

July 26, 2016

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Recommendations of the JPMA on the G7 Health Ministers' Meeting (Outline)

At the G7 Ise-Shima Summit, the G7 countries adopted the "G7 Ise-Shima Vision for Global Health," by which concrete commitments were set out to achieve the United Nations' Sustainable Development Goals (SDGs). JPMA considers it to be a great achievement, fully supports the Ise-Shima Vision's scope and commits to collaboration with all relevant stakeholders. JPMA believes the R&D pharmaceutical industry has an important role in addressing global health challenges and contributing to solutions.

The G7 Health Ministers' Meeting to be held in Kobe in September under Japan's leadership will feature concrete discussions to promote policies in each G7 countries to address several health priorities. In view of this meeting, JPMA would like to make the following actionable recommendations in particular tackling infectious diseases, in line with what we believe our industry is best fit for:

1. Promoting R&D for drugs, vaccines, and diagnostics for infectious diseases with low marketability and predictability

Under the leadership of G7, promoting and improving efficiency of R&D upon, among other, developing global guidelines for clinical evaluation and promoting the international harmonization of regulatory systems; introducing of "push" and "pull" incentives within each G7 countries; prioritizing the targeted diseases and product profiles and promoting existing and potential international R&D public-private partnerships and consortia to develop new drugs.

2. Solving issues in the supply of medical products for infectious diseases

2-1. Developing a mechanism to supply medical products at the time of a pandemic

At the time of situations of a public health emergency, each G7 countries should consider distribution mechanisms that do not put excessive burden on those pharmaceutical companies aspiring to make social contributions. Mechanisms should clarify responsibilities when distributing unapproved medical products, and consider supply chain capabilities and financial implications for all parties.

2-2. Overcoming challenges of antimicrobial resistance (AMR) through international efforts

In order to achieve Antimicrobial Stewardship (AMS), each G7 countries should develop an AMR surveillance system and introduce evaluation systems that use therapeutic efficacy and epidemiological outcome as indicators. G7 countries could also consider incentive models to promote appropriate use of antimicrobial agent for multi-drug resistance.

2-3. Promoting comprehensive efforts for the control of Neglected Tropical Diseases (NTDs)

In order to ensure access to drugs provided by pharmaceutical companies for people who need them, WHO, G7 countries, international organizations, and pharmaceutical companies should support the control of NTDs efforts by collaborating with endemic countries. Also, they should enhance the financial foundation for NTDs control by utilization of the Global Fund.

Details of the above proposals are explained in dedicated annexes.

The Ise-Shima Vision also refers to Active Aging as a priority issue. JPMA would like to collaborate with the Government of Japan after the Health Minister's Meeting and discuss separately how the R&D-based pharmaceutical industry can play a significant role, including related challenges.

Recommendations

July 26, 2016

Japan Pharmaceutical Manufacturers Association

JPMA's Recommendations on the G7 Health Ministers' Meeting

At the G7 Ise-Shima Summit, the G7 countries adopted the "G7 Ise-Shima Vision for Global Health" and set out concrete commitments to achieve universal health coverage (UHC), including infectious diseases, and the rising burden of non-communicable diseases. The Japan Pharmaceutical Manufacturers Association (JPMA) applauds this great achievement and underscores how building strong health care systems as the foundation for any of these commitments to be fulfilled is what Japan has been proposing based on its experience and achievements. This is the demonstration of Japan's strong leadership in this area.

To implement the specific directions and policies mapped out in this Vision, it is essential to have political commitments from the government of each country including the G7 countries and coordination and cooperation of all the stakeholders. The global realization of these commitments will in turn ensure the achievement of the SDGs. In particular, the announcement of the Japanese Government to provide new assistance of approximately 1.1 billion USD as its contribution in the global health area to achieve the SDGs is a strong message to the international community.

As R&D-oriented pharmaceutical companies, JPMA members recognize that their mission is to contribute to the improvement of the health and welfare of people around the world through continuous development of innovative medical products and improved access to such products. The R&D-based pharmaceutical industry has been making efforts on global health issues for the long haul, including participating in the Global Health Innovative Technology (GHIT) Fund, drug discovery of and research on three major infectious diseases and neglected tropical diseases (NTDs), and supply of medical products and vaccines. JPMA will further strengthen cooperation with the governments of the G7 countries and international organizations to address the issues by leveraging our know-how and experience in pharmaceutical innovation. It has been clearly confirmed at the G7 Ise-Shima Summit that international cooperation will be promoted to accelerate research and development in infectious diseases area, and JPMA believes this will be the foundation for to steadily play our role in this area.

The G7 Health Ministers' Meeting to be held in Kobe in September under Japan's leadership will feature concrete discussions to promote policies in each G7 countries to address several health priorities. In view of this meeting, JPMA would like to make the following actionable recommendations in particular tackling infectious diseases, in line with what we believe our industry is best fit for.

1. Promoting R&D for drugs, vaccines, and diagnostics for infectious diseases with low marketability and predictability

Because of the low marketability and predictability, it is difficult for an individual company to tackle on its own the R&D and commercialization of drugs, vaccines, and diagnostics for pandemics, AMR, and NTDs. Therefore, it is essential to promote and improve the efficiency of international partnerships between industry, governments, and academia. It is also necessary for the G7 countries to deliver policy measures to allow for continuous research and development of new drugs in this area and to expand public financial assistance.

[Specific recommendations]

- 1) Develop global clinical evaluation guidelines and realize international harmonization of the pharmaceutical regulatory affairs to promote efficient R&D and early access to healthcare solutions. When considering these matters, G7 countries should consider the need for cooperation with WHO and national regulatory authorities of each country and make efforts to achieve the following proposals. In particular, JPMA would like Japan to lead the discussions based on the international consensus to develop global clinical evaluation guidelines for AMR.
 - As there are times in this area when efficacy and safety information is extremely limited in the clinical development stage, it is recommended to both minimize and harmonize the clinical data package required for the necessary scientific evaluation of regulatory applications. Moreover, as the accumulation of registry data after the launch of the product is useful, collaboration between industry-government-academia is necessary in order to consider the development of a framework that will enable the accumulation and sharing of data.
 - In order to improve the efficiency of approval review and accelerate access to medical products for NTDs and AMR in countries that need them, JPMA suggests the standardization of approval requirements based on the leadership of the G7 and WHO as well as the cooperation with the regulatory authorities of the endemic countries. With regard to infectious diseases that have no effective treatment, JPMA believes it is essential to create a prompt and efficient national approval systems (especially in developing countries), such as a simplified approval process based on the international regulatory harmonization.
 - In order to collect clinical data based on the globally accepted guidelines and realize an approval review under the international regulatory harmonization in developing countries, the G7 countries are required to strengthen the support for capacity building of healthcare professionals involved in clinical trials and reviewers within the regulatory authorities.
- 2) In order to incentivize research and development of medical products pandemics, AMR, and NTDs and improve business predictability, JPMA supports introduction of "push" (e.g., support to cover R&D cost) and "pull" (e.g., making advance purchases and support creating markets/demands) incentives considering regulatory and healthcare system of each countries, and the promotion of new drug R&D public-private partnership. The following are the specific examples of incentive models being considered or already introduced in some countries:

<Push incentives>

- Extension of the patent term or the data exclusivity period of the relevant product [US: GAIN Act]
- A subsidy system or preferential tax treatment (tax break) measure for research and development expenses [US: Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act]
- Establishment of public-private partnership R&D fund (Japan: GHIT fund)

<Pull incentives>

- Measures under the current drug pricing system, such as premiums [Japan: premium for development of innovative drugs and unapproved drugs etc]
- A system of reimbursement for selection and changing of the drug based on the appropriate criteria [US: 21st Century Cures Act (under deliberation)]
- A system in which the government reimburses the minimum revenue for AMR drugs [UK: Under discussion between the government and companies]
A system in which the government establishes a fund or the like to buy the patent of innovative
- antimicrobials [Establishment of a fund is being considered by the governments of the G7/G20 member countries]

3) Funding support to accelerate the R&D for drugs, vaccines and diagnostics of AMR and NTDs is not sufficient and R&D collaboration needs to be further strengthened. Pharmaceutical companies are making efforts to enhance infectious disease control by participating in focused public-private collaborations such as the GHIT Fund. JPMA relies on continued support from the G7 and suggests enhanced international cooperation among industry-public-academia as follows:

- In cooperation with the health ministry, universities, and research institutions in each G7 country, WHO and international organizations will develop epidemiological data, decide the priority of diseases to be controlled and drug/diagnostic profile, and form the international consensus.
- Forming of consortia that promote research and development of drugs, vaccines, and diagnostics utilizing the promising seed compounds of universities and academia around the world as well as the compound libraries of pharmaceutical companies

2. Solving issues in the supply of medical products for infectious disease

2-1. Developing a mechanism to distribute medical products at the time of a pandemic

JPMA highly supports, among others, WHO's efforts to streamline preparedness for public health emergencies, the development of a funding mechanism by WHO and World Bank (WB) to enable rapid action in the time of emergencies, and the implementation of WHO's International Health Regulations (IHR). JPMA supports the Ise-Shima Vision for Global Health as it clearly lays out the leadership and commitments of the G7. However, since the supply of unapproved drugs is expected to be an important countermeasure at the time of a pandemic, the G7 countries should promptly develop a mechanism of drugs and/or vaccines supply in an expedited manner under the cooperation with international organizations.

[Specific recommendations]

- 1) To promptly supply effective drugs and medical technologies at the time of a pandemic, JPMA suggests developing a mechanism that allows a pharmaceutical company to supply unapproved medical products. This mechanism should clarify responsibilities during pandemic situations, including collection of safety information, and reduce the potential financial liabilities associated to prevent an excessive burden on pharmaceutical companies who actively want to contribute.
- 2) Establishing a system (e.g., national stockpile) which fully takes into account the capacity of companies to supply drugs and/or vaccines during a pandemic in order to reduce the financial burden of doing so. With regard to vaccines, in particular, since it takes time to manufacture them and their shelf life is short, it is necessary for the public and private sectors to fully discuss the type and amount

of vaccines (to stock). Moreover, it is also necessary for the public and private sectors to discuss and consider the policy for development of vaccines against infectious diseases that can be a new threat.

- 3) As initial response is extremely important at the time of a public health emergency, Japan's role is called upon to take action against global risks. In order to dispatch healthcare professionals and promptly supply drugs and/or vaccines at the time of a public health emergency, JPMA supports the establishment of an organization within the Japanese government that can play a *control tower* function upon referring to the responses and systems of other G7 countries.

2-2. Overcoming "issues of AMR" through international efforts

JPMA welcomes the strong commitment set forth by the G7 leaders at the G7 Ise-Shima Summit on international cooperation towards implementation and enhancement of One Health Approach to AMR. JPMA looks forward to the outcome of the G7 Health Ministers' Meeting and relevant implementation in each country under the G7 leadership.

As the pharmaceutical companies have a significant role in the fight against AMR, it is important to setup a platform that allows each government to cooperate with pharmaceutical companies, such as in drug development, stable supply, information collection, information provision, and awareness activities, as well as to facilitate active cooperation and collaboration between the public and private sectors.

[Specific Recommendations]

- 1) Antimicrobial Stewardship (AMS) is to administer an appropriate drug based on scientific evidence at a correct dose for the necessary duration. To achieve this, antimicrobial resistance surveillance systems should be timely developed, alongside with evaluation systems that use therapeutic efficacy and epidemiological outcome as indicators. These measures should be preferred to efforts to just control the usage volume of antimicrobials drugs.
- 2) New incentive models should be considered for the promotion of appropriate use of antimicrobials especially drugs against multidrug resistant bacteria.
- 3) It is extremely important for the achievement of AMS to understand the appropriate type of antimicrobial to be administered based on prompt diagnosis. In order to prompt the development of testing and diagnostic technologies, (push and pull) incentives similar to those for antimicrobials should be introduced for the development of new diagnostics.

2-3. Promoting comprehensive efforts for the control of Neglected Tropical Diseases (NTDs)

In order to achieve the goal of ending the epidemics of NTDs by 2030 in the SDGs, pharmaceutical companies have been expanding the supply of medical products (through donations, among others) to control NTDs. However, realizing the SDGs vision needs a strong political commitment, the development of a medical product distribution system – all efforts aimed to ensure the timely delivery of these products to the people most in need. As such, JPMA urges the promotion of the following concrete actions under the leadership of the G7 and WHO:

[Specific Recommendations]

- 1) Through partnership between WHO, the governments of the G7 countries, international organizations, pharmaceutical companies, etc., develop a strategic control program targeting 2030 (e.g., mapping of infected areas, construction of epidemiological data, planning of medical product supply, vector control, education to raise awareness of diseases among the general public, human resource

development of healthcare professionals, framework to collect safety information and enhancing the distribution system) in cooperation with the governments of epidemic countries that have shown a commitment to NTD control, implement the relevant financial support, and further reflect the evaluation of outcomes in the program.

- 2) Harmonize many different international initiatives and increase their efficiency under WHO's control strategies, as well as efficiently expand funding for NTD control upon expanding the application of the Global Fund to drugs and diagnostics for NTDs.

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