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### **Proposals from the pharmaceutical industry for the G7 Hiroshima Summit Health Agenda**

Member companies of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the Japan Pharmaceutical Manufacturers Association (JPMA) undertaking research & development contribute to the improvement of the health and welfare of the people of the world. We continuously discover and develop innovative medicines and vaccines, provide a reliable supply of those products, and contribute to economic growth. Even under the turmoil of global economy and supply chains caused by the recent COVID-19 pandemic and the Ukraine crisis, we significantly contribute to healthcare security and maintaining socio-economic growth through stable supply of pharmaceuticals and appropriate provision of information to consumers and healthcare professionals.

To ensure an ongoing pipeline and reliable supply of innovative vaccines and medicines to people in need, a supportive policy environment, including commercial incentives that appropriately reward innovation, is essential. Furthermore, even in the event of pandemics, wars, and natural disasters, it is important for the industry to secure "a more resilient, more equitable and more sustainable health system" to continuously realize our business. We believe three measures are necessary for realizing this health system: "Sustainable universal health coverage (UHC)," "Pandemic preparedness and response," and "Antimicrobial resistance (AMR)." We also need a foundation of reliable primary healthcare (PHC) that works even in times of crisis, along with sustainable investments in innovation.

The Japanese government has the development experience of achieving and maintaining domestic PHC, such as community awareness on health, hygiene, and nutrition, and national qualification system for medical professionals, and development of mass immunization system, etc. In addition, Japan has supported the development of health systems in many developing countries through international development cooperation based on that experience. In the post-COVID19 era where healthcare security is required globally, we expect Japan to demonstrate leadership that leverages Japan's experience and knowhows in achieving UHC.

In 2023, the Japanese government will host the G7 Summit for the first time since Japan announced its international leadership in achieving UHC at the 2016 G7 Ise-Shima Summit. Furthermore, 2023 is the midpoint year to 2030, the target year to achieve SDGs. For Japan's leadership to further clarify the path to achieving UHC, we hope that further discussions will be held regarding the realization of the above-mentioned health system and other solutions to global health issues.

## **1. Sustainable UHC (including Active aging)**

### **1) Background and issues**

- Due to multiple ongoing crises, such as the COVID-19 pandemic, major military conflicts, and climate change, public health challenges are increasing globally. We have witnessed the spread of infectious diseases, malnutrition, and hunger, the destabilization of supply chains, and the vulnerability of health systems, especially in low- and middle-income countries (LMICs). This reinforces the need for increased multilateral cooperation to accelerate global innovation, increase regulatory convergence and harmonization, use reliance procedures, and securing free trade.
- During the COVID-19 pandemic, even in developed countries that had usually achieved UHC, healthcare systems were temporally overwhelmed and supply chains became unstable, severely affecting the provision of essential healthcare services. It is important for each country, including developed countries, to develop reliable PHC that can function even in emergencies.

- With societies aging, problems such as increasing medical expenses and a growing nursing care burden are becoming more serious. The increase in patients with non-communicable diseases (NCDs) has become a global issue. Chief among them are patients with dementia and cancer. The social cost of dementia is estimated to exceed US\$2.8 trillion in 2030, while the total cost of cancer medicine spending is estimated to exceed US\$300 billion in 2026\*. While there are concerns about an increase in the number of patients due to reduced activity levels and delayed or missed diagnoses during the COVID-19 pandemic, progress in technological innovation and the effects of interventions on risk factors have also been achieved. If the pharmaceutical industry can extend healthy life expectancy through comprehensive measures for dementia and cancer prevention, treatment, and care, we can expect to curb rising costs and improve the sustainability of UHC.

\* ref. IQVIA Institute, Global Oncology Trends 2022, p 51

- The COVID-19 pandemic has made clear that adults are at increased risk of infectious diseases and reinforced the need to use all available resources to reduce this risk. Unfortunately, adult immunization remains stubbornly low in nearly all geographies. COVID-19 taught us that investment in resilient adult immunization services and infrastructures will be critical in preventing and controlling future outbreaks and pandemics, in reducing complications of co-existing chronic conditions such as heart diseases or diabetes, and in slowing down health decline throughout the life-course. The economic consequence of productivity lost through emerging infectious diseases and ill health are significant.

## 2) Industrial efforts

- The pharmaceutical industry is intensively working on the discovery and development of innovative biopharmaceutical products and on the reliable supply of products. This is done in collaboration with academia and other public and private partners.
- The pharmaceutical industry is supporting the efforts of governments to achieve UHC and PHC. This includes capacity building for both non-communicable and infectious disease awareness, prevention, diagnosis, and treatment, particularly in developing countries where medical infrastructure may be underdeveloped. These efforts are implemented by individual companies and public private partnerships, such as Access Accelerated, a public private partnership to accelerate access to healthcare for NCDs, the Global Health Innovative Technology (GHIT) Fund, a public private partnership that contributes to research and development for tropical diseases in a sustainable manner, and the Gavi Alliance, to increase access to immunization in poor countries.
- The pharmaceutical industry is working to expand the health solutions it offers, often collaborating with other industries. Utilizing new technologies and modalities, we work to develop preventive measures and non-invasive diagnostic methods, promote the development of more elderly-friendly communities, and raise awareness of dementia, cancer, and NCDs more widely.

## 3) Proposals

- We request that the Japanese government take the lead in enabling further international cooperation on the delivery of treatments to patients and securing the stable supply of pharmaceutical products. The robust supply chain should enable continuous procurement of active pharmaceutical ingredients, raw materials, packaging materials, as well as international distribution and local supply in each country.
- We encourage enhanced global solidarity by deepening and expanding ODA healthcare projects, such as capacity building implemented by the private sectoral civil society and academia. Intervention by local governments in collaboration with local attachés and local embassies is essential for private support activities to take root in the local public health system. In addition to supporting the achievement of local equitable access to healthcare and UHC, this will also serve as a foundation for further contributions to local healthcare by the private sector.
- In medical fields where there are no or limited treatment options due to the complexity of drug development, or with drugs that requiring emergency approval, we request that the Health Agenda includes promotion for the widespread use and implementation of regulatory convergence and reliance. This will mitigate some of the current delays and disadvantages patients may face based on their place of residence.

- The industry addresses disease areas where market principles are difficult to work, such as rare diseases, neglected tropical diseases, and infectious diseases, including AMR. We request the enhancement of the push and pull incentive system as a mechanism to accelerate the research and development of new drugs in these disease areas.
- We request to Japan to enhance international data exchange utilization. Aggregation and utilization of digital information such as clinical data, real-world data, health data and real-time drug demand/supply data is the foundation of medical research and development. They are critical to accelerate the creation of innovative pharmaceuticals, and to improve the quality of medical care.
- Considering the global aging of the population and the tightness of medical costs, we request to enhance international cooperation to promote the prevention and early detection of dementia and other non-communicable diseases, including cancer, to realize the extension of healthy life expectancy. We request G7 leaders to set specific goals and measures for preventive intervention and early detection of dementia, and global industry-academia-government partnerships to promote participation in clinical trials at an early stage.

## **2. Pandemic preparedness and response**

### **1) Background and issues**

- In the case of COVID-19, the pharmaceutical industry has achieved unprecedented success in development and large-scale manufacturing of vaccines and therapeutics. However, for a multitude of reasons, equitable access to vaccines was not fully realized.
- To allow companies to deliver vaccines to people who need them, governments should commit to unrestricted trade refrain from imposing export bans. They should also work improve their health infrastructure such as pharmaceutical administration, distribution, and sufficient medical professionals. This includes improved primary care, capability to run population-wide vaccination programmes, including the necessary cold-chain, and planning to meet the unique healthcare requirements during pandemics.
- The G7 Cornwall Summit in 2021 launched the '100 Days Mission', aiming to develop safe and effective vaccines, treatments, and tests within 100 days of the outbreak of the pandemic. Industry, academia and government should work together to accelerate development of pandemic products to achieve this aim days mission. A well-funded and coordinated biomedical R&D ecosystem is important to achieve this goal. During Germany's Presidency in 2022, the G7 leaders reaffirmed the 100 Days Mission efforts and underscored the importance of open and timely sharing of health data and biological samples. In addition, G7 leaders support for the Financial Intermediary Fund (FIF), and the new WHO funding model. They also committed to assist at least 100 LMICs in implementing IHR (International Health Regulations) (2005) core capacities for 5 more years, until 2027.

### **2) Industrial efforts**

- In the fight against COVID-19, several vaccines were authorized within one year of the WHO declaration of a Public Health Emergency of International Concern (PHEIC). Since then, more than 380 voluntary partnerships, of which over 80% involving technology transfer (as of June 2022), have scaled up vaccine production, with 11.2 billion doses produced in 2021.
- The pharmaceutical industry is already working to prepare for future pandemics. In May this year, we published the "Applying Lessons Learned from COVID-19," which analyzed and organized the lessons learned from the COVID-19 pandemic.
- To help advance the debate, the biopharmaceutical industry launched the Berlin Declaration in which it proposes a framework to further improve the real-time delivery of vaccines, treatments and diagnostics for priority populations in lower income countries for future pandemics. As part of this framework, industry committed to reserve an allocation of real-time production for these populations. This could further improve equitable access if national health systems, funding mechanisms and absorption capacity are strengthened. A prerequisite for the declaration to succeed is to ensure that health systems in lower income countries are better prepared to absorb and deliver vaccines and treatments, and for high income countries to provide the necessary political and financial support.

### 3) Proposals

- Intellectual property rights are essential for innovation in vaccines and therapeutic, to support R&D partnerships, and to enable voluntary technology transfer. We request the Japanese government to take the lead in international discussions so that intellectual property rights, which are indispensable for preparing for future pandemics, can be robustly protected.
- We request that Japanese government advocates for an international system for pharmaceutical companies to conduct research and development of medical countermeasures rapidly and freely in future pandemics. It is essential to have a comprehensive surveillance system, incorporating a One Health Approach, which allows for early detection of emerging pathogens and variants, and the global sharing of real-time epidemiological information. Pathogen samples and their associated information need to be freely available to pharmaceutical companies, via a system where provision of medical countermeasures in the event of a pandemic is decoupled from sharing of pathogens and their information.
- We request the Japanese government to play a leading role in international discussions for promoting international regulatory convergence, reliance procedures so that all countries can urgently implement vaccination, testing and treatment in a future pandemic.
- A system for emergency use authorization should be established and developed in each country so that pandemic products can be put into practical use rapidly. We hope that the emergency use authorization in Japan will continue to be actively utilized to accumulate operational know-how and enhance this system.
- Trade restrictions and export controls slowed the manufacturing of COVID-19 vaccines and reduced the ability to ship them to the countries that needed them most. To achieve equitable access in future pandemics, we ask the Japanese government to support the establishment of mechanisms to ensure unrestricted trade in pandemic products and their ingredients.
- Procurers of vaccines, medicines, and diagnostics for lower income countries in future pandemics need to have immediate access to funding in order to sign purchase agreements with manufacturers at the same time as other (governmental) procurers. COVAX was left waiting in the queue because it lacked this ability in the early months of the COVID-19 outbreak. We ask the Japanese government to play a leading role in international discussions for the proper funding of agencies procuring vaccines and therapeutics on behalf of lower income countries.
- Undoubtedly, many more countries have immunized adults against COVID-19 during the pandemic. Investment in adult immunization services, infrastructures, and access points, including vaccine confidence programs and address on vaccine hesitancy, need to be sustained to build more resilience and be better prepared for future pandemics.
- We hope further global collaboration to address infectious diseases can be established more consistently. We request that the Japanese government establish a new agency for infectious diseases crisis management and the “Japanese CDC (Centers for Disease Control and Prevention)” as soon as possible, and that they realize a framework for training researchers, strengthening research institutes and clinical research sites, and data aggregation for drug research and development, while leveraging industry’s expertise.

### 3. Antimicrobial Resistance (AMR)

#### 1) Background and issues

- The 2016 O’Neill Report noted that in 2013, the number of deaths due to AMR was about 700,000 and estimated that if no measures are taken, the AMR death toll could exceed those from cancer and diabetes combined by 2050, reaching 10 million per year. In this context WHO has adopted the Global Action Plan on AMR, and majority of countries formulated a National Action Plan to tackle AMR. A new landmark study published in The Lancet this year estimated that 4.95 million deaths were associated with antimicrobial-resistant bacterial infections, of which 1.27 million deaths were directly attributable to such infections in 2019. This is more deaths than malaria and AIDS and represents a worrying increase of the AMR burden in a short amount of time.

- In the "G7 Ise-Shima Vision for Global Health (2016)," the G7 leaders made a commitment to strengthening the response to AMR and accelerating research and development. Since then, AMR has been on the health agenda every year at G7 Summits and Health Ministers' Meetings. However, the threat of AMR remains unabated and some are concerned about it accelerating during COVID-19. On the other hand, many companies which launched an antibiotic in the last decade have gone bankrupt due to the broken market and many pharmaceutical companies have had to withdraw from research and development of antibacterial agents due to scientific, pharmaceutical and economic issues. As a result, the number of new antimicrobial agents on the market that are effective against resistant bacteria is decreasing year by year, with WHO and other experts agreeing the pipeline is insufficient relative to the challenge.
- In 2022 G7 leaders reaffirmed their commitment to address the issue of antimicrobial resistance by: 1) Promoting the prudent and responsible use of antibiotics in human and veterinary medicine; 2) Raising awareness of sepsis; 3) Leading the development of integrated surveillance systems based on a One Health approach; 4) Advancing access to antimicrobials; 5) Strengthening research and innovation for new antibiotics in international partnerships; and 6) Incentivizing the development of new antimicrobial treatments with a particular emphasis on pull incentives.

## 2) Industrial efforts

- The pharmaceutical industry established the AMR Industry Alliance in 2017 to progress on R&D, access, stewardship, and responsible manufacturing for antibiotics, and the \$1bn AMR Action Fund to support R&D of key antibiotics while sustainable economic incentives are established. As for surveillance, seven global pharmaceutical companies are participating in the NPO Vivli's AMR Register to promote the utilization of industry surveillance data.
- The JPMA is also promoting appropriate use of antimicrobial agents and working together with industry, academia, government, and citizens as a member of the AMED public and private partnership for infectious diseases R&D (APID), AMR Alliance Japan, and Nikkei FT Communicable Disease Conference AMR consortium to address this problem.
- Among the six items of AMR countermeasures listed in the 2022 G7 Elmau Summit Leaders' Statement, the pharmaceutical industry places emphasis on the following three points, "strengthen research and innovation for new antibiotics in international partnerships, and encourage the development of new antimicrobial treatments with a particular emphasis on pull incentives", " Advance access to antimicrobials ", and " Development of integrated surveillance systems ".

## 3) Proposals

- The industry requests the Japanese government, which will host the G7 Hiroshima Summit, to build on the outcomes of 2021 UK and 2022 Germany G7 and i) take the lead in driving forward the implementation of market incentives, ii) revise the National Action Plan on AMR, and iii) discuss these details at G7 special session on AMR. On that basis, we expect these items to be included in the discussions at the G7 and in the leaders' statements.
- To encourage research and innovation of new antimicrobial agents under international partnerships, we request to strengthen both push and pull incentives, firstly through financial support to international organizations such as CARB-X and GARDP, and secondly to make specific and actionable member commitments to implement pull incentives, including securing the necessary financial resources required for pull incentives (estimated at \$1.6B to 4.2 billion globally, per antimicrobial) , and to promote international harmonization of selection criteria for products eligible for pull incentives.
- To facilitate access to antimicrobial agents in low resource settings, we request the Japanese government to take the lead in the discussion including support for SECURE planned to launch by GARDP and WHO, establishment of a new international framework, and support for companies that are working in transfer technology to produce antimicrobials in LMICs.
- We request the Japanese government to take the lead in eliminating surveillance gaps, pathogen sharing and promoting further utilization of data through the development of a global integrated surveillance system.