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Japan Pharmaceutical Manufacturers Association (JPMA)

Requests for the Health Agendas at the G7 Ise-Shima Summit

At the previous G7 meetings, namely the G7 Schloss Elmau Summit in May 2015 and the G7 Health Ministers' Meeting in Berlin in October, world's leaders discussed critical health issues such as the Ebola hemorrhagic fever crisis, the issue of antimicrobial resistance (AMR), and neglected tropical diseases (NTDs). The G7's commitment to and leadership in implementing measures against these infectious diseases was a significant step towards addressing the challenges linked to them.

Addressing the control of the three major infectious diseases (HIV/AIDS, Malaria and Tuberculosis) and NTDs remain a critical focus of the recently Sustainable Development Goals (SDGs¹). As the Ise-Shima Summit is the first summit to be convened since the adoption of the SDGs, we believe that it is essential to discuss the implementation of measures against infectious diseases, following up to the Schloss Elmau Summit.

The members of the JPMA recognize that the mission of research-based pharmaceutical companies is to contribute to the health and welfare of people around the world through the continuous discovery of innovative new drugs and improvement of access to such drugs. To achieve the above, we have been making several efforts, including the participation in the Global Health Innovative Technology (GHIT) Fund as well as discovery and supply of drugs and vaccines to address the three major infectious diseases and NTDs. We remain committed to resolving these issues by effectively utilizing our technological capabilities and experiences in new drug development as well as further strengthening our ties with, among others, each of the G7 governments and international organizations. We would greatly appreciate if the following issues concerning the building and strengthening of a system to promote R&D and international cooperation could be incorporated into the discussions when the Japanese government chairs the upcoming Ise-Shima Summit and the Kobe Health Ministers' Meeting. We believe that it is crucial to address those issues in order for us to be able to steadily fulfil our roles in the global health sector.

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¹ The Sustainable Development Goals (SDGs) are the global agenda, which follow the Millennium Development Goals (MDGs) that expired in 2015, and are being discussed with a focus on ensuring the sustainability of the environment. It is stipulated in the SDGs that all the member countries of the United Nations are to commit to achieving the SDGs, including No poverty, Zero hunger, Affordable and clean energy, Climate action, and Peace, justice, and strong institutions, from 2015 to 2030.

Importance of international cooperation and promotion of new drug R&D in the measures against infectious diseases

Drugs and vaccines addressing conditions such as pandemics, bacterial infections, or NTDs have low marketability and predictability. As such, in this area of research, R&D and commercialization are extremely difficult undertakings for any individual company if it were to attempt them alone. Addressing the above, promotion and improved efficiency of <u>international cooperation</u> between industry, government, and academia as well as expansion of public financial assistance will be essential for the R&D and supply of drugs and vaccines. In particular, in order to unceasingly foster new drug development, we encourage further discussions on how G7 countries could design and implement sustainably <u>measures to facilitate</u> R&D (e.g., introduction and strengthening of a system that incentivize research and development in these areas and better predict the marketability as well as harmonization and improved efficiency of the R&D and regulatory approval processes).

In addition to the above-mentioned development of infrastructure, we would also like to invite to consider that the issues in the following areas be recognized and discussed at the Ise-Shima Summit and the Kobe Health Ministers' Meeting as key agenda items.

1. Development of a drug supply system for "pandemics"

In case of an outbreak of a globally-threatening infectious disease, supply of unapproved drugs or drugs under development will likely be an important measure to address an immediate public health risk. As pharmaceutical companies play a significant role in drug supply, JPMA would like to underscore the need to streamline relevant regulations, including the clarification of the scope of companies' responsibilities during pandemic outbreaks, as well as to build a system that allows for the prompt supply of drugs and vaccines without putting an excessive financial burden on the companies. The latter system, should be developed in each G7 country in cooperation with international organizations as a crucial measure for pandemic preparedness.

2. Overcoming "antimicrobial resistance issues" via international efforts

JPMA urges G7 countries to promote the appropriate use of antimicrobials, the development stewardship², and a One Health approach³. Particular focus should be placed on the development and strengthening of surveillance programs for resistant bacteria. In addition, we would also like to underscore the critical role that vaccination plays in curbing resistance. Hence, G7 leadership should consider

² Antimicrobial stewardship is a program that supports the use of antimicrobial treatment aiming to achieve the maximum therapeutic effect and minimum adverse reactions upon creating a medical team consisting of physicians, pharmacists, laboratory technicians, and nurses who are specialized in infectious diseases.

³ One Health is an approach to examine the health of humans and the health of animals as a set of challenges as part of the measures against zoonotic infections, such as avian influenza.

promoting global efforts for vaccination as an effective long-term measure against infectious diseases.

3. Promotion of comprehensive efforts to control NTDs

In order to ensure that the drugs we develop and provide will contribute to the achievement of SDGs, JPMA calls for G7 countries and WHO, to further prioritize capacity building efforts in endemic countries. These include disease awareness programs for the public, development and training of professional health workforce, and efforts to strengthen clinical infrastructure, regulatory and supply chain systems.