human resources able to play a vital role in international-level decision-making for communicable disease control to international institutions and organizations.
- (3) Strengthen manufacturing bases for vaccines in normal times so that diagnostics, therapeutics, and vaccines developed in Japan and abroad for emergency situations can be manufactured in Japan and distributed globally. Supply chains should also be established in Japan for raw materials and resources.
- (4) Establish a structure to provide diagnostics and rapid test agents which are Japan's strengths in particular, not only domestically but to other countries, and to make them available for use by the community instead of just by medical institutions. Also make technology such as Japan's digital-based diagnostic imaging available for diagnosing and testing.
- (5) Promote international coherence for pharmaceutical regulations.

<What is anticipated by achieving the 100 Days Mission>

By achieving the 100 Days Mission, Japan will become more highly regarded in the field of communicable diseases, and will be counted on to contribute to global society.

[Crisis response for communicable diseases, etc. with active participation by consenting citizens]

<What behavioral science and social marketing shows>

- For citizens to understand concepts behind each other's behaviors and agree for the most part on directionality of measures regarding communicable diseases measures, it is effective to use knowledge from behavioral science such as social marketing, and to exchange opinions and communicate information appropriately.
- Once a certain level of agreement has been reached, it is important for state and local governments to change the communicator of information and what is being conveyed, depending on the target and nature of the desired behavior.
- By doing so, consent among the people will increase, and by changing their own behavior, they can come to feel value in themselves and society which can lead to efficacy of measures.

<Dilemmas faced by society>

At the start of the pandemic in 2020, information available was extremely limited and people feared the unknown disease, so it was easy to see what society would do. But as the pandemic prolonged, information about the communicable disease became known and people accumulated experiences. Perspectives on COVID-19 diversified driven by individual values and experiences, and directionality of society as a whole became unclear.

<Actions required>

Short-term:

- (1) Reach a certain level of agreement regarding an exit strategy for COVID-19. For that, prepare a forum for dialogue among citizens, decision makers, and experts. Related parties including civil groups, NPOs, universities and other academia would host. Initially, several local governments would hold the

discussions by segment, and spread out from there.

(2) Make practical guidelines for using behavioral science and social marketing.

Medium-term:

(1) To elevate efficacy of state and local government measures, foster experts in behavioral science and social marketing. Secure funding to do so.

(2) Consider development of a digital platform such as an app that can be used in normal times, and diverted in emergency situations. (Assume utilization online as a remote, non-contact, distribution-type digital dialogue/ communication tool)

[Expectations on the government for the G7 Summit in Hiroshima]

Unlike last time, messages that Japan can communicate globally at the G7 in Hiroshima are not necessarily clear.

Importance of measures against communicable diseases is being recognized due to COVID-19, and the need for global society as a whole to commit to crisis management for communicable diseases overall, not only tuberculosis, malaria, and AIDS, should be highlighted.

- Foster human resources who can get an overall view of measures against communicable diseases
- Create a structure for international clinical trials
- Achieve the 100 Days Mission, etc.

1. Preparing for the Next Pandemic:

Issues Around COVID-19 and Actions Required

1-1. Functions Required of Japan's Command Post

[Background and issues]

The Japanese government set up various expert advisory groups to obtain advice regarding COVID-19. In February 2020, the Novel Coronavirus Expert Meeting was created consisting mostly of experts in communicable diseases and medicine. In July 2020, the Subcommittee on Novel Coronavirus Disease Control was formed that included not only specialists in public health and communicable diseases but also in economics, as well as local government heads. The Ministry of Health, Labour and Welfare also created the COVID-19 Advisory Board consisting of experts in public health, communicable diseases, and medicine for advice regarding measures against communicable diseases.

Despite various restrictions placed on expert advisory groups, they provided advice for more than 80 measures along with supporting data and evidence on various different topics. The government then adopted many of those recommended measures. As a result, the mortality rate in Japan was lower compared to other nations, and numbers for severe cases and deaths were kept low. However, with human resource and time constraints, there was a limit to quantity and quality of proposals and amendments for measures. Roles and authority of the expert advisory group including with regard to exemption of liabilities were also unclear.

With regard to planning and executing measures against communicable diseases, the number of experts available to take on communicable diseases, public health, epidemiology, and crisis management was insufficient, and a structure for cooperation among experts in other areas including data analysis engineering, information technology (IT), artificial intelligence (AI), economics, laws and regulations, and ethics was not in place. Ability was also lacking to make use of experts in risk communication and social marketing that could convey to the public any policies set forth by the government.

Furthermore, overall status of the R&D taking place in Japan was not known, and because a structure was not in place to conduct research and clinical trials while handling the pandemic, development of diagnostics, vaccines, and therapeutics that was newly needed for measures against COVID-19 as a concerted effort among government, industry and academia was delayed.

Amidst such issues, the government will set up an agency in the cabinet for communicable disease crisis management in FY2023 to strengthen the command post function for the response to communicable disease emergencies. In FY2024, the Communicable Diseases Control Division (tentative) will be launched within the Ministry of Health, Labour, and Welfare. To provide high-quality scientific expertise regarding communicable diseases to the government, the National Institute of Infectious Diseases and the National Center for Global Health and Medicine will merge in FY2025 to make a new expert organization (new independent legal entity).

Participants of the Nikkei FT Communicable Diseases Conference over the past three years since the start of the COVID-19 pandemic have contributed in various ways both in Japan and abroad. Based on such

experience, an emergency recommendation is made for the ideal command post in both emergency situations and in normal times (proposed) so that the government can create the best command post.

[Ideal command post: In emergency situations (proposed)]

The ideal state in a communicable disease emergency involves three parties: the agency in the cabinet for communicable disease crisis management that is the command post made up of the prime minister, relevant ministers, and the chief medical officer who is the head of the medical field; network of experts and the R&D-related network comprised of various experts and corporations; and the MHLW Communicable Diseases Control Division.

■ Function of the three parties in emergency situations

(1) Measures recommending unit (network of experts): consists of various experts, conducting D. survey and research necessary for proposing and readjusting measures as required according to the status of the pandemic, and upon E. evaluation of risks, proposes measures for communicable disease control to the command post. With D in particular, although the expert advisory group were compelled to revise measures according to the status of the COVID-19 pandemic, for which surveying and researching was essential, they could not afford such surveys and researches at all.

R&D unit (R&D-related network): made up of medical institutions involved in R&D for vaccines, therapeutics, and diagnostics, regulatory authorities, corporations, experts, and relevant institutions, promoting F. R&D for vaccines, therapeutics, and diagnostics.

(2) Command post (agency in the cabinet for communicable disease crisis management): the most important role is A. final decision-making, execution, follow-up of communicable disease control, including whether or not to adopt the measures proposed by the network of experts. In addition, advice by experts is to be received on communicable diseases, risk communication, and social marketing regarding measures adopted, and B. communication is to be dutifully made with citizens. Regarding the survey and R&D conducted with D and F, C. grasping the overall picture of ongoing survey and R&D also becomes necessary. R&D of companies developing diagnostics, vaccines, and therapeutics and R&D of Japan Agency for Medical Research and Development (AMED) need to be understood in a centralized way.

(3) Cooperative role (the MHLW Communicable Diseases Control Division): coordinate collaboration between the government and experts.

Up until now, only limited experts dealt with D and E at their own expense, and experts and companies handled F on their own accord. Going forward, the government may request them to do certain surveys and research depending on the situation of the pandemic that Japan faces at any given moment. For R&D also, the government could request certain diagnostics or therapeutics to be developed.

■ Up until now, decisions regarding communicable disease control tended to be made centering on Tokyo. But in rural areas, status of the pandemic and available structures for medical and nursing care provision vary among local governments. Network of experts must include people involved in communicable disease control in local governments so that the situation in rural areas can be known. This ideal state for emergency

situations should be required both on a prefectural and municipality level.

■ A system should be created for inspection based on records to ensure legitimacy of the ideal state during emergency situations by checking if the three parties were functioning properly. In particular, it must be transparent on whether or not measures for communicable diseases proposed by the network of experts were adopted. In normal times, a third-party review committee should be set up to assess with a high level of transparency based on records whether the three parties are functioning.

[Ideal command post: In normal times (proposed)]

The ideal state during emergency situations should be agreed upon in advance mainly by three parties, i.e., the agency in the cabinet for communicable disease crisis management, a network of experts and the R&D-related network, and the MHLW Communicable Diseases Control Division.

■ Function of the three parties in normal times

(1) Strategy planning unit (network of experts): strengthen commitment to antimicrobial resistance (AMR), communicable disease control against tuberculosis and sexually transmitted diseases, and UHC to support such measures during opportunities on a global scale such as G7 gatherings where international relations can be built. Establish a network for various experts in Japan to cooperate in emergency situations and conduct information exchange on a regular basis. Gather information on communicable diseases occurring outside of Japan and make risk assessments and plan strategies. Then as necessary, propose measures against communicable diseases and strategy plans.

R&D unit (R&D-related network): establish a structure for clinical trials in advance so that speedy clinical studies can be conducted both in Japan and abroad during emergency situations in communicable disease crises. Diversify procurement routes and strengthen supply chains in advance so that raw materials and resources necessary for manufacturing diagnostics, vaccines, and therapeutics, and vaccines can be procured in emergency situations. Also strengthen establishment of bases necessary for manufacturing and fostering human resources. Then, propose R&D as necessary.

(2) Command post (agency in the cabinet for communicable disease crisis management): prepare laws, secure financial resources, and develop human resources for times of crisis in communicable disease emergencies. Establish the network of experts and the R&D-related network so that they function in emergency situations. Make preparations to strengthen surge capacity for elevated states in emergency situations for related organizations such as medical institutions and health centers, and promote activities that are easy to understand when informing the public about communicable diseases, fully utilizing private sector and other funding.

(3) Cooperative role (the MHLW Communicable Diseases Control Division): coordinate collaboration between the government and experts.

[What is anticipated with the establishment of a command post]

■ For the command post to function successfully, it must (1) secure financial resources and position appropriate human resources in the command post for proper functioning both in emergency situations and in normal times, and (2) foster human resources strategically within industry, government, and academia so

that the command post and network of experts function as they should.

■ By setting up a functioning, ideal command post in emergency situations and in normal times as declared in the emergency recommendation, the following can be anticipated:

- (1) Communicable disease control can be practically and resourcefully implemented, minimizing the effects communicable diseases pose on Japan's socioeconomic activities, which can be expected to lead to economic growth in Japan.
- (2) The 100 Days Mission announced at the G7 Summit and speedy deployment of vaccines, therapeutics, and diagnostics made in Japan become achievable. This can be expected to allow socioeconomic activities to resume at the fastest possible time and lead to economic growth for Japan.
- (3) Make use of Japan's limited resources, use tax funds efficiently and resourcefully, leading to consent among citizens.
- (4) First establish the crisis management structure for communicable disease crises that will help in the medium term to create an all-hazards crisis management structure to respond to all types of emergencies, including natural disasters, nuclear accidents, transport accidents, crime, terrorism, conflict, and war.

1-2. R&D for Vaccines, Therapeutics, and Diagnostics - To Achieve the 100 Days Mission

[Background]

R&D for diagnostics, vaccines, and therapeutics for COVID-19 progressed at an unprecedented speed. However, if diagnostics and vaccines were available even faster, the number of cases and deaths would be lower and could lead to a faster end to spread of the disease with less socioeconomic effect.

The 100 Days Mission was announced in June 2021 at the Group of Seven (G7) industrialized nations summit held in the U.K. It aims to achieve deployment of medical countermeasures (MCM) including medicine for crisis response such as diagnostics (Dx), vaccines (Vx), and therapeutics (Tx) within 100 days of the World Health Organization (WHO) declaring a public health emergency of international concern. With the 100 Days Mission, assuring equal access and delivery (A&D) of MCM throughout the world, including low-income countries, is also a goal. To achieve the 100 Days Mission, 25 actionable recommendations were made at the G7 Summit in the U.K. for governments, industry, philanthropic organizations, civil society and international organizations to take. At present, the secretariat for the 100 Days Mission is temporarily set up in the U.K., monitoring progress of the 25 actionable recommendations.

Japan will host the G7 Summit in 2023. Japan must gain a diplomatic perspective on how it can contribute to achieving the 100 Day Mission. Taking into account a lack of its own COVID-19 vaccine at present, Japan must also take a domestic affairs perspective on how it can strengthen its pharmaceutical industry structure to contribute to the 100 Days Mission.

The Nikkei FT Communicable Diseases Conference was an opportunity to discuss issues facing Japan in

achieving the 100 Days Mission and preparing for future pandemics, and what contributions can be made and the actions required by industry, academia and government from their respective standpoints, all putting into consideration Japan's inability to provide diagnostics to the world in the early stages of COVID-19 and the lack at present of its own developed and deployed vaccines and therapeutics.

[Issues]

R&D in Japan for MCM against COVID-19 faced many issues. First, risk assessment of communicable diseases showing what pathogens led to pandemics was not sufficiently being conducted during normal times, and participation in global intelligence was also insufficient, which caused a delay in moving forward. There was also no system in place for centralized information gathering regarding where and what kind of R&D was taking place. Clinical development took too much time since platforms were not in place to conduct clinical trials of therapeutics and vaccines for communicable diseases, especially a structure for conducting a large-scaled placebo-controlled clinical study on a global scale for vaccines. Though medical institutions designated for communicable diseases who treat patients are expected to play a central role in clinical studies for communicable disease therapeutics, they do not have sufficient human resources and facilities especially during a pandemic, which caused R&D functions to be weak. With no structure in place to guarantee profit such as with pull incentives, vaccines as a business means poor profitability and predictability for companies in Japan, making it difficult for them to maintain manufacturing bases, raw materials, resources, and human resources. Supply chains for raw materials and resources in particular rely on overseas sources, and procurement itself becomes difficult in times of communicable disease crises.

In light of these issues, the Japanese government approved the Strategy for Strengthening the Vaccine Development and Production System in June 2021. Based on this strategy, the government established the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) within the Japan Agency for Medical Research and Development (AMED). At SCARDA, R&D for vaccines and new modalities and formation of a global top-class R&D base for vaccine development are taking place.

However, strengthening strategy for the development and manufacturing structure applies only for vaccines, not for diagnostics and therapeutics. Also, SCARDA in its current scope is limited to R&D only, and the steps before and after that, i.e. upstream information gathering to downstream regulatory, manufacturing, stockpiling, distribution, and other areas, are not included. For Japanese corporations to truly contribute to the 100 Days Mission, domestic structure must be strengthened further. In collaboration with such activities, the Japanese government should take the following action to promote R&D of MCM in Japan toward achieving the 100 Days Mission.

[Actions required]

Efforts in R&D of communicable diseases so far have mainly been separated for differing diseases such as tuberculosis and malaria, but COVID-19 became an incentive to reaffirm gravity of communicable diseases including emerging diseases. Initiatives against communicable diseases collectively are necessary.

(1) Strengthen the domestic structure including human resources development

Strengthen domestic structure - link with industry and security policies -

- Human resources are key in emergency responses to public health crises and addressing the 100 Days

Mission. Fostering human resources has conventionally taken place individually among companies and organizations, but human resource development should be handled uniformly across sectors throughout Japan. At the same time, since response by Japan by itself has limits, it is important to cooperate with other countries in an organic and agile manner. It is important to develop human resources both comprehensively throughout Japan and in cooperation with other countries so that Japan can dispatch human resources able to play a vital role in international-level decision-making for communicable disease control to international institutions and organizations.

- To realize the 100 Days Mission and speed up A&D, as well as to strengthen the structure for communicable disease control in emergency situations, the government is to formulate policies and strategies comprehensively including for diagnostics and therapeutics. In doing so, MCM is a field that must be addressed as a nation from the perspective of national security despite its poor marketability in normal times. Therefore, it is key to establish industrial policies for MCM (MCM policies), have the government lead formation of a market for MCM, and prepare a business environment for corporations.
- As an example, the government should create an MCM fund over multiple fiscal years that would guarantee business certainty for companies. Such measures to provide incentives for corporations are being carried out in the defense and semiconductor industries. The government should apply the same measures for corporate development that are being utilized in such industries for the MCM field as well.
- As MCM policies rest on several government agencies such as the Ministry of Health, Labour and Welfare and the Ministry of Economics, Trade and Industry, the agency in the cabinet for communicable disease crisis management to be newly established should take charge in integrating MCM policies of the government, coordinating with the National Security Council.

Promote cooperation with the Asian region

- Japan is in an advantageous position within Asia geopolitically and from an international strategy perspective. The fact that many pandemics in the past have originated in Asia makes it significantly meaningful to focus on covering Asia. Including cooperating with the ASEAN Center for Public Health Emergencies and Emerging Diseases (ACPHEED), cooperation and collaboration with Asia on matters from R&D of MCM to its manufacturing, supply, and access, are put into consideration.
- For example, a structure could be created for international cooperation in clinical trials mainly in the Asian region, strengthening of manufacturing capabilities in Asian countries can be promoted through technical transfer and other methods, and regulatory coherence within the Asian region can be arranged in advance. Japanese corporations can study how to enable such entry into Asian countries in advance through cooperation among industry, academia, government, and private sectors.
- At the same time, it is difficult for the MCM value chain to be complete by a single country. We also must rid ourselves of the concept to complete it all within Japan, and consider how to promote cooperation with other countries organically for critical points within the value chain.

(2) Formulate specific actions

By delving into discussions among industry, government and academia cooperation including the

government, analyzing gaps in achieving the 100 Days Mission and identifying issues as well as setting future goals and creating specific action plans to achieve them can be accomplished.

To prevent, prepare, and respond to communicable disease crises can be considered to be a business opportunity for Japanese corporations. It is necessary to be speedy and strategic accordingly. While placing weight on health and economic security during emergency situations in Japan, policies, strategies, and an even more specific action plan should be created in advance through cooperation with the Japan International Cooperation Agency (JICA), etc. as to how to undergo international collaboration and cooperation.

R&D

- The role that start-up companies play in R&D for MCM is significant. However, when looking at the global market, Japan's bio startups do not necessarily have a strong presence, so developing such startups should be further promoted.
- In recent years, the trend has been for not one major corporation to take charge of everything from R&D to manufacturing of MCM, but rather for several companies to share the work by processes in a horizontal division of labor. In developing startups, it is necessary in Japan for a perspective to encourage bio startups becoming actively incorporated into MCM value chains horizontally.

Clinical trials and drugs regulations

- Japanese pharmaceutical companies and bio startups should take initiatives in advance so that they are able to conduct international joint clinical trials on a global scale during emergency situations. Specifically, a network should be established for global clinical trials for vaccines and a structure created for endemic areas to participate in clinical trials.
- So that international joint clinical trials can be conducted globally in emergency situations, and based on their results, vaccines and therapeutics can be approved in each country and region, it is necessary to promote coherence of regulations in advance.

Manufacturing and Procurement

- Manufacturing and procurement of MCM are also important. In addition to strengthening R&D of pharmaceutical companies, it is therefore important to strengthen manufacturing capability of companies including contract manufacturing organizations (CMO) for vaccines, therapeutics, and diagnostics. It is necessary in that case to check all processes, from securing raw materials and resources to mass manufacturing, development and approval, and supply. Methods for development, manufacturing, and supply to be carried out efficiently, effectively and rapidly should be considered and prepared. There is also a need for policies that will establish a mechanism for joint procurement between Japan and places such as the Biomedical Advanced Research and Development Authority (BARDA) in the U.S. and the Health Emergency Preparedness and Response Authority (HERA) in Europe.
- It is important to strengthen manufacturing bases for vaccines in Japan in advance so that diagnostics, therapeutics, and vaccines developed in Japan and abroad for emergency situations can be manufactured in Japan and distributed globally through cooperation with BARDA, HERA, and similar entities in Asian countries. Supply chains should also be established in Japan for raw materials and resources.
- Specific measures should be created for pull incentives, where the government purchases and stockpiles

vaccines and therapeutics manufactured by companies so they can secure profits, or provide vaccines through the framework of official development assistance (ODA).

- The policy for stockpiling MCM that reflect the purchasing pattern of the Japanese government is not standardized, and is insufficient for guaranteeing companies' business certainty. The government should clarify the perception of threats in Japan and also raise certainty for the business of companies by standardizing its stockpile criteria for MCM.

(3) 100 Days Mission - Therapeutics, diagnostics -

- While discussions around vaccine R&D continue internationally and in Japan, the same cannot be said for therapeutics and diagnostics. Japan is strong in development of diagnostics and rapid test agents, so the GHIT Fund and others should be utilized to take on international leadership and role in coordination to achieve the 100 Days Mission for diagnostics.

- Establish a structure to provide diagnostics and rapid test agents which are Japan's strengths in particular, not only domestically but to other countries, and to make them available for use by the community instead of just by medical institutions. Also make technology such as Japan's digital-based diagnostic imaging available for diagnosing and testing.

(4) Access and delivery (A&D)

- Japanese corporations possess technology contributing to vaccines for easy management and use in developing countries, such as technology for administering intradermal and intranasal immunization. The development of vaccines is suited for A&D in developing countries, since the vaccines do not require low temperatures in transport and storage like mRNA vaccines do. Japan should also consider the development of effective vaccines from an A&D perspective.

(5) Funding needs and procurement methods

- To achieve the 100 Days Mission and A&D, analyze what funding is required in which part, and the current status and gaps, while discussing funding needs and procurement methods to create an action plan. Funding does not need to be limited to sources in Japan when doing so. Funding also needs to be considered from international organizations such as the Coalition for Epidemic Preparedness Innovation (CEPI) as well as venture capital (VC) in Japan and abroad. At the same time, startups and pharmaceutical companies in Japan should participate in the overall global R&D ecosystem and also consider ways to bring funding into Japan from abroad.

1-3. Crisis Response for Communicable Diseases, Etc. With Active Participation by Consenting Citizens

[What behavioral science and social marketing shows]

For citizens to understand concepts behind each other's behaviors and agree for the most part on directionality of measures regarding communicable diseases measures, it is effective to use knowledge from behavioral science such as social marketing, and to exchange opinions and communicate information appropriately.

Once a certain level of agreement has been reached, it is important for state and local governments to

change the communicator of information and what is being conveyed, depending on the target and nature of the desired behavior. By doing so, consent among the people will increase, and by changing their own behavior, they can come to feel value in themselves and society which can lead to efficacy of measures.

[Dilemmas faced by society]

At the start of the pandemic in 2020, information available was extremely limited and people feared the unknown disease, so it was easy to see what society would do. But as the pandemic prolonged, information about the communicable disease became known and people accumulated experiences. Perspectives on COVID-19 diversified driven by individual values and experiences, and directionality of society as a whole became unclear.

Many measures have been taken by state and local governments to encourage behavior change among individuals and participation by citizens. For example, the model for stages of behavior change was utilized for vaccinations in Sumida Ward, Tokyo, which encouraged citizens to participate and led to a high rate of vaccination at an early stage.

Tokyo Metropolis set up the Tokyo Center for Infectious Disease Control and Prevention (iCDC) in October 2020. Since its establishment, the Tokyo iCDC has conducted PR, public information gathering, and dialogue continuously as part of risk communication activities. Surveys among citizens have been conducted seven times so far, and interviews with single parents as well as other segment bases have been selected for group interviews. Results have been shared with the governor and relevant departments, and reflected into measures.

There have been cases where citizens themselves, and not the government, led efforts with their awareness of issues. In Okinawa, the Okinawa Yagumai Project was set up by young volunteers, and the COVID-19 Task Force Okinawa was created among volunteers from the prefecture's medical, economic, welfare, and educational sectors.

While such activity took place among certain parts of Japan, the country as a whole cannot be perceived as successfully having created a mechanism functioning sufficiently in leading to behavior change among individuals and society through communication. The country as a whole was unable to overcome hurdles and issues as seen below.

- (1) The medical system was unable to provide regular treatment as it worked to save as many lives as possible during the pandemic, and patients are being forced to choose a different option under the circumstances. In the latter phase of the pandemic, opinions emerged that suggest a conflicting structure between the economy and the medical system, making medical providers choose whether to prioritize COVID treatment or regular medicine.
- (2) Various types of testing were conducted, but with a break in communication and a lack of consent from regional communities, several testing options had issues of efficacy. For example, issues arose with tests targeting individuals working in red light districts when incentive for testing was insufficient and when testing got a bad reputation. Wastewater surveillance met issues with reputation and its horizontal expansion to other areas was difficult.
- (3) Japan faced great difficulty communicating information in the unprecedented crisis. Especially at the beginning of the pandemic, the spread of misinformation, when the nature of the virus and treatment methods were not known, was a problem. How to communicate information and elevate literacy of the receiving end of the information became issues.
- (4) The government created COCOA, a contact tracing app, but because it was made so that no information

on individuals could be collected, it was not effectively linked to other related systems, making it unsuccessful as an app to confirm status of the pandemic. As a result, a PDCA cycle did not result and efficacy as an app did not come to fruition.

[Actions required]

<Short-term>

- (1) Reach a certain level of agreement regarding an exit strategy for COVID-19. For that, prepare a forum for dialogue among citizens, decision makers, and experts. Related parties including civil groups, NPOs, universities and other academia to host. Initially, several local governments would hold the discussions, and spread out from there.
- (2) Make practical guidelines for using behavioral science and social marketing.

<Medium-term>

- (1) To increase implementation of state and local government measures, foster experts in behavioral science and social marketing. Secure funding to do so.
- (2) Consider development of a digital platform such as an app that can be used in normal times, and diverted in emergency situations. (Assume utilization online as a remote, non-contact, distribution-type digital dialogue/ communication tool)

2. Contributing to Global Health

- For Japan to Play a Leading Role in Times of Crisis

2-1. Tuberculosis, Malaria, Neglected Tropical Diseases, Nutrition, and Immunization

- Innovations from Industry-Government-Academia Collaboration Stemming from the COVID-19 Experience

Awareness is growing regarding the need for measures against existing communicable diseases, such as tuberculosis, malaria and neglected tropical diseases (NTD), and not just COVID-19. Consortia for tuberculosis and malaria have continued to be active after the Nikkei FT Communicable Diseases Conference held last November. An NTD consortium was also newly established to have many deliberations, and a portion related to nutrition and immunity was newly created this time. During the session, each consortium presented results of deliberations, and reported on recommendations to be made at the G7 Summit to be held in Japan next year.

The tuberculosis consortium explained the target set by WHO to reduce tuberculosis cases by 80% and deaths by 90% by 2030 in line with SDGs. Activities by industry, academia, and government to prevent the spread of diseases in Africa and Asia, as well as technological development and deployment of therapeutics, test agents, etc. toward achieving the target, were reported on. Specifically, Eiken Chemical's TB LAMP test agent was approved by the WHO and is deployed in six countries through budget from the Global Fund. Nipro's genetic test agent for multi-drug resistant tuberculosis and others have also received WHO approval. Otsuka Pharmaceutical's new therapeutics for multi-drug resistant tuberculosis are being used in over 120 countries worldwide, and a pediatric formulation has been approved in Europe in 2021. It appears in the WHO's Essential Medicines List. Konica Minolta's diagnostic imaging equipment using artificial intelligence (AI) and Fuji Film's super compact x-ray equipment have also been made available, examples that products created by Japanese corporations are preventing infections in communities.

The Ministry of Foreign Affairs explained the policy of the Japanese government to allocate up to USD 1.08 billion over the next three years toward ending the three major infectious diseases including tuberculosis by 2030. It also reported that as the host of the G7 Summit in 2023, Japan will make proposals in three areas, namely (1) create a global health architecture related to health equipment, (2) lead efforts toward achieving universal health coverage, and (3) innovation.

From the NTD consortium, measures being taken that target 20 infectious diseases were presented. It was emphasized that three pillars are necessary for measures against communicable diseases: (1) combat poverty; (2) strengthen measures for public health; and (3) gain public support for R&D. It was pointed out that Japan is in a very advantageous position. A case example was given with topical medicine for jigger infestations developed by Saraya, which is scheduled to be approved for Kenya shortly and deployed as early as next year. Even as R&D for therapeutics is progressing, a structure to provide the medicine swiftly to patients remains an issue. It was also reported that recommendations on access and delivery of test agents and therapeutics were made in advance of next year's G7 Summit.

Information was also provided on action being taken by the malaria consortium in the fields of vector control, diagnosis, and drug discovery through cooperation among Japan's industry, academia, and government. According to the Asian task force, Sysmex's diagnostic tool XN-31 received regulatory approval in Japan in 2020 and gained insurance coverage by 2021. Eiken Chemical's LAMP test was approved in 2021 as one of several diagnostic standards for Japan, then gained approval for Europe in August 2022. Both companies are conducting performance evaluation tests for commercialization at Mahidol University, a base for clinical research overseas under the National Center for Global Health and Medicine (NCGM). It was also explained that Neopharma Japan is conducting clinical research to develop therapeutics.

The African task force reported that to handle the presence of asymptomatic patients and mosquitos that can resist pesticides, which both cause spread of communicable diseases in the Lake Victoria area of Kenya located on the eastern side of Africa, they aim for comprehensive extermination efforts such as mass drug administration and mosquito control. Finally, the African business consortium reported on the start of an integrated approach against malnutrition, anemia, and malaria by a cross-industry, co-creation project (Sysmex, The Ajinomoto Foundation, NEC) to improve maternal and child health and nutrition in the Republic of Ghana. It was pointed out that going forward, coordinating and expansion with international organizations on results by the task force need to be addressed.

Specific activities and initiatives were introduced for nutrition and immunity after an explanation of the aim to heighten comprehensive ability of measures against communicable diseases through food culture and fermentation nutritional technology that are strongholds of Japan. The Ajinomoto Foundation is working to improve nutritional status in Ghana through food, and examples of initiatives to prevent developmental disorders were presented. It was pointed out that leveraging the latest technologies such as data analysis with AI and surveillance would be key going forward.

2-2. Cooperation Among Developed Countries in the Fight Against AMR

The annual number of deaths from communicable diseases caused by bacterias 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 bacterias with AMR. On the other hand, new development of antimicrobial drugs for treating communicable diseases caused by bacterias with AMR 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. Aiming to secure profitability through assistance after a drug is approved and by creating pull incentives for continuous support of R&D, the AMR consortium was formed as the fifth consortium for the Asia Africa Medical Innovation Consortium (AMIC). The consortium released a document in March 2021 proposing to the government the implementation of a system for pull incentives in the antimicrobial drug market and initiated activities to recommend it.

At the conference, it was reported that the consortium submitted a proposal to the Minister of Foreign

Affairs and the Minister of Health, Labour and Welfare prepared in advance of the 2023 G7 Summit in Hiroshima. An official from the Federal Ministry of Health of this year's host country, Germany, explained that all countries agreed to strengthen the surveillance system and raise awareness regarding the use of antimicrobial drugs, and the importance of promoting innovation for the R&D of new drugs. The U.K. indicated that they have employed pull incentives and confirmed a certain level of effectiveness, expressing hope for Japan as the next host country to set milestones toward achieving the incentives system.

The clinical forefront spoke about the presence of antimicrobial drugs as a condition of modern medicine such as advanced surgery and chemotherapy, and reported that antimicrobial resistance is a big issue in the three major communicable diseases as well. The corporate side spoke of pull incentives enabling a prevention of linking the dosage of antimicrobial drugs with sales, allowing for proper amounts to be used and a certain level of manufacturing quantity to become foreseeable. This heightens economic predictability and the suggestion by many of an environment being created allowing more investment for companies that will develop antimicrobial and other drugs to treat communicable diseases. In Japan, a budget for pull incentives has been added to the appropriations request for the next fiscal year, and discussions were held regarding the source of funding. The proposal by the consortium estimates 20-80 billion yen in total per drug (with payment period of ten years, two to eight billion yen per year), and discussions were held regarding the amount to be borne by Japan in terms of fair share in which countries contribute a share amount that is equally fair based on GDP or other measure, referencing recent academic studies.

The government reported that work is taking place on revising Japan's action plan formulated in 2016, in consideration of the achievement status for antimicrobial drugs dosage and other numerical targets. It was also revealed that the next plan is to be completed within FY2022, and AMR is being given weight in the agenda for next year's G7 Summit. To achieve implementation of pull incentives and for efficacy of AMR measures, all agreed that deployment of the next plan should be made clear and Japan must show leadership at the G7 and that the consortium would fulfill its role.

2-3. Expectations for Japan Regarding UHC - What to Do in Advance of the G7 Summit in Hiroshima

Universal health coverage (UHC) is a comprehensive policy concept that aims for all people to have access to effective and quality health services without financial hardship. To achieve UHC, access in three areas must be improved, namely physical access to medical institutions and medicine, economic access for medical fees, and social access including language and customs. The U.N.'s sustainable development goals (SDGs) aim to achieve UHC by 2030.

UHC is the foundation for measures against communicable diseases, such as tuberculosis and malaria.

[Background and issues]

Japan's universal health insurance started in 1961, achieving UHC at an early stage. At the 2016 Summit in Ise-Shima, host country Japan made the promotion of UHC the main theme for the first time at a G7 Summit. Japan has supported the promotion of UHC in Asia, Africa, etc. and has led the international debate.

COVID-19 has seriously affected countries with a weak health system in particular. Vaccine inequality, etc. arose between developed countries and developing countries. Many people are unable to receive basic medical services, and poverty has spread.

Developing countries have especially been deeply impacted. For example, low income countries have a declining rate of vaccinations. In 57 low income countries supported by Gavi, the Vaccine Alliance, the rate of children receiving immunizations decreased by 5 percentage points to 77% since the start of the pandemic.

Even in Japan where UHC has been achieved, weaknesses in crisis management came to light. Health centers and local health research facilities that are bases for primary care played a part in measures against clusters with backward active epidemiological surveys. But as the structure for medical provision emphasized nursing care and supporting daily life for the elderly, preparation for treating acute illnesses including communicable diseases was not sufficient, leading to severe strain in medical care. There was no system functioning to immediately gather information pertaining those infected, and a delay in development of domestic vaccines and therapeutics revealed a serious problem with crisis management. We need to be aware that Japan is not in a position of superiority internationally in terms of crisis management.

Diseases such as tuberculosis and malaria continue to be widespread in countries around the world, and the silent pandemic associated with AMR is also spreading. However, now having experienced COVID-19 for three years, political momentum for UHC on a global scale is not being maintained and in fact, is starting to wane.

Japan as the host of the 2023 G7 Summit is now in a position to lead this debate on UHC.

[Actions required]

Propose projects, at the G7 Summit in May 2023, for helping solve issues that participating countries share within the large framework of UHC. To do so, recommend policies incorporating logistics and distribution for the 100 Days Mission. Use this to share specific case examples with the international community for prevention and preparedness for UHC.

3. Conclusive Words

As the COVID-19 pandemic continues for three years around the world, each person from the medical front, corporations, government, and expert organizations participating in the Nikkei FT Communicable Diseases Conference possesses experience having closely dealt with communicable diseases from their respective positions. It is now important for the government to seize the opportunity to strengthen its function as the command post for communicable diseases to communicate and utilize the on-site experience gained. The emergency recommendation incorporated in the statement at this time is a proposal by the conference embodying such in detail. Participants of the ninth round of the Nikkei FT Communicable Diseases Conference agreed to this statement.

End

4. Appendix

The Nikkei FT Communicable Diseases Conference conducted an awareness survey online regarding COVID-19 in August 2022 on 1,000 men and women aged 20 to 69.

The main points of the results are outlined below:

(Edited based on presentation material by Professor Yoko Uryuhara of Doshisha University who supervised and analyzed the survey)

(Hesitation to vaccinate, intention to vaccinate next time)

- Seventy-three percent of respondents did not hesitate to vaccinate for the first and second doses.
- Those who did not hesitate were more likely than those who did to
 - believed that vaccination was effective in preventing infection and severity of disease.
 - expected the vaccine to be effective in preventing serious infections, even if there were adverse reactions.
- Among 854 individuals who received at least the first dose, 56.5% intended to get another (plan to or have already booked second vaccination).
- The degree of convincing with **previous vaccination, external behavioral** were statistically significant for the intention to vaccinate next time, indicating that the higher the degree of convincing, the higher the intention to vaccinate next time.

< Degree of convincing in infection control behaviour (Voluntary infection control behaviour) >

- Degree of convincing in voluntary infection control behavior: mean 5.61 (7-point scale).
- The most highly convinced (very convincing ~ fairly convincing) were “washing hands and gargling when going home” (87.3%), “regular ventilation” (86.4%) and “staying away from crowds and being aware of social distance” (84.9%).

< Degree of convincing in infection control behaviour (vaccination behaviour). >

- Degree of convincing in vaccination behavior: mean 5.11 (7-point scale).
- Even those with a high degree of convinced about vaccination thought that adverse reactions were hard to deal with. It was suggested that the key is to raise awareness that the vaccine is expected to prevent serious disease, even if there are adverse reactions, and to avoid misleading people into thinking that adverse reactions are more serious than the symptoms of infection.

<Degree of convincing with infection control behaviour (external behavioural restrictions)>

- Degree of convincing in external behavioural restrictions: mean 4.86.

<Degree of convincing with infection control behaviour (lack of systems in place)>

- Degree of convincing in lack of systems in place: mean 4.06 (7-point scale).
- The highest rate of non-conviction was 'hoaxes and misinformation on social networking sites' (39.0%) followed by effect on treatment of illnesses other than COVID-19 (31.4%) and inability to be tested when

spread of diseases was at high levels (29.7%).

<Messengers to increase conviction>

- Messengers to increase conviction need to vary according to the behaviour they want to encourage.
- Influence of 'family and friends' in all behaviours.
- Messengers to increase conviction for Voluntary infectious behaviour: infectious disease professionals > family and friends
- Messengers to increase conviction for Vaccination behaviour: infectious disease experts > heads of local government > managers in the organization > family and friends
- Messengers to increase conviction for External behavioural restrictions: infectious disease professionals > family and friends
- Messengers to increase conviction regarding Lack of systems: politicians > Ministry of Health, Labour and Welfare and other government > Community influencers > Family and friends

<Information to increase conviction>

- The content of the transmission to increase conviction need to vary according to the behaviour they want to encourage.
- Information to increase conviction for voluntary infection behaviour: information on scientific evidence, various examples of people who have behaved.
- Information to increase conviction for vaccination behaviour Information clearly stating what the disadvantages are of not vaccinating.
- Information to increase conviction for external restrictions on action: Information that makes them proud to behave, information that aligns the politician's actions with the demands of the people.
- Information to increase conviction regarding lack of system: Information that makes them proud to behave, information that aligns the politician's actions with the demands of the people, and information that shows specifically how they should act.

<Message to increase conviction>

- The message to increase conviction need to vary according to the behaviour they want to encourage.
- Message to increase conviction for voluntary infectious behaviour: gain frame, peer effects.
- Message to increase conviction for vaccination behaviour: scientific efficacy, gain frames and social norms.
- Message to increase conviction for external action restrictions: loss frames.
- Message to increase conviction for lack of systems: loss frame, peer effects.

<Measures to increase conviction>

- Common measures desired by people to increase their conviction were the establishment of local centers where they could easily ask about infection control behaviours, and a system to visualize the real situation in each hospital and health center.
- Measures to increase conviction for voluntary infectious behaviour: a mechanism for visualizing and publicizing the results achieved by citizens working together.
- Measures to increase conviction for vaccination behaviour: a system for everyone to share and utilize good practice on outstanding initiatives of communities.
- Measures to increase conviction for external restrictions on action: mechanisms for people taking infection

control behaviours to gain qualifications.

- Measures to increase conviction for lack of systems: mechanism for people's representatives to participate in national and municipal meetings on infectious disease control.

The 9th Nikkei FT Communicable Diseases Conference

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<Reference Material>

Summary of the 9th Nikkei FT Communicable Diseases Conference Special Sessions / Breakout Sessions

■ Special Session 1 (Daiichi Sankyo Co., Ltd.): Issues in vaccine development and new challenges for future pandemics

Vaccine development progressed at an unprecedented speed around the world against the COVID-19 pandemic crisis. Including initiatives with new technology in mRNA vaccines, Europe and the United States had been preparing for new diseases in advance. In the United States, vaccine development was underway by the industry, government, and academia under strong leadership and large-scaled public funding as a national project. As a result, pharmaceutical and biotechnology companies in Europe and the United States deployed vaccines in only eleven months after genome sequencing.

In contrast, Japan's pharmaceutical and biotechnology companies have been late in deploying domestic vaccines.

Vaccines are positioned as an important strategic resource for national security while also being an effective defensive measure against communicable diseases. To respond to a pandemic, R&D and technological development ability that enable domestic manufacturing under a command post functioning in a nation with strong leadership are essential. To prepare for emergency situations in the form of future pandemics, issues uncovered by COVID-19 must be reviewed so that initiatives can be taken in advance by industry, government, and academia to overcome those issues. To date, vaccine manufacturers in Japan have not had opportunities to mutually share issues with the government and discuss ways to resolve those issues. As this is a factor in the delay of vaccine development in Japan, a structure for government and private sectors to continuously hold dialogue must be newly established, and initiatives taken to resolve issues on a regular basis, as essential actions for speedy vaccine development and manufacturing when a pandemic hits.

The Japanese government approved the Strategy for Strengthening the Vaccine Development and Production System in June 2021. As part of this strategy, the government established the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) within the Japan Agency for Medical Research and Development (AMED) in March 2022, proceeding to develop a base for academia. Going forward, it is important that public funding for fundamental research in communicable diseases and vaccines are heavily invested in advance, that academia and corporations to cooperate, and that efforts are made for technological development and fostering human resources.

It is also essential to create a structure in advance for vaccine businesses to function, and to establish policies that will help pharmaceutical and biotechnology companies in Japan, with the government requesting development of vaccines for priority diseases and buying up developed vaccines as stockpile. Additionally, as it was difficult for large-scaled international joint clinical trials to be conducted globally by Japanese pharmaceutical and biotechnology companies, a network should be established for global clinical trials for vaccines and coherence of regulations promoted in advance. It is believed a scheme for academia to analyze samples from patients collected in clinical trials at an early stage and evaluate efficacy of vaccines must be considered.

It is vital to aim for the creation of a new vaccine ecosystem in the medium- to long-term with continuous effort by industry, government, and academia so that development of vaccines in Japan can start with urgency when future pandemics strike and for speedy provision to citizens.

■ **Special Session 2 (Pfizer Japan Inc.): Accelerating R&D for manufacturing novel vaccine with mRNA technology in Japan**

~ Think through experiences of COVID-19 and a perspective of Global-Health ~

The latest pandemic has made it clear that global cooperation and candid partnerships are essential in the development and manufacturing of superior vaccines, and that the fight against communicable diseases should be one for which the entire world unites.

German startup BioNTech and U.S. company Pfizer have been cooperating on developing influenza mRNA vaccines since 2018, and the vaccine they developed for COVID-19 can be said to be a result of open innovation. mRNA technology which was the basis for the creation was developed by Katalin Kariko from Hungary, but researchers from Japan also played a part. Vaccines are manufactured by a network that spans the globe, with ingredients for manufacture originating in many countries throughout the world.

It is of course important to have a structure in place for vaccines to be developed solely in Japan, but to achieve initiatives like the 100 Days Mission, Japan will need to be actively involved in global networks and be expected to play a part in making vaccines. However, Japanese corporations will need to have a certain level of ability to do so. An element of national security is contained in vaccines for pandemics that may arise in the future. Establishing domestic manufacturing bases in advance will allow Japan to contribute in international cooperation in an emergency situation.

The latest pandemic has made it evident what is essential in vaccine development. First there is agility, or speedy decision-making. Companies that succeeded in developing vaccines first made decisions early every time it was necessary, including making heavy prior investments knowing the risks, and action was taken just as early for development, manufacture, and requesting regulatory approval.

Also, development should not be random but rather conducted after the target product profile for R&D is identified, and it is important to have a structure in place in advance for vaccine clinical trials to take place in a speedy manner.

A voluminous amount of data was created related to the mRNA vaccine. It will also be important to have a structure in place to analyze and share such real-world data and be able to monitor efficacy and safety of vaccines.

■ **Special Session 3 (ICheck): Infectious disease screening: Considerations for the post-COVID era**

How will initiatives globally to end a pandemic benefit future society? Research outcome for cholera, which to this day causes two million fatalities every year, is being accumulated over the past 40 years toward its eradication, and leading-edge research work has been presented regarding everything from the mechanism of outbreaks to the predicting of pandemics, with data including sea surface temperature, humidity, and human density utilizing satellites. That knowledge combines analysis of virus present in regional community's sewage found through drainage surveillance with risk forecasting to project the number of COVID-19 cases.

Meanwhile, with concentrated populations in cities and proceeding global warming, we are faced with a situation in which the threat of new diseases and how to prepare for them must be dealt with globally. Reflecting on past experience alone will be insufficient, and we will need to take a foresight approach in

unity throughout the world leveraging artificial intelligence (AI) and addressing several scenarios and how to manage them.

The pandemic in Japan peaked at 600,000 cases during the fifth COVID-19 wave in the summer of 2021. It was then that private corporation ICheck singlehandedly provided a package distributing 200,000 rapid antigen tests kits along with free PCR testing and online diagnosis. They also communicated and educated online proper understanding and decision-making, and such activities as a package were widely accepted by society. ICheck analyze that raising awareness of testing on an individual-level basis and encouraging speedy action was one of several factors that led to a relatively early end to the wave. From the United States, a status report was made on conditions including a low rate of booster shots and stockpiling behavior leading to a strain in medical care, as well as lack of medical supplies and daily items. Opinions were expressed that Japan was a good case to follow in educating the public which led to suppressed spread of the disease.

Many citizens voluntarily taking the rapid testing and the results being reflected into their mobile devices could potentially lead to predicting outbreaks in the future geopolitically. With the 100 Days Mission initiative globally to significantly reduce the time it takes to develop vaccines and therapeutics for new communicable diseases, the area that Japan can contribute to the most is with testing, and hopes were expressed that it would continue leveraging that strength.

**■ Special Session 4 (Moderna Japan Co., Ltd.): What is needed to be ready for the next pandemic?
The role of industry-government-academia cooperation**

The COVID-19 pandemic provided us with various knowledge into emerging diseases. The compatibility between pharmaceuticals and communicable diseases is one of them. Various available antiviral and anti-inflammatory medication were tested, but a lot of time was required to determine the proper method of use.

On the other hand, development at an early stage was achieved with positive results by the mRNA vaccine. The decline in number of deaths with the spread of the vaccine is evident from WHO data.

Non-pharmaceutical intervention in the form of calls to stay-at-home were effective. Japan's response to COVID-19, that is stay-at-home measures at the outset such as declaring a state of emergency and strategy to suppress spreading of the disease through aggressive vaccination after development of vaccines, was consequently a success. Meanwhile, strain on the medical system was an enormous problem.

Through such experience, the first thing we must address is swift vaccine development and expanding manufacturing and provision. For example, vaccine development should be accelerated for the 15 priority pathogens identified by the WHO (COVID-19, Ebola virus, malaria, etc.), and a system should be in place to conduct Phase 3 studies in no time during a pandemic.

Establishing a system for manufacturing and providing vaccines is also key. For rapid provision, a manufacturing base should be created in each of the five continents. The plants should manufacture various therapeutics using mRNA technology even in normal times, and ideas to keep the production line running at all times is important.

It is also true that a factor in the strain on the medical system was an uneven distribution of medical

resources. We could perhaps refer to the Fukushima model for a solution. This model divides medical institutions into four levels such as severe, mild, etc., and patients are transported depending on the severity of their symptoms. By sending patients to the relevant hospital based on changes in condition, efficiency in the use of medical resources was made possible.

Mankind has experienced numerous pandemics. And pandemics are a certainty in the future. It is essential that industry, government, academia, and private sectors throughout the world cooperate in preparation.

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

Strategies to end AIDS epidemic - multisector approaches as key enablers

AIDS was once considered the same as death, but now there are various drugs and treatment, allowing HIV positive patients to live long. However, there are still 1.5 million new infections each year around the world, and 650,000 people die an AIDS-related death.

In such conditions, the Joint United Nations Programme on HIV/AIDS (UNAIDS) is targeting the reduction of new infections and deaths to 370,000 and 250,000, respectively, by 2025. The specific strategy is to achieve “95-95-95.” This means 95% or more of individuals with HIV will be aware of their status, out of which 95% or more will receive proper treatment, and a further 95% or more out of that will achieve viral suppression. HIV patients for which viruses are no longer detected (U: Undetectable) will not be able to sexually transmit the disease (U: Untransmittable). This scientific fact is known as U=U. In Japan, after the spread of COVID-19, the number of tests conducted for HIV at health centers significantly decreased, and restrictions of the medical system made the time between HIV transmissions diagnosis and start of treatment very long, preventing achieving the first and second 95’s.

To see an end to the spread of AIDS, a 4-pillar strategy with a combination of U=U, promotion of testing, and the use of condoms, as well as the use of PrEP, would be effective. PrEP is pre-exposure prophylaxis against HIV, intended for use by individuals at high risk for contracting HIV. It is highly effective, and PrEP at present is approved in many countries as a preventive measures against HIV. Japan should also rush to approve it.

It is expected that the AIDS prevention guidelines in Japan which are the backbone of AIDS measures will be revised shortly. A structure to treat HIV positive patients has been established, and it will be important to prevent HIV along with other sexually transmitted diseases. To do so, mail-in testing, self-testing, and new methods such as PrEP should be spread and utilized, along with making target individuals for testing and prevention the key population, enhancing AIDS measures that take into consideration their viewpoints.

Development of drugs to cure HIV is also progressing. With HIV, viruses remain latent in immune cells, and since infection occurs continuously, it is a difficult disease to cure. Treatment is therefore being considered that would reactivate the latent viruses and proceed to remove those infected cells. There is a promising method that would combine the three elements of immunomodulating drugs, neutralizing antibodies, and therapeutic vaccines.

To end the spread of AIDS in Japan, initiatives by various sectors under government leadership, with society at the core, is anticipated.

■ **Special Session 6 (The Japan Pharmaceutical Manufacturers Association):**

Establishing a Drug Discovery Ecosystem for Infectious Disease Area

~ Focusing on Cooperation among Industry, Government, and Academia ~

COVID-19 infections spread quickly around the world since it emerged, but companies overseas developed highly effective vaccines at an unprecedented speed of under one year since the start of the pandemic. Behind this speed were continuous R&D support from the government, a high level of drug discovery ability, and speedy cooperation with major pharmaceutical companies and bio startups. To prepare for the next pandemic, Japan should also have such an environment ready, so that it can meet expectations it will succeed in constantly bringing about new drugs in the realm of communicable diseases.

With such problem awareness in mind, the government prepared in March 2022 a tentative list of priority diseases for communicable diseases that require securing the use of MCM such as medicine and medical equipment, that will serve as countermeasures for public health emergencies. The list includes 5 categories, for diseases based on whether they are completely unknown so far, new diseases that are related to ones that existed in the past like with COVID-19, diseases caused by bacterias with antimicrobial resistance (AMR), and other such groupings. Eight diseases were selected from among them and policies were formed to provide MCM R&D assistance and to stockpile, etc.

During the session, opinions were exchanged among industry, government, and academia as to how best investment and support should be provided for academia and bio startups that bear the seeds of revolutionary new drugs, in order to support the initial stages of drug discovery. Discussion was also held on pull incentives that could contribute to predictability in the antimicrobial drugs business as requirements that would make such investment and support fruitful. The clinical forefront offered opinion that local medical institutions providing care for infected patients also need human resources and facilities to engage in R&D. The venture capital side noted the importance in possessing technology that can be utilized other than for communicable diseases and in support for the creation of drug discovery seeds that will lead to continuous creation of startups, in light of the field of communicable diseases being generally difficult to invest in due to the unpredictability in demand and economic uncertainty.

Through discussions regarding drug discovery for communicable diseases, it was agreed that creating a system for pull incentives to raise certainty for businesses is vital. Also, creating a favorable cycle in the form of a drug discovery ecosystem is necessary by fostering drug discovery seeds for academia and bio startups by supporting venture capitals, and by institutional investors investing in startups that become listed or in major pharmaceutical companies that tie up with or acquire startups. Toward that end, fostering human resources to link various value chains is urgent, and it was unanimously agreed that it was important to elevate awareness of the value that discovery of drugs for communicable diseases would create with therapeutics including antimicrobial drugs, not only financially but also in terms of social value.

■ **Breakout Session A (Takeda Pharmaceutical Company Limited):**

Challenges and proposals for developing and producing vaccines made in Japan in preparation for unpredictable pandemic

With the spread of COVID-19, Takeda Pharmaceutical made the decision to import Moderna's mRNA vaccine to develop and supply it for Japan, and also develop, manufacture, and supply a vaccine from

Novavax's protein-based vaccine. The Novavax vaccine was authorized for use in Japan in April 2022. Authorization gained for manufacture and sale of the Moderna vaccine was transferred to Moderna Japan in August 2022.

Takeda had considered creating a vaccine in-house, but believed their utmost contribution would be to make any promising vaccine elsewhere in the world available in Japan soonest so that vaccination in Japan could start at the earliest possible time. Takeda Pharmaceutical has been developing and manufacturing vaccines since 1946 for commercialization in Japan, and such efforts led to the early collaborations with Moderna and Novavax.

Viruses mutate and cause changes in the infection and pathogen just as they did with COVID-19. It takes an enormous toll for manufacturing bases to continue developing vaccines for mutating diseases. Since procurement of raw materials rests on competing in global competition for the resources, public-private partnerships need to be enhanced. Being able to respond in emergency situations requires preparation and cooperation, and expectation rests on the government's command post functions.

To achieve the 100 Days Mission, it is important to stockpile vaccines and prototype vaccines* on a regular basis. To be of help not only for those in Japan but worldwide, manufacturing capabilities should be reinforced and prepared in advance.

R&D and establishment of a manufacture system for vaccines, which are biopharmaceuticals, require an enormous amount of investment, which is difficult for private corporations alone to cover. Long-term support by the government, including push incentives in the form of aid for R&D, and pull incentives such as purchase of product after it is approved and immunization plans, along with partnerships with other companies becomes vital. The importance in creating a business environment where innovation is rewarded in normal times is significant.

In preparation for the post-pandemic stage for a virus where the end of the pandemic is near, it is essential to raise the rate of vaccinations, and to maintain a perspective for the pandemic to not recur. It is important to lower the economic burden through immunization plans for the vaccines, and to enable an environment for as many people as possible to get vaccinated by giving them more choices in vaccines through improvements in currently available products as well as development of new vaccines.

*Prototype vaccine: a mock-up vaccine for speedy development and manufacture of a vaccine in a pandemic, for the future virus assuming changes to its strain

**■ Breakout Session B (The Research Foundation for Microbial Diseases of Osaka University):
Review infectious disease control in companies, applying learnings from COVID-19 pandemic**

Learnings from COVID-19 spanning a long period should be incorporated into the business continuity plan (BCP) formulated by a company for the event of a disaster or other emergency. The focus of BCPs created by many companies rests on assuring continuity of business that assumes natural disasters such as earthquakes and flooding, and what to do if business is in fact interrupted. Taking the experiences we have undergone over many stages since the original state of disarray faced in the wake of the COVID-19 pandemic, it is urgent that action to be taken is incorporated that assumes new pandemics in the future. For unforeseen pandemics going forward, a system enabling access to accurate information in a speedy manner is crucial in addition to maintaining risk communication with employees ahead of time.

What has changed with COVID-19 in terms of health management is that the head of companies have

become apt in decision-making to prioritize employee health over costs for the company, as evidenced by workplace vaccinations. Efforts in health management taking into consideration the health of employees throughout the supply chain are also starting to emerge.

The aging population of employees is sounding an alarm as an issue going forward. Analyses suggest that one of the factors to be so is that labor productivity in Japan is at a level only 60% compared with the United States or France, leading to unresolved health issues of workers. In particular, it is important to put measures in place against infections caused by bacteria such as *Helicobacter pylori* linked to cancer which is the top cause of deaths among groups middle-aged and over, and to incorporate testing and vaccination for rubella (5th phase immunization) into health exams for men born between April 2, 1962 and April 1, 1979 when immunizations were suspended, so that women desiring pregnancy can work in a safe health environment. It was emphasized that companies are tasked with creating an environment for employees to work energetically toward the future.

Having experienced the COVID-19 pandemic, it has become clear that measures are necessary that exceed conventional health management expectations in terms of compliance with laws and regulations, safety consideration obligations, and corporate social responsibility. The message delivered was that companies should move forward in implementing such measures taking them as investment for the future, not as costs.

■ Breakout Session C (FUMAKILLA Limited):

Personal care as a control of mosquito-borne diseases: Protect people's lives using mosquito insecticides and repellents.

The number of deaths from mosquito-borne malaria has decreased since 2000 with the spread of mosquito nets and therapeutics, but the rate of decrease has been leveling off since 2015. Diseases other than malaria such as zika and dengue are spreading worldwide and regions requiring measures against mosquito-borne diseases are only increasing.

The first choice in mosquito extermination is the use of pesticides. In areas where infections spread, the municipality is usually in charge of extermination activities, but in private spaces, residents are forced to handle it themselves. And when economic activity increases globally, the number of people traveling abroad rises. It is essential that they do not become infected abroad, and do not bring the disease back to their country. The Centers for Disease Control and Prevention (CDC) in the U.S. recommend use of insect repellents containing deet and picaridin, mosquito coils, and aerosol sprays as highly effective means to control mosquito-borne diseases when traveling to tropical regions.

FUMAKILLA offers single-spray mosquito insecticide and battery-operated mosquito repellent as even more effective mosquito-repelling items. One spray of the former item offers long-lasting repelling effects as a very effective means against mosquitos in a household situation. The battery-operated item is suited for use during outdoor activities. FUMAKILLA also offers the single spray insecticide in Indonesia, where mosquitoes have roughly five times the resistance against insecticides as mosquitos in Japan, by adjusting the amount and method of use. A problem is with a large number of countries where regulations restrict mosquito insecticides. FUMAKILLA asserts the need to break down these barriers to spread the effectiveness of the latest insecticides to protect the lives of those in need of such items.

In addition to enrichment and dissemination of mosquito insecticides, public awareness activities including proper use of insecticides are indispensable to educate people, particularly children, who are unaware that a mosquito bite can cause disease. In Asia where forest malaria is a problem, workers at rubber plantations

learned and spread the fact that infections can be prevented by applying repellent. The key is for companies developing highly effective personal care products to play an important role in carrying out public measures along with spreading awareness for individual behavior with a bottom-up approach.

■ Breakout Session D (Saraya Co., Ltd.): Jigger infestation in Kenya; WHO NTDs road map

Jigger infestation is an infectious disease in which a female sand flea, a type of parasite and flea, burrows itself into skin, especially tips of the toes and under the feet, laying eggs and causing pain, itching, and inflammation of the affected area. It can lead to complications such as abscesses, gangrene, and tetanus, and death may result in the worst case. The affected area may also become deformed causing difficulty walking, and bad appearance that can also be caused may lead to discrimination. It is found in most tropical and subtropical regions throughout the world, with 4% of the population in Kenya affected and approximately 20 million people in North and South America at risk of infection. It is closely associated with the issue of poverty, and the WHO added soil-transmitted helminth to the list of neglected tropical diseases (NTDs), launching a road map to control jigger infestations.

The status in Kenya was explained as an example at the breakout session. Sufficient effectiveness is not evident with current antiparasitic drugs for jiggers, such as ivermectin. A continuous regimen for two weeks applying potassium permanganate to the affected area then treating with various oils is recommended, but with limited medical access in the region, information is not sufficiently disseminated. Prevention is also limited to traditional methods using coconut oil, and the reporting revealed that effective prevention and treatment were not being achieved.

Meanwhile, Japanese universities and corporations are working toward controlling jiggers. Nagasaki University is currently working on-site in the region, aiming to bring the morbidity rate down to 1% or less in five years. They are getting results with their efforts to strengthen the surveillance system for detecting and reporting jigger infestations, improve patient diagnosis and treatment ability of local health workers and volunteers, and help citizens change behavior such as maintaining sanitary feet.

Saraya succeeded in developing a topical liquid for jiggers that is more effective and convenient for use. It has already received approval locally and is anticipated to be available next year, with preparations underway for manufacturing in Saraya's Uganda factory. Results Japan continues working to provide washed second-hand shoes locally, delivering 17,000 pairs weighing a total of 10 tons to individuals being treated with jiggers.

■ Breakout Session E (SHIONOGI): Issues and next action on the access of anti-AMR agents to global countries

The process in developing AMR (antimicrobial resistance) therapeutics is extremely difficult. In addition to international coherence not in place for regulations, clinical studies for patients with infectious diseases caused by multi-drug resistant bacteria in particular cost an exorbitant amount. This is due to the fact that in addition to frequency of those patients being low, identifying multi-drug resistance is complex, with patients prone to becoming severely affected. Patients are then less likely to agree to participation, causing a severely low figure of individuals in contrast to the number of screenings that are taking place.

Forming a sound market is also not an easy task. Even after therapeutics for infectious diseases caused by multi-drug resistant bacteria are introduced into the market, they must be administered with the correct dosage continually, but only to individuals who are identified as suffering from those diseases or are regarded as highly likely to be afflicted. Follow-up of patients, including susceptibility surveillance, is also challenging. Such is the background surrounding companies selling antimicrobial drugs in the U.S. as of late going bankrupt or being acquired at a price that fails to gain returns on money invested into development.

In considering global access, we have to face reality that anti-AMR agents are not available to not only low and middle income countries, but even to high income countries. Therapeutics not being available in high income countries is due to the fact that in addition to cases in each country being limited, the market is also limited due to strict limitations regarding proper usage, with no incentive to make up for it, causing limited profit for companies. Meanwhile, many people are dying from AMR in low income countries. It is extremely difficult to create an environment to have AMR patients accurately identified and take appropriate dosages. In addition, response to regulations, data follow-up, and managing supply chains in each country are also difficult.

In June 2022, Shionogi entered into a three-way partnership with the Global Antibiotic Research & Development Partnership (GARDP) and the Clinton Health Access Initiative, Inc. (CHAI) based in the U.S., and also signed a technology transfer license agreement with GARDP. Access to Shionogi's antimicrobial drug "cefiderocol" was expanded to 135 low and middle income countries around the world and a portion of high income countries. GARDP enters into supply licenses with generic manufacturers for the manufacture and sale of cefiderocol.

There is a growing tendency in developed countries to implement pull incentives. For example in the U.K., a subscription-based payment model was started in June 2022. The model puts antimicrobial drug prescription amounts aside, with the government offering a fixed payment for development by companies, and the government, in exchange for it, is able to obtain the necessary antimicrobial drugs in times of need, with cefiderocol being eligible for the program.

Momentum is building in Japan as well to implement pull incentives. A trial program is being planned in which the Ministry of Health, Labour and Welfare guarantees a certain amount of payment to companies, with 1.8 billion yen being included into the FY2023 budget estimate.

Development of anti-AMR agents, which involves difficulty in conducting clinical trials, also carry elements that make a global, harmonized approach more reasonable than an individual country basis. Major developed countries will need to cooperate and take action to provide smooth global development and access with pull incentives. Japan is expected to take leadership at the G7 Summit in 2023 and command discussions toward implementation of pull incentives based on cooperation by G7 countries.

■ Breakout Session F (KM Biologics): Development of inactivated vaccine for COVID-19

~ A vaccine that meets the needs of post pandemic era ~

KM Biologics of the Meiji Group, in collaboration with Meiji Seika, a pharmaceuticals segment of the same group, is working on initiatives in the field of communicable diseases. The two companies are currently joining forces, aiming to achieve a domestic vaccine against COVID-19 (code name: KD-414).

Several types of vaccines against COVID-19, such as the new type mRNA vaccine, viral vector vaccine, and long-established types of inactivated vaccine, have been commercialized and vaccination is taking place

around the world. One such vaccine, the KD-414 being developed by KM Biologics, is an inactivated vaccine with an extensive track record such as for the influenza vaccine and DPT-IPV.

KM Biologics started clinical studies on humans ten months after starting development of KD-414. Phase 1/2 study to assess safety and Phase 2/3 study to assess safety and immunogenicity on more test subjects were conducted, and it was confirmed that immunogenicity (antibody level) heightened for test subjects the younger they were, and safety was high in the same way as conventional inactivated vaccines.

Currently, 1,500 adult cases are subjects of Phase 3 study in Japan and the Philippines for approved vaccines and KD-414, to compare their immunogenicity and safety. KM Biologics is also in the middle of developing pediatric KD-414 for children and currently in Japan, 600 pediatric test subjects are undergoing Phase 2/3 study to test immunogenicity and safety, with Phase 3 study also scheduled going forward. With the results of these clinical studies, application for approval in Japan is expected to occur in April through June 2023. In addition, the company plans to hold discussions with the government toward commercialization of an inactivated vaccine for the strain currently spreading, and a combination vaccine for the seasonal flu and COVID-19.

And to prepare for the next pandemic, their policy is to cooperate with the government and academia to work on initiatives including R&D of new vaccines in cooperation with academia, development of vaccines against priority diseases designated by the government, and preparing manufacturing bases that can be converted to government-led facilities in emergency situations, etc.