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Recommendations from Pharmaceutical Industry for G20 Health Ministers Meeting

In the G20 Osaka Leaders' Declaration adopted at the G20 Osaka Summit, it was agreed to achieve universal health coverage (UHC), to promote healthy and active aging, as well as to accelerate anti-microbial resistance (AMR) measures. We welcome the newly added parts especially for the access to medicine in primary healthcare, aging society and dementia because they indicate the strong leadership of the Japanese government. We are grateful that many of the recommendations from the pharmaceutical industry for the G20 Osaka Summit Health Agenda, which were submitted to the Prime Minister and the related ministers in January 2019, were included in the declaration.

For the upcoming G20 Health Ministers' Meeting in October, we expect that the Japanese government will keep demonstrating its leadership as the chair, build the specific consensus for UHC promotion, response to aging, and measures for AMR, as well as accelerate the initiatives to resolve the issues in the global health area in G20 countries and other emerging and developing countries. The industry's proposals in addition to the previous recommendations are as follows:

1. UHC

We expect that the commitment to move forward to achieve the UHC described in the G20 Osaka Leaders' Declaration will be materialized, and the efforts will be accelerated in G20 countries.

[Proposals]

- Formulation of Action Plans

In September 2019, a Political Declaration was adopted at the UN General Assembly High Level Meeting on UHC. The declaration reconfirmed the objectives including provision of basic medical care to all people by 2030, eradication of poverty due to the payment of medical expenses. A strong political commitment to achieve UHC was indicated by setting specific measures on strengthening healthcare finances, promoting primary health care, and tackling infectious and non-communicable diseases. At the G20 Okayama Health Ministers' Meeting, we expect that discussions on specific administrative initiatives under these political-level commitments will lead to formulation of Action Plans in G20 countries regarding the promotion of PHC and the measures against infectious and non-communicable diseases, both of which closely relate to the pharmaceutical industry. Being requested from the Prime Minister Abe in his speech at the UN UHC meeting to "promote cooperation with the private sectors and increase

effectiveness and efficiency”, we will cooperate and contribute to the formulation and implementation of action plans including establishment of new public-private partnerships, leveraging the learnings and successes from GHIT Fund and Access Accelerated¹ for non-communicable diseases.

2. Aging Society

We expect that comprehensive policy initiatives for dementia, described in the G20 Osaka Leaders' Declaration, will be accelerated in G20 countries.

[Proposals]

- Accelerate the formulation and implementation of comprehensive policies
Japanese government has established the Basic Act on Measures for Aging Society and the General Guidelines on Measures for Aging Society, and has implemented various measures for a society in which elderly people can spend their time in peace. For dementia, Japanese government has continued to promote comprehensive policies, including the Orange Plan 2012, the new Orange Plan, the Dementia Policy Promotion Charter, and the Basic Act on Dementia, currently under Diet deliberation. By sharing these experiences at the G20 Okayama Health Ministers Meeting, We would like the Japanese government to encourage G20 countries to accelerate the formulation and implementation of comprehensive measures.

3. Response to Health Crisis

We expect to progress the improvements in the public health, preparedness, and response including supporting capacities of other countries in compliance with the WHO International Health Regulations (2005), described in the G20 Osaka Leaders' Declaration.

[Proposals]

- Development of Stockpiling Programs
As a preparation for health crisis such as pandemics, we would like that pharmaceutical companies should cooperate in stockpiling relevant pharmaceuticals and the G20 countries should consider formulating a stockpiling program.
- Stable Supply of Antimicrobials
As the number of incidents on the discontinuation of production and impairing stable supply of antimicrobials with high medical needs are increasing, we would like G20 countries to stimulate dialogues among them on mutual cooperation so that pharmaceutical companies, which supply the antimicrobials, can establish a system to easily increase the supply of antimicrobials when necessary by securing multiple manufacturing routes.

4. AMR

We expect to further accelerate the One Health Approach, which has been continuously appealed to date, in G20

¹Access Accelerated is a global initiative aimed at improving access to prevention, diagnosis and treatment of non-communicable diseases in low-income countries and low- and middle-income countries

countries and to maintain the sustainable R&D and stable supply of new AMR drugs

[Proposals]

- Commitment to One Health Approach

We expect to further promote the action plan and to accelerate the One Health Approach in each country by sharing the results of the National Action Plan on AMR, which will be ended in 2020, and Japan's excellent efforts on infection control and antimicrobial stewardship between the Japanese government and G20 countries.

- Establishment of new business model

We would like the Japanese government to take initiatives to build a new volume-independent business model due to the reevaluation of the values of antimicrobials from various viewpoints on the premise of promotion of antimicrobial stewardship. Also, we request that the best model analysis (push and pull mechanism) for R&D, which is stated in the G20 Osaka Leader's Declaration, will be carried out, the necessity of pull incentives for promoting research and development of AMR drugs² will be shared among G20 countries, and concrete discussions on specific pull incentives will take place. When the innovative anti-infectives are developed, we expect the Japanese government will lead the discussions with G20 countries on potential regulatory reform such as mutual recognition system and strengthening supply chains by taking into consideration the collaboration with international funds.

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² Proposal from the pharmaceutical industry about the introduction of pull-type incentives for promoting research and development of AMR drugs (Submitted to the Minister of Health, Labor and Welfare on June 12,2019)

January 17, 2019

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Prime Minister of Japan

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Recommendations from the pharmaceutical industry
for the G20 Osaka Summit Health Agenda

Member companies of the Japan Pharmaceutical Manufacturers' Association undertaking research & development contribute to the improvement of the health and welfare of the people of the world, by continuously discovering and developing innovative medicines and providing a reliable supply of those medicines. As a value-added industry, we also contribute to economic growth. We seek a higher level of cooperation with the governments of G20 countries and international organizations in tackling health issues.

In order to ensure an ongoing pipeline of innovative medicines and a reliable supply of those medicines to patients in need, a supportive policy environment, including commercial incentives that appropriately reward innovation, is essential. Furthermore, in order to ensure access to innovative medicines to people in need all over the world, international harmonization of pharmaceutical regulations, streamlining of processes, closer coordination among regulators such as mutual recognition of inspections and approvals, are also essential.

In addition to the above, we would like to request that the Japanese government lead discussions at the G20 Summit in Osaka on three major G20 health challenges: achieving Universal Health Coverage (UHC), preparing for aging societies, and tackling antimicrobial resistance (AMR).

1. Universal Health Coverage (Health System Strengthening and Sustainable Health Financing)

1) Background

- The achievement of Universal Health Coverage (UHC) is included under Goal 3 of the United Nations 2030 Sustainable Development Goals (SDGs).
- In July 2017 the United Nations General Assembly adopted “coverage of essential health services” and “proportion of population with large household expenditures on health as a share of total household expenditure or income” as indicators of progress for UHC.
- According to the 2017 UHC Global Monitoring Report published by the World Health Organization and the World Bank in December 2017, half of the world's population, 3.5 billion people, still lack access to quality essential healthcare services.

2) Response

- Pharmaceutical companies are contributing to the achievement of the UHC through capacity building in developing countries and regions. For example, where shortage of doctors and nurses, poor infrastructure, and lack of disease awareness are the major barriers to access to medicines, the industry has responded by training health workers,

introducing mobile medical services, running disease awareness programs etc.

- In addition to individual company programs, a number of global pharmaceutical companies have joined the public sector and NGOs to tackle non-communicable diseases (NCDs) in developing countries through a partnership called Access Accelerated¹. This partnership supports the prevention, diagnosis, and treatment of NCDs in an effective and sustainable way. The industry is engaged in another public private partnership called GHIT, which enables us to contribute to research and development for tropical diseases in a sustainable manner. It is another example of the industry's effort to respond to patient needs in developing countries.

3) Recommendations

- In order to achieve UHC, it is critical to both strengthen health systems and secure sustainable financing for health. Given that investment in health is an investment in long-term economic growth, WHO and World Bank at global level, and Ministries of Health and Finance at national level, must collaborate with each other and work with stakeholders to develop financing models for promotion of health, and prevention and treatment of and recovery from disease at an affordable price. Once achieved, UHC will only be sustainable if healthy life expectancy of the population increases and thus promoting health and healthy lifestyles, life course immunization and prevention of disease are very important. Equally important is the need to reduce waste and improve the efficiency of medical procedures. We urge the Japanese government to lead G20 discussions on achieving UHC with these points in mind.
- We urge the Japanese government to lead the establishment of a platform for industry-government-academia dialogue in the G20 with the objective of setting up a public-private partnership for improving access to healthcare in developing countries. Based on our experience with GHIT Fund and Access Accelerated, we anticipate the platform would select target countries and developing mechanisms for strengthening the health system in response to the most challenging health issues faced by those countries.

2. Aging

1) Background

- The aging of society brings a heavier social welfare burden from increases in pension, medical, nursing care and other welfare costs as well as labor shortages and workers leaving the workforce to become caregivers for elderly family members. An increase in traffic accidents caused increasing numbers of elderly drivers is another issue. At the same time, aging could provide huge business opportunities for new services that utilize existing social infrastructure and new technologies such as IoT, AI, robotics, virtual reality (VR), drones, and driverless cars.
- The issues associated with aging societies are becoming global and will have a social

¹ Access Accelerated is a global initiative aimed at improving access to prevention, diagnosis and treatment of non-communicable diseases in low-income countries and low- and middle-income countries

and economic impact not only in developed countries but also in developing countries. In 2050 one in five people in the world will be over 60 years old, and the population of this age-group is predicted to exceed 2 billion people worldwide. The increase in incidence of NCDs due to aging is also becoming a global issue.

- Among NCDs, dementia, in particular, is becoming an urgent and important age-related health issue in G20 countries. The coordinated prevention, treatment, and care of dementia as a means to prolonging healthy life expectancy is essential for ensuring the sustainability of UHC and keeping medical costs under control. For example, a survey by the American Alzheimer's Association showed that a delay of five years in the onset of dementia would save approximately US\$367 billion in the United States.

2) Response

- Pharmaceutical companies are committed to providing solutions for age-related diseases. For example, in dementia, we are intensively working on the discovery and development of innovative medicines, noninvasive diagnostics, and prevention using new technologies such as AI, and in consortiums such as ARUK (Alzheimer's Research UK), DIAN (The Dominantly Inherited Alzheimer Network), and IMI (Innovative Medicines Initiative) and various multi-stakeholder partnerships. Also in cooperation with other industries, we are joining efforts to promote the development of more elderly-friendly communities and raising awareness of dementia more widely.

3) Recommendations

- In the interests of increasing healthy life expectancy, we urge G20 countries to provide incentives for medical institutions to become actively involved in the prevention of dementia in addition to the diagnosis and treatment of dementia.
- We urge the G20 to support the seven action plans developed under the WHO's Global Action Plan on Public Health Response to Dementia. We also recommend the establishment of a new government-led public private partnership that includes the pharmaceutical industry and academia for investigating the fundamental causes and mechanisms of Alzheimer's disease, developing preclinical testing models and new biomarkers for diagnostics, and ultimately, innovative treatments for this disease.
- Developing medicines for dementia is exceptionally complicated and challenging, requiring large-scale and long-term clinical trials. In order to bring cutting-edge treatments to patients as quickly as possible we recommend, under Japanese government leadership, that the G20 countries improve the regulatory environment for development of dementia treatments including conditional approval based on surrogate endpoints and introduce mutual recognition schemes.

3. AMR

1) Background

- Antimicrobial drug resistance (AMR) is a very serious threat to public health and the world economy. Unless action is taken deaths from AMR could reach 10 million

annually by 2050². In the meantime, many pharmaceutical companies have withdrawn from antibiotic research and development for the following reasons:

- ① Scientific challenges: The development of bacterial resistance is never-ending and thus there must be intensive, ongoing research into new drug targets for the discovery and development of next-generation antibiotics.
- ② Regulatory challenges: Although there has been a certain amount of progress with the formulation guidelines for internationally harmonized clinical evaluation for the development of human antimicrobials, further agreement is required among Japan, the United States and Europe on the criteria for and timing of efficacy assessments.
- ③ Economic challenges: The price of novel antibiotics does not reflect the huge investment needed by pharmaceutical companies in research and development nor the value of those drugs to society. At the post-launch stage too, difficulties in making a clinical diagnosis and insurance reimbursement systems such as bundled payments tend to discourage the use of new antimicrobials. A new post-launch system is required.

2) Response

- In an effort to address the above three challenges: ① the AMED Antibiotic Industry, Academic and Government Consortium has been established, ② an accelerated approval scheme for drug candidates treating resistant bacteria in Japan has been set up and some progress has been made in terms of international cooperation between the Japanese, US and European regulators PMDA, FDA and EMA, ③ progress has been made on push incentives in response to the economic challenges but no progress has been made on pull incentives.
- The pharmaceutical industry, together with over 100 companies and trade associations, made the AMR Davos Declaration in January 2016 and founded the AMR Industry Alliance thereafter
- AMR Industry Alliance is committed to investing in research and development for innovative diagnostics and treatments for antimicrobial resistance, improving access to high quality antimicrobial drugs, and promoting stewardship to prevent excessive use of antimicrobials and thereby reducing the spread of drug resistant bacteria. Also in terms of the manufacturing environment, members have agreed to reduce to a minimum antibiotics contained in wastewater discharge from the manufacturing process.

3) Recommendations

- Based on the one-health approach to preventing the spread of drug-resistant bacteria, we urge each G20 government to commit to antimicrobial stewardship.
- We request the grant of pull incentives for pharmaceutical companies that undertake research and development of antibacterial drugs including: (1) market entry rewards,

² O'Neill, J. 'Tackling Drug-Resistant Infections Globally: Final Report and Recommendations'. Review on Antimicrobial Resistance. May 2016.

(2) Transferable Exclusivity Extensions; grant of exclusivity extensions applicable to other pharmaceutical products, (3) purchase guarantee systems, and (4) pre-examination pricing systems based on drug profile. We request that the G20 create not only a framework for pull incentives that is adaptable to the circumstances of each country but also an international framework. We also request the G20 consider new sources of finance for pull incentives (such as an international solidarity levy).

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