

Tokyo, Monday, 3rd June 2019

Dear Prime Minister Abe,

We are the Biopharmaceutical CEO Roundtable members representing global R&D-based pharmaceutical company. We have committed to deliver innovative medicines/medical technologies all over the world including Japan, to build a vibrant society that enables people live longer, healthier, and happier without suffering from disease through access to new medicines. We appreciate your leadership in designating the biopharmaceutical industry a key strategic industry for Japan. For the coming G20 meetings in Japan, as a country committed to advancing medical innovation, we welcome Japan's solid leadership globally, but also in the following three global health issues for the realization of our ultimate goal.

The first aspect is we still do not have enough engagement for health systems strengthening to reach the goal of universal health coverage (UHC) – ensuring access to appropriate healthcare services with reasonable cost – especially, in developing countries. We commend the Government of Japan's continued support for the Global Fund and the Gavi Alliance, and its leadership in hosting the Gavi replenishment launch event in August. So far, GOJ, as part of its global leadership on healthy aging, has greatly supported moving towards UHC, together with the international community, and raised the health agenda as a prioritized topic at the international fora (e.g., United Nations, G7 Summit, or TICAD). In particular, the GOJ reaffirmed the following needs at the UHC Forum 2017 in Tokyo: 1) to strengthen global momentum towards UHC, 2) to develop and implement a framework for cooperation at the country level, 3) to monitor progress continuously, 4) to secure sustainable financial resources for UHC, and 5) to promote innovation. Furthermore, G7 Ise-Shima vision reaffirms the importance of immunization, throughout the life course, as one of key measures to prevent the spread of infectious disease and address emerging pandemics. We, the pharmaceutical companies, would like to support PM Abe's strong leadership in these areas. Also, we have been proactively engaged to establish our contribution toward health systems strengthening through our own Initiative (Access Accelerated*) to bring all relevant stakeholders together. Recognizing that substantial hurdles remain, we need to encourage individual countries to further implement or strengthen actions to promote UHC. To this end, we look forward to your continuous support to mobilize country-led processes towards UHC, increase alignment of individual efforts, and accelerate UHC goals globally.

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The second aspect is although many medical products have become available to date for certain diseases, there are still either no treatments for, or ineffective or inadequate treatments for many other diseases. This is a common issue for both developed and developing countries. We, the R&D based pharmaceutical companies, underscore the value of partnership and believe that partnerships are a fundamental component for fostering innovation. The AMR (Anti-microbial Resistance) Industry Alliance initiative**, our multi-stakeholder coordination platform that addresses a global public health concern of antibacterial drug resistance, is just an example.

To facilitate innovation, governmental understanding and support are crucial. We are grateful for your commitment to support innovation as one of the five commitments mentioned above. In order to implement the commitment and deliver innovative medicines to patients, we are making all-out efforts to develop innovative medicines. It is vital to institute harmonized regulatory systems as well as an enforceable reward system for innovative technology in each country, in particular the predictable and reasonable protection of intellectual property (IP) rights. Although some view the IP system as a barrier to access to medicines, the weight of evidence demonstrates that focusing on areas like pricing and IP in isolation will not achieve long-term successful health outcomes or better access to new medicines, and must be linked to the core healthcare system issues.

The third aspect is the need to make the shift to a new healthcare system utilizing various kinds of medical data, especially, taking into consideration the recent advancements of digital technologies like AI or big data, and to develop legal frameworks that facilitate these advancements, including with respect to data flows. We think the shifts also advance the aforementioned two challenges: 1) accelerating progress towards UHC, and 2) resolving unmet medical needs. Japan established a national health insurance (NHI) system a long time ago, and the large amount of health and medical data collected under the NHI system has the potential to enable the achievement of UHC in response to the aging society through the seamless coordination of preventive measures, early diagnosis and treatment, effective use of precision medicines, and efficient use and optimization of healthcare expenditures. Furthermore, the shift to a new system would enhance utilization of real world data for innovative drug and technology development, thereby enabling the R&D pharmaceutical industry to discover and develop innovative medicines more quickly and efficiently. For example, use of a public medical information database or combination of IoT technology and virtual clinical trial can potentially reduce drug development time and costs and improve the probability of success. As a result, our innovative products can be delivered earlier to patients in need.

In conclusion, we continue our efforts to join with others to accelerate progress towards UHC, to resolve unmet medical needs, and to transform to a new healthcare system utilizing various medical data, so that we can contribute to people's health globally. We look forward to Japan's leadership to guide constructive and evidence-based discussions on these global topics and shape a strategic policy decision in the G20 and beyond. We look forward to continuing to work with you to advance our goals.

Yours sincerely,

David A. Ricks Chairman and Chief Executive Officer Lilly and Company

President, IFPMA

George Nakayama Chairman and Chief Executive Officer Daiichi Sankyo Co. Ltd.

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^{*} Access Accelerated: Access Accelerated brings together over 20 biopharmaceutical companies committed to tackling the growing burden of non-communicable diseases in low and middle-income countries. By collaborating with partners, we co-create scalable and sustainable solutions to improve people's health.

^{**} AMR Industry Alliance: The AMR Industry Alliance is one of the largest private sector coalitions set up to provide sustainable solutions to curb antimicrobial resistance, with over 100 biotech, diagnostics, generics and research-based pharmaceutical companies and associations joining forces.

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