U.S. Chamber of Commerce International Affairs | U.S.-Japan Business Council | JUBC Japan-U.S. Business Council

Healthcare Innovation

Urgent and sustained investments in healthcare innovation are needed to promote health system resilience, timely patient access to new treatments, workforce productivity and stability, and economic competitiveness. Declining birth rates and rapidly aging populations present new health challenges in the U.S. and even more so in Japan, where almost one-third of the population is now aged 65 or older. At the same time, the younger generation is being diagnosed with certain cancers at unprecedented rates, chronic diseases strain healthcare systems, and preparedness for global-scale threats remains critical. These global issues require increasingly efficient, personalized, and scalable solutions.

The life sciences industry rises to the challenge by investing in research and development (R&D) that results in the creation of cutting-edge innovation. Breakthrough treatments and technological advancements, such as artificial intelligence (AI) and new digital tools, make healthcare more accessible and data driven. However, the policies that dictate access to these innovations for Japanese and American patients are failing to keep pace. Instead, these policies create significant obstacles for patients and industry, preventing optimal healthcare services and economic outcomes.

As the United States and Japan continue leading the biopharmaceutical and medtech ecosystem, we must work together to ensure innovation receives balanced and sustainable support. Ensuring that the value of innovative medicines is appropriately supported—particularly in pricing mechanisms—is critical. A shared commitment to fair and predictable trade frameworks will safeguard patient access and foster continued innovation. Additionally, both countries should support digital transformation and cut bureaucratic red tape preventing deeper bilateral cooperation on healthcare as economic security.

By committing to the critical reforms we recommend below, the U.S. and Japan can cement their ongoing leadership in life sciences:

1. **Pricing and Patient Access Policy:** Negotiations should include reforming pricing policies to advance best practices, promoting investment for medical innovation and timely and continued patient access. A new, holistic strategy with cross-ministerial engagement is needed to support ambitious outcomes across all parts of the health innovation ecosystem. The private sector can offer guidance on targets and policy approaches, as well as lessons learned from similar endeavors in other countries.

2. **Create a U.S.-Japan Digital Health Transformation:** USJBC and JUBC recommend leveraging the new public-private council to design and launch a U.S.-Japan partnership on digital health. The council will share best practices for: telemedicine and remote care, digital therapeutics, use of AI, cross-border data flows and privacy, and the creation of efficient regulatory pathways to enable patient access to these technologies.

3. **Increase Supply Chain Resilience and Economic Security:** The Councils recommend that negotiated outcomes address specific opportunities for the U.S. and Japan to promote supply chain resilience, including improvement of regulatory transparency and due process, and reducing regulatory disparities. The commitments should also address other tariff and non-tariff barriers that increase the cost of supply chain integration, industry competitiveness, and national economic security. As noted above, the Councils urge both countries to avoid imposing tariffs on medicines and medical devices, as these measures will not contribute to competitiveness and will harm patients.

The U.S. and Japan need to ensure innovation and patient access are at the heart of their healthcare strategies. We recommend the following reforms to ensure both countries have access to the best, most effective healthcare innovation. These items are not comprehensive, hence we welcome continuous conversation from both countries:

1. Pricing and Patient Access Policy

In a positive development for Japan, the 'Basic Policy on Economic and Fiscal Management and Reform 2025' highlights the need to strengthen drug discovery capabilities and raise official medical care prices in response to rising costs, although it does not explicitly mention drug pricing. However, unpredictable drug price revisions and policies, such as using a cost-effectiveness evaluation to cut price premiums, have disincentivized R&D and resulted in drug lag/loss and quality issues. In the United States, the Most Favored Nations (MFN) Executive Order presents a monumental challenge to long-term R&D and patient access should the threat of international reference pricing be realized.

- For both: Commit to developing and improving the current R&D, regulatory, and reimbursement systems to encourage adequate investment in the market. Ensure that regulatory and pricing systems are evolving to keep pace with the incredible breakthroughs and advancements in science and technology associated with new pharmaceutical and medical technology products.
- For both: Support high-standard intellectual property (IP) regimes. IP protections create the foundation for and drive investment in biopharmaceutical research and are essential to current and future research partnerships in Japan and the United States.
- For both: Introduce financial initiatives that reflect the value of innovation to support innovative therapeutics such as regenerative medicine, cell therapy, gene therapy, and digital therapeutics such as software as a medical device ("SaMD").
- For both: Prevent and eliminate harmful price control policies that discourage innovation and patient access, including provisions stipulated in the Inflation Reduction Act (IRA). These provisions disincentivize the development and stable supply of small molecule medicines, medicines for rare diseases, and R&D for new uses of medicines following an initial regulatory approval.
- For both: Our understanding of human pathology has advanced remarkably, and some interventions for diseases are now initiated before symptoms appear. Discussions should be initiated on improving the healthcare system and patient access to innovative interventions regardless of a patient's finances.
- For both: Enhance Patient Public Involvement (PPI) in the formation of health policy.
- For the U.S.: Address the unintended consequences of pricing reforms and proposals on provider reimbursement, so that all physicians can afford to administer the most appropriate medicines for their patients.
- For the U.S.: Ensure that patients benefit directly from the discounts provided by biopharmaceutical companies to 340B hospitals and off-site entities serving low-income communities.
- For Japan: Given Japan's economic inflation and the negative impact it has had on drug innovation and shortages, lift the ceiling on growth of social security-related expenditures. Reform the current fiscal framework of social security-related expenditures to promote investment in biopharmaceutical innovation by recognizing health system savings (care burden reduction and well-being improvement, etc.) and economic growth from innovative medicines.
- For Japan: Maximize multinational company engagement in the new public-private council (PPC) starting in 2025 and listen sincerely industries' advise on the development of rules impacting the healthcare sector. Ensure that the drug pricing system is addressed within the framework of the PPC, with the active participation of all relevant ministries. Recommendations from the PPC should be jointly formulated through close collaboration between the public and private sectors.
- For Japan: Exclude patented innovative new drugs from the scope of price revisions (including off-year), market expansion, and spillover repricing to ensure a simple and predictable system.
- For Japan: Promote practical pricing approaches that consider the wide range of benefits derived from therapies, including clinical outcomes as well as social, population-level, economic, and health system benefits. In addition, add more flexibility to apply comparative pricing methods or create a new pricing mechanism for innovative products with no comparator to ensure fair and adequate value is given to novel

drugs without a subjective transparency penalty. Given that innovative cell and gene therapies are produced through personalized manufacturing processes, reducing the price of those based on increased patient numbers would have a significant negative impact on the sustainability of patient access and the supply system.

- For Japan: Do not expand the scope of the Health Technology Assessment (HTA) system. Proposed expansion of the cost-effectiveness evaluation system will discourage investment for innovative drugs and medical technologies. When conducting evaluations, consider that drug prices in Japan are determined by a sophisticated drug pricing system. It is necessary to maintain consistency with the existing drug pricing system. Avoid the mechanistic use of cost-effectiveness thresholds when determining value, including for insurance reimbursement decisions, to limit barriers to innovations.
- For Japan: While the Optimal Use Promotion Guidelines (OUG) serve as a meaningful tool to balance patient benefit and financial sustainability of National Health Insurance (NHI) it is important to ensure that they do not overly restrict patient access in clinical practice. The OUG for each medicine or device should be reviewed regularly.
- For Japan: With respect to medical devices, abolish the Foreign Average Price adjustment system, which compares medical device pricing without considering differences in healthcare systems, economies, and reimbursement environments among countries. This abolishment will ensure innovative medical devices remain available to patients in Japan. The outlier rule applied for the calculation works to omit its price in the U.S. in most cases.
- For Japan: Exclude innovative medical devices, such as those classified under unique designated functional categories, from market expansion repricing.
- For Japan: When reviewing functional categories for medical technologies, work closely with industry to ensure that any changes do not undermine innovation.
- For Japan: Provide early access to diagnostics and screening assays for diseases like cancer and rare diseases given screening, prevention, and better targeted therapies lead to lower healthcare costs in the long term. Work to align regulatory and reimbursement systems with global standards to ensure timely patient access to innovative medicines.
- For Japan: The Ministry of Health, Labour and Welfare should promote transparency in the drug review process for the public/patients and biotech companies. Deepening understanding of the process is important to improve drug loss issues in Japan.
- For Japan: Advance discussions on the ideal way to ensure the stable supply of medicines, while further developing an effective system which enables the prompt withdrawal of off-patent medicines from the market.

2. Digital Health Transformation

The U.S. and Japan share a commitment to leadership in digital services, and industry welcomes constructive actions like the FDA's draft guidance on the use of AI. Early guidance ensures we have the level playing field we need to succeed.

- For both: Reinforce a comprehensive commitment to swift and effective digitalization in healthcare, supported by strong leadership and adequate government backing.
- For both: Promote alignment between U.S. and Japanese regulators in developing and implementing new digital health policies, reduce the cost of new innovative therapies, and improve health outcomes by collecting data and supporting physician/patient interaction. Health data platforms should be designed with consideration for the secondary use of collected health data, which may be utilized for R&D, safety monitoring activities, and evidence generation.
- For both: With appropriate protections and meaningful incentives, promote the development, adoption, and use of interconnected/interoperable health data platforms – whereby individuals can access their own health data. Use 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 advancements achievable through the voluntary sharing of anonymized medical data,

which can drive evidence-based treatment solutions and policymaking.

- For both: Address barriers to data-sharing mechanisms, while maintaining appropriate privacy protections, to enable the discovery of novel targets and therapies. Integrate genomic/multiomic data into the healthcare system through collaboration with researchers and clinicians and the bilateral exchange of best practices.
- For both: Further promote the application of decentralized clinical trials, enabling a hybrid model of in-person and remote visits to medical institutions for the benefit of trial participants.
- For both: Align U.S. and Japanese regulators in cybersecurity risk management to protect against cyberattacks and data intrusions, ensuring patient safety, and minimizing enterprise risk.
- For both: Support diverse treatment modalities, such as telemedicine, which can be effectively utilized at home.
- For both: Foster partnerships between U.S. and Japanese healthcare institutions, technology companies, and academic researchers to share best practices and jointly develop innovative digital health solutions. Establish bilateral working groups to address common challenges and identify opportunities for collaboration.
- For both: Train healthcare professionals with the necessary skills to effectively use digital health technologies. Encourage continuous education and certification programs to ensure healthcare workers are up to date with the latest digital tools and practices.
- For both: Develop digital health solutions that prioritize patient engagement and empowerment. Encourage the use of patient feedback in the design and implementation of digital health platforms to ensure they meet the needs of diverse patient populations.
- For both: Facilitate the integration of AI and machine learning technologies in healthcare systems to enhance predictive analytics, personalized medicine, and operational efficiency. Encourage the development of ethical guidelines for AI use in healthcare.
- For both: Develop data governance frameworks that ensure the ethical use of health data, protect patient privacy, and promote transparency in data sharing practices. Encourage international collaboration to establish global standards for data governance.
- For Japan: Implement a comprehensive health data policy that encourages the government to build data infrastructure and include legal frameworks, which enables the private sector's utilization of health data while also protecting patient privacy.
- For Japan: The Ministry of Health, Labour and Welfare should enact a bill to amend the Medical Care Act by the end of 2025, enabling pharmaceutical companies and other entities to utilize public databases held by the Ministry for secondary purposes.
- For Japan: Establish a digital mechanism that allows the healthcare industry to effectively deliver necessary information regarding pharmaceuticals and medical devices to patients and the public.
- For Japan: Further support the development of a data platform for the traceability of pharmaceuticals and medical devices.
- For Japan: Expand telehealth infrastructure to ensure equitable access to digital health services across rural and underserved areas. Provide subsidies or incentives for healthcare providers to adopt telehealth technologies and reach remote populations.
- For Japan: Create innovation hubs and fund startups in the digital health sector. Encourage collaboration between startups, established companies, and academic institutions to drive innovation and accelerate the development of new digital health solutions.
- For Japan: Educate the public about the benefits and potential of digital health technologies. Provide resources and support for patients to understand and navigate digital health platforms effectively.

3. Supply Chain Resilience and Economic Security

On the U.S. side, tariff proposals create new concerns. Increased tariffs will hamper American and Japanese healthcare due to our deeply interconnected global supply chains.

- For both: Promote economic security policies that enhance diverse and resilient supply chains and encourage free and fair trade with trusted partners. During cross-border crises, such as pandemics, it would

be desirable to establish a system under which both countries would share raw materials, active pharmaceutical ingredients (APIs), and end-products with each other as a top priority.

- For both: Avoid tariffs on medicines and other medical goods, which both governments have recognized for decades require special consideration. Such measures do not contribute to economic security, risk shortages, and ultimately raise healthcare costs.
- For both: Reinforce global supply chains through alliances between the U.S. and Japan. Support the removal of unjustified trade barriers on medical products to ensure timely and equitable access for patients and stable supply of health products. In particular, the supply chain for biopharmaceuticals is complex and globally optimized, and relocating manufacturing sites requires long-term economic certainty, significant time, and expense, including compliance with many regulations. Therefore, it is important to promote policies that do not hinder access.
- For both: Establish initiatives to enhance mutually beneficial cooperation between the U.S. and Japan regarding components, materials, and manufacturing technology from the viewpoint of promoting industry development and creating a stable supply of medical products and technologies.
- For both: Support joint U.S. and Japan countermeasures against infectious diseases and health emergencies. Establish an appropriate market-based incentive system for R&D for antimicrobial drugs and vaccines while also countering against antimicrobial resistance ("AMR"). It is beneficial to share data on disease factors such as pathogens, as well as development and manufacturing technologies for vaccines and medicines.
- For both: Create fast-track review processes 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.
- For both: In cooperation with the Japan and U.S. authorities, establish a Mutual Recognition Agreement (“MRA”) on Good Manufacturing Practice (“GMP”) 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-a-vis pandemic, seasonal, and endemic diseases.
- For both: Recognize the evidence-based benefits of fundamental health solutions, such as a well-balanced diet, exercise, and adequate sleep. These benefits should be communicated to promote public health and enhance primary disease prevention for healthy longevity in aging societies.
- For Japan: The Ministry of Health, Labour and Welfare should promote use of digitalization and establish a database to understand actual distribution of the medical product in supply chain.