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# Healthcare Innovation



Sustained investment in healthcare innovation is essential for developing new medicines and technologies, strengthening healthcare systems, improving patient access to innovative treatments, and enhancing economic competitiveness. However, demographic shifts are straining healthcare systems in the United States and Japan. While both countries seek cost containment through pharmaceutical spending controls, approaches prioritizing cost over patient value rely on outdated or unpredictable pricing and reimbursement policies and undermine the long-term sustainability of healthcare systems, hindering the quality and efficiency of healthcare services, weakening incentives for innovation, and undermining economic security.

The United States and Japan must deepen bilateral cooperation to ensure modernized healthcare policies and support continuing innovation for sustainable development. This joint statement outlines priority reforms across three interconnected pillars:

1. Patient Access and Pricing
2. Digital Health Transformation
3. Supply Chain Resilience and Economic Security

## 1. Patient Access and Pricing

Sustainable healthcare innovation depends on predictable, and value-based pricing and reimbursement systems that reward innovation. The U.S. and Japan should ensure that regulatory and payment frameworks incorporate the flexibility and predictability to evolve alongside innovation and maintain strong incentives for research and development.

### Shared U.S.-Japan Priorities

- Establish an open dialogue on adopting pricing policies that advance investment in healthcare innovation, promote regulatory and reimbursement policy cohesion, and enhance patient and public involvement in healthcare policy development, ensuring the system better reflects patient needs and outcomes.
- Improve R&D, regulatory, pricing, and reimbursement systems to encourage long-term investment, innovation, and timely patient access to healthcare innovations.
- Support high-standard intellectual property protections as the foundation for healthcare innovation and cross-border research collaboration, including a robust patent linkage system that guarantees adequate enforcement throughout the protection period of patents and patent term extensions.
- Promote equitable patient access to innovative healthcare interventions given the healthcare cost reduction benefits of preventative care, such as through early screenings and targeted therapies.

### U.S.-Specific Considerations

- Develop pharmaceutical and medical technology pricing systems that are implemented to preserve incentives for future innovation, enhance market predictability, and maintain timely patient access to healthcare solutions.
- Ensure that rebates and discounts retained by pharmacy benefit managers and other intermediaries are appropriately passed through to patients to improve affordability and access to medicines.
- Ensure that patients directly benefit from manufacturer discounts provided to 340B hospitals and affiliated entities serving low-income communities and remove unintended incentives that drive consolidation of costs in the healthcare system.
- Pursue trade policies and agreements that ensure all parties invest in innovation.

### **Japan-Specific Considerations**

- Advance a sustainable, innovation-driven healthcare system by reconsidering the ideal balance of access, cost, and quality; supports adequate funding, predictable pricing, and accounts for inflation for innovative medicines and medical technologies; and accelerates clinical development and patient access to breakthrough therapies, vaccines, and treatments addressing unmet medical needs.
- Address regulatory and operational barriers to participation in international multi-regional clinical trials.
- Consistent with the 2026 Honebuto and Japan's Growth Strategy, grow the domestic patented medicines market by 9.6% annually, a rate comparable with leading markets. To achieve this level of growth, Japan should (1) improve how it sets initial prices for patented medicines by aligning with U.S. price levels after adjusting for GDP; and (2) abolish rules that prevent the maintenance of prices during the patent period, including market price revisions, market expansion repricing and related policies, and cost-effectiveness analysis (CEA).
- CEA should not be used to reduce prices during the patent period of medicines. Considering the current policy environment, CEA should be frozen for 2027. Ideally, it should be abolished to secure active industry investment.
- Ensure meaningful multinational industry participation in policy reform, including during Chuikyo and other meetings with active engagement from all relevant ministries.

## **2. Digital Health Transformation**

Digital health is central to improving care delivery, expanding access, measuring outcomes, and enabling innovation and policy making. The United States and Japan are committed to leading in digital services and should deepen cooperation to accelerate responsible digitalization of their respective healthcare systems.

### **Shared U.S.-Japan Priorities**

- Reinforce national commitments to healthcare digitalization through strong leadership, coordinated policy frameworks, and sustained government support.
- Align on regulatory approaches to digital health, including artificial intelligence, cybersecurity, and software-based medical technologies, to reduce barriers and promote patient access.
- Promote interoperable health data platforms using international standards to support integrated care, secondary data use, safety monitoring, and evidence generation.
- Address ethical, legal, and social barriers related to data sharing, privacy, and non-discrimination, while encouraging voluntary sharing of de-identified health data for research and policymaking.
- Enable secure data sharing, supporting new target and therapy discovery, while protecting patient privacy. Advance genomic and multiomic integration into healthcare through researcher-clinician collaboration and sharing best-practices.
- Support decentralized and hybrid clinical trial models to reduce patient burden and improve trial participation.
- Invest in workforce training to ensure healthcare professionals are equipped with the knowledge and training to utilize digital health technologies.

### **Japan-Specific Considerations**

- Promote health data infrastructure and establish a legal framework that ensures patient data privacy protection while enabling secure, trustworthy access to and effective use of health data, including by AI tools, for research and innovation.
- Develop digital platforms to improve patient access to information on pharmaceuticals, medical devices, and product traceability.
- Advance a trusted data partnership designation under the Act on the Protection of Personal Information (APPI), building on the U.S.-Japan Technology Prosperity Deal to establish shared standards, security commitments, and AI governance frameworks.
- Fast-track reimbursement pathways for Software as a Medical Device (SaMD), with MHLW directed to publish updated reimbursement criteria for AI-enabled digital therapeutics within a defined timeframe.

### 3. Supply Chain Resilience and Economic Security

Resilient and diversified supply chains are essential to healthcare security and patient access. The interconnected healthcare supply chain amongst the U.S., Japan, and likeminded countries requires coordinated policies that promote free and fair trade while preparing for future crises.

#### **Shared U.S.-Japan Priorities**

- Promote economic security policies that strengthen supply chain resilience, and reward responsible sourcing, without undermining global integration or patient access.
- Eliminate tariffs on medicines, medical devices, and essential health goods, recognizing their negative impact on availability, affordability, and innovation.
- Enhance cooperation on supply chain transparency, regulatory alignment, and crisis response, including sharing national stockpiles, priority raw materials, key starting materials, active pharmaceutical ingredients, and finished products during an emergency.
- Ensure healthcare security for critical medicines and medical technologies in each country by strengthening stable access to critical health products and technologies through upgrading aging supply infrastructure, diversifying sourcing, and expanding national stockpiles where appropriate.
- Maintain access to global clinical research and clinical trial infrastructure to ensure geopolitical tensions do not delay patient access to innovative therapies.
- Establish fast-track regulatory processes for manufacturing changes during crises.
- Advance U.S.-Japan regulatory coordination to reduce duplicative inspections and enhance cooperation on pharmaceuticals, medical device quality oversight, supplements, and other related products, and facilitate trade in such products between the two countries.
- Support joint countermeasures against infectious diseases, antimicrobial resistance, and future health emergencies through data sharing and coordinated R&D incentives.