U.S. Chamber of Commerce International Affairs

U.S.-Japan Business Council

JUBC Japan-U.S. Business Council

Healthcare Innovation

Now more than ever, sustainable and predictable investments in healthcare innovation are urgently needed to promote health system resilience, workforce productivity and stability, timely patient access to new treatments, and economic competitiveness. While the emergency responses to COVID-19 are ending, the virus and the risk of another pandemic remain, as well as the growing burden of non-communicable diseases. The continued utilization of vaccines, therapeutics, and other medical technologies is critical for individual and communities' public health and well-being. Additionally, Japan has the fastest aging population of any post-industrial nation on earth where deaths have outpaced births for over a decade. The impact of an aging and shrinking population is already visible across metrics from economic performance to public policy priorities around infrastructure and supply chain stability. Greater investment is needed to improve the distribution of and access to healthcare supplies vulnerable to geopolitical and other shocks, market uncertainty, and economic disruption. As the pandemic demonstrated, investment across life sciences is also needed to unlock breakthrough innovation that holds historic promise for patients; maximizing the benefits of digital transformation, for example can accelerate drug discovery and improve healthcare services and outcomes.

The United States and Japan share a history as global leaders in life sciences. Yet dozens of changes in pricing rules and annual/biannual price cuts, including to patented medicines and medical technologies in Japan, have put pharmaceutical and medical technology ("medtech") innovation ecosystems in Japan at risk. On the medtech side, changes made to functional categories and to price reductions calculated against the Foreign Average Price have also put the innovation ecosystem in Japan at risk. These changes have decreased Japan's share of the early-stage pipeline, precipitated stagnation in new clinical trials, and exacerbated the drug/device lag and drug/device loss, in which innovative medicines and technologies to treat unmet medical needs are increasingly not launched in Japan in a timely manner – or not launched at all. Likewise, recently adopted U.S. price-setting policies will hinder the development of new treatments overall while failing to fully address affordability issues in the health care system. Furthermore, labor shortages, increases in materials and transportation costs, and devaluation of the Japanese Yen, have made it difficult for both U.S. and Japanese companies to supply existing products and necessary ingredients to Japan.

The U.S.-Japan Business Council and Japan-U.S. Business Council (hereafter "the Councils") encourage both governments to take the following three steps to maintain competitiveness as healthcare innovation leaders:

1. **Restore market-based incentives for investment in life sciences and medtech innovation.** Reimbursement policies must reward technological breakthroughs and improvements, to encourage continued investment and permit access for patients. For Japan, the Councils urge adoption of the recommendations reflected in the April 2023 PhRMA, EFPIA and JPMA Joint Statement on Proposals for the 2024 Drug Pricing Reform.

2. **Establish a bilateral public-private dialogue to improve timely access to innovative medical products.** The Councils welcome recent efforts to cooperate on pharmaceutical supply chains and biotechnology start-ups under the Japan-U.S. Commercial and Industrial Partnership. We call for the governments to formally incorporate public-private dialogue into the new initiative, with a renewed focus on the full range of issues that affect the competitiveness of the life sciences industry in both countries. In addition, we urge the governments to consider expanding the scope of the dialogue to address other challenges facing the health sector.

3. **Launch a new U.S.-Japan partnership to share best practices on digital health.** New policies are needed to promote access and integrate digital therapeutics and health solutions, such as telemedicine digitalization and utilization of healthcare data. Enabling the deployment of digital tools, including AI, will accelerate R&D and

facilitate patient access to medical technologies that improve patient outcomes. Therefore, the Councils encourage the governments to launch a new partnership guided by the Framework for U.S.-Japan Cooperation on Digital Health contained in the Appendix.

This Joint Statement represents the collective priorities of the Councils. We believe that the following recommendations will help both government and industry improve health systems and outcomes, while strengthening innovation in both the U.S. and Japan.

1. Innovation Ecosystem

Reimbursement policies must reward technological improvements and breakthroughs to encourage investments in health and permit access to treatments for patients. For business and private sector investors to prioritize innovation, policies must acknowledge and compensate for the risks sustained and financial losses associated with R&D. Fair and predictable reimbursements will ensure that innovators continue to explore, develop, and refine cures and treatments for diseases and conditions to improve health.

1.1 Innovation in Healthcare

- For both: Develop and improve the R&D, regulatory environment, and reimbursement systems to encourage continued investment in the market. Ensure that regulatory and pricing systems are keeping pace with the incredible breakthroughs in science and technology associated with new pharmaceutical and medtech products.
- For both: Create new initiatives to further public-private research collaborations and facilitate dialogue with industry, academia, medical-research institutions, health providers, and investors to identify opportunities for greater partnership and policy reform.
- For Japan: Establish the command tower function to develop a comprehensive strategy as expeditiously as possible, per this year's *Honebuto*, to would promote more effective and substantive dialogue moving forward between MHLW and the industry, enabling productive implementation of identified measures.
- For Japan: Reform policies and regulations to resolve the lag and loss in bringing treatments to market by reviewing and implementing the recommendations of the MHLW Expert Panel on Comprehensive Pharmaceutical Policies which were issued in June 2023.
- For Japan: Promote MHLW's "Whole Genome Analysis Action Plan" with a broader continuum of disease areas and accelerated implementation plans, with the timely establishment of an implementation organization. Such efforts could be enable enhanced innovative drug discovery capabilities and further collaboration between the two countries.
- For Japan: Reform regulatory policies to promote the development of innovative medicines and medical devices in Japan by reducing the need for Japanese specific data and allow the consideration of other real-world evidence.
- For both: Encourage adoption and implementation of high-standard IP regimes; prevent the erosion of intellectual property protections that drive investment in biopharmaceutical research and are essential to research partnerships in Japan and the United States, as well as around the world.

1.2 Evaluation of Innovation

- For Japan: Promote pricing approaches that consider the benefits derived from therapies, including clinical outcomes as well as social, population and economic benefits, including those that will affect the health system generally and frontline healthcare workers in particular.
- For the U.S.: Eliminate harmful price control policies that discourage innovation and patient access, including provisions that disincentivize the development of small molecule medicines and R&D of new uses following a medicine's initial regulatory approval.

- For both: Ensure that any movement towards implementing Health Technology Assessment ("HTA") at a minimum include consideration of socioeconomic value and the importance of patient access and physician choice. Also, make healthcare, nursing care, and other data available for assessment.
- For Japan: Exclude patented new drugs from the scope of price revisions (including off-year) and market expansion and spillover repricing, similar to other G7 countries.
- For Japan: Address the current challenges of low business predictability due to numerous changes to pricing rules and little room for negotiation by the industry in the pricing process.
- For both: Introduce financial initiatives that can reflect the value of innovation to encourage the development of innovative therapeutics such as regenerative medicine, cell therapy, and gene therapy, and for digital therapeutics such as software as a medical device ("SaMD").
- For Japan: With respect to medical devices, abolish the Foreign Average Price adjustment system, which bluntly compares medical devices pricing without any consideration to differences in healthcare systems and business and reimbursement environments among countries, to ensure U.S.-approved innovative medical devices remain available in Japan.
- For Japan: When reviewing Functional Categories for medical technologies, work closely with industry to ensure that any changes do not undermine rewarding innovation.
- For Japan: When conducting cost effectiveness evaluations for breakthrough medical technologies, ensure that available published evidence and internationally accepted cost-effectiveness modeling are considered; avoid the mechanistic use of benefit thresholds when determining value to avoid creating barriers to the entry of innovations.

2. Digital Transformation

- For both: Redouble an overarching commitment to swift and effective digitalization in healthcare with strong leadership and adequate support from the government.
- For both: Promote alignment between U.S. and Japanese regulators in developing and implementing new digital health policies to reduce the cost of developing innovative therapies and improve health outcomes by collecting data and supporting physician/patient interaction.
- For both: Develop an environment in which individuals can access their own health data, particularly as healthcare providers and researchers both domestically and internationally can exchange health data among different institutions to treat the same patient with adequate privacy protections.
- For Japan: Implement a comprehensive health data policy that promotes building data infrastructure by the government and includes legal frameworks that enable utilization of health data by the private sector while appropriately protecting patient privacy.
- For both: With appropriate protections and meaningful incentives, promote the development, adoption, and use of interconnected/interoperable health data platforms using international standards such as HL7/FHIR to support integrated care across diagnosis, treatment planning and delivery, patient follow-up, and patient data management.
- For both: Address Ethical, Legal, and Social Issues ("ELSI") including privacy, information protection, and antidiscrimination to accelerate the sharing of de-identified health data. Conduct an education campaign to raise awareness of the advances that can be achieved with the voluntary sharing of anonymized medical data in driving evidence-based treatment solutions and evidence-based policy making.
- For both: Enable Decentralized Clinical Trials, allowing a hybrid of in-person and remote visits to medical institutions for trial participants.
- For both: Promote alignment between U.S. and Japanese regulators in cybersecurity risk management to protect against cyberattacks and data intrusions, ensure patient safety, and minimize enterprise risk.
- For Japan: Establish a mechanism by which the healthcare industry can properly deliver necessary information regarding pharmaceuticals and medical devices for patients and the public by using digital technology.
- For both: Promote the use of diverse treatment modalities such as telemedicine, which can be utilized in the home.
- For Japan: Further support the development of a data platform for the traceability of pharmaceuticals and medical devices.

3. Economic Security and Resilience

- For both: Promote economic security policies that enhance resilience and encourage trade with trusted partners.
- For both: Reinforce global supply chains through alliances between the U.S. and Japan and with their allied countries for stable supply of pharmaceuticals and medical devices.
- For Japan: Define drugs with high medical needs, especially for long-time established therapies, and build a system to support their drug prices to secure stable supplies.
- For Japan: Establish regulatory data protection period for pharmaceuticals including new modalities with the highest global standard.
- For both: Reinforce investment in R&D for advanced healthcare technologies to improve the technological capabilities and industrial competitiveness of the U.S. and Japan.
- For both: Establish initiatives to enhance mutually beneficial cooperation between the U.S. and Japan regarding components, material, and manufacturing technology from the viewpoint of industry development and stable supply of medical products and technologies.
- For both: Support joint U.S. and Japan countermeasures against infectious diseases and disasters. Establish a market incentive system for R&D for antimicrobial drugs and vaccines and promote the fight against drug resistance (“AMR”).
- For both: Support removal of unjustified trade barriers to medical products to ensure timely access for patients.
- For both: Establish expedited regulatory review procedures for improved supply chains such as the relocation of manufacturing sites in the event of an emergency and regulatory reliance/sharing of reviews of post-approval changes related to manufacturing, and consider other initiatives to support supply chain resilience.
- For both: Establish a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) between the U.S. and Japan to improve supply chain management.
- For both: Adopt and strengthen science-based pro-vaccination policies and public information campaigns, understanding that high vaccine uptake is essential to preserving economic and social resilience vis-à-vis pandemics and seasonal and endemic diseases.
- For both: Recognize the evidence-based health benefits of functional foods, so that the benefits can be communicated to promote wellness.