

SUPPLEMENT on HEALTHCARE INNOVATION

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Executive Summary

Section I: Creating a more Transparent and Predictable Environment for Innovation to Continue Improving People's Health Worldwide

R&D Environment: Pursue R&D paradigms that foster collaboration among industry, government, academia, patients and non-profit organizations to accelerate the translation of innovative biopharmaceutical science into impactful health products.

Regulatory Approvals: Further develop regulatory systems to be more transparent, predictable, and efficient. Such systems, for example, should help foster simultaneous global clinical development of experimental therapies, leading to first-in-world approvals by minimizing country-specific requirements and optimizing international standards and common practices.

Evaluation of Innovative Therapies: Ensure that pricing and reimbursement schemes and their reforms are designed and implemented to fully recognize the value of innovation in a transparent, predictable and efficient manner. Such schemes should equally optimize patient outcomes and physician choices, encourage innovative R&D, and allow full and equitable access to innovative products and services by those who need them within existing healthcare systems.

IPR Protection: Strengthen Intellectual Property Rights (IPR) systems to fully protect inventions and related data. By ensuring full protection of innovators' rights through transparent, predictable and effective means of enforcement and redress, such systems will contribute to spur further innovations.

Section II: Maintaining Workforce Health and Productivity, Reducing Economic Burdens of Diseases, and Extending Healthy Life Expectancy

Preventive Care and Health and Productive Management: Create incentives to promote wellness through preventive care measures, such as use of vaccines and health and productivity management initiatives inside public and private organizations through systematic process management and behavioral modification.

Healthcare System Efficiency: Pursue more efficient healthcare systems through appropriate adoption of outcome oriented healthcare management and digitalization combined with a community-based approach.

Global Leadership: Collaborate globally to improve people's health and welfare, including in the U.S., Japan and the Asia Pacific region, laying a stronger foundation for more sustainable economic growth and greater international trade.

SECTION I: Creating a more Transparent and Predictable Environment for Innovation to Continue Improving People’s Health Worldwide

1. R&D Environment

Innovation is at the center of the healthcare industry in the United States and Japan. In the U.S., the Councils welcome the passage of the 21st Century Cures Act (HR 6) that is expected to accelerate the development and delivery of new medical devices and biopharmaceuticals. The Councils applaud the opening of the Japan Agency for Medical Research & Development’s (AMED) overseas offices.

Biopharmaceuticals and Medical Devices

- To further promote innovation in both countries, increase regular discussion between industry and governments throughout the discovery, development and delivery of innovations.
- Ensure sufficient government funding is secured and managed independently by AMED. The Councils are encouraged by the progress of AMED’s use of English as the primary business language to facilitate cross-border collaboration, and hope to see its further development.
- The Councils welcome initiatives aimed at promoting healthcare ventures in Japan. Such measures could include setting up clear regulatory guidelines/requirements and tax incentives to attract foreign investments into healthcare.
- Maintain and expand the Japanese R&D Tax Credit permanent while deregulating the Open Innovation Tax Credit in order to promote R&D investments and enhance the international competitiveness of Japan.
- Make the current two-year suspension of the U.S. Medical Device Excise Tax permanent.
- Continue to foster development of “next generation” innovative therapies through engagement by U.S. and Japanese government agencies to support convergence of stem-cell and regenerative medicine policies and legislation.
- As the Clinical Research Law is implemented, the Councils urge the Government of Japan to fully take into account the characteristics of medical devices, including its procedure-driven nature; short product life cycle; more frequent minor and major modifications; and longer service life that make it difficult to conduct large scale studies.
 - Continue to promote “seamless innovation”, or what is referred to as “open innovation” in Japan by reducing regulatory barriers and creating incentives for collaboration between industry, government, academic and non-profit sectors.

2. Regulatory Approvals

The Councils welcome implementation of the *Sakigake* strategy with the inclusion of regenerative medicines and medical devices, as well as the introduction of the Act on the Safety of Regenerative Medicine. The Councils applaud continued timely reviews of pharmaceuticals in Japan as well as its adoption of new “fast track” pathways.

Biopharmaceutical and Medical Devices:

- Encourage PMDA to increase its focus on clinical relevance of data, as well as to improve internal capacity to evaluate newer statistical methodologies and study designs,

including the flexible acceptance of Phase I clinical and pivotal study data from outside of Japan.

- Ensure that user fees are reasonable and that any increases in them are linked to agency performance.
- Increase the active sharing of Good Clinical Practices (GCP) inspection reports between FDA and PMDA to reduce redundant on-site inspections and increase regulatory efficiency.
- Apply the concept of the “least burdensome approach” to regulation in the U.S. and Japan. In particular, the Councils strongly encourage FDA to: (1) make further improvements to the regulatory environment through more risk-based assessment and better balance between pre- and post-market requirements; and (2) make sure that the introduction of new approaches, such as “estimand” and associated “missing data collections,” do not add significant burdens or delays to the development timeline of clinical trials. The Councils believe these approaches will lead to greater investment by healthcare companies in the United States and Japan.
- Ensure that sufficient budget and human resources are allocated to the PMDA to support the "priority review designation system" based on the *Sakigake* strategy.
- Building on the progress of the U.S. and EU’s mutual recognition of good manufacturing practices (GMP) for pharmaceuticals, pursue such GMP mutual recognition between the U.S. and Japan.
- Promote alignment between US and Japan regulators in developing and implementing new “digital health” policies that can accelerate and reduce cost of development of innovative therapies

Biopharmaceuticals

- Harmonize the regulatory and legal requirements of the electronic record/electronic signature for electronic regulatory submissions.
- Make sure that the legal requirements for the sharing of genomic data are harmonized to global standards to accelerate pharmacogenomics (PGx) research and development.
- Define clear and harmonized regulatory guidelines and policies on preclinical data requirements prior to clinical investigation for biotechnology products.
- Fully utilize Real World Data (RWD) such as medical information database and/or patients disease registry for post marketing surveillance (PMS).

Medical Devices

- Utilize the Medical Device Innovation Consortium (MDIC) in the U.S. to create forums for collaboration and dialogue between regulators, manufacturers & other stakeholders; fund key regulatory science projects (such as the Case for Quality); and provide tools to drive innovation (such as searchable databases linked to standards & test methods, educational training programs, etc.).
- Promote the Harmonization by Doing (HBD) program as a mechanism to streamline the processes of global medical device development, reduce overall medical device development costs, and provide faster patient access to new medical technologies.
- PMDA significantly raised the review fee and the contribution of safety measures from April 2017. The councils expect PMDA to improve their performance of review process and strengthen its organizational governance.

- Continue improvements to the efficiency and consistency of pre- and post-market (e.g. surveillance, facility inspections, etc.) regulatory processes in the United States.
- Establish mutual recognition between the United States and Japan of good clinical practices and quality management audit results.
- The Council welcomes the Japanese government’s commitment to promote medical device R&D, as communicated through the Basic Plan. Industry looks forward to working with the government and other stakeholders to support implementation of the Basic Plan.
- Promote a harmonized approach to Unique Device Identification with the aim of ensuring quality, logistical efficiency, and traceability for medical safety.

Diagnostics

- Continue efforts to create clear, transparent, and predictable regulatory path and reimbursement policies for companion diagnostics. As part of this process the Councils welcome MHLW’s decision to provide the IVD industry a meaningful opportunity to provide the industry’s views at Chuikyo.
- The governments of the U.S. and Japan should collaborate in global efforts to streamline and harmonize the regulatory pathway for the development of companion diagnostics for use in the growing area of personalized medicine.

3. Evaluation of Innovative Therapies

Innovation in the biopharmaceutical and medical device sectors benefits millions of people worldwide by helping them living healthier, longer and more productive lives. Such innovation is also critical to drive economic growth and development. It is therefore critical for the U.S. and Japan to build sustainable systems that fairly evaluate and reward innovation, including exploring possible new healthcare financing measures to further spur innovation.

Biopharmaceuticals and Medical Devices

- Recognize that innovation delivers improved clinical value and outcomes over conventional or existing clinical interventions. Innovative products leading to improved clinical outcomes should be fully rewarded and accessible under the existing universal health coverage systems in Japan.
- Abolish the anti-innovative application of the “Special Re-pricing for Market Expansion Rule”
- Ensure that the current clinical trial-based health technology assessment (HTA) system and procedures in Japan aim at promoting innovation, including taking into account physician fees and welfare fees as well as the impact of innovation on overall welfare spending. It should also, be inclusive of all the various impacted stakeholders. Ensure that HTA recommendations do not restrict patient access and outcomes or physician choice, and do not delay drug or device regulatory approval and/or access.

Biopharmaceuticals

- Make the Japanese “Price Maintenance Premium” permanent while ensuring that its scope of application is not diminished to provide price stability over the patent life and/or exclusivity period of innovative biopharmaceutical products, which would continue to make the Japanese market more attractive. Combined with policies to

promote greater use of generic medicines, this is a budget neutral policy that supports innovation.

- Ensure the price revision process in Japan is conducted every two years with off-years price revisions limited to generic and long-listed biopharmaceutical products (LLPs) that have a significant discrepancy between the National Health Insurance price and the actual market price.
- Ensure drugs are not repriced based on indication extrapolation alone, which will discourage investment in additional clinical trials to meet unmet medical need.
- Preserves recognition of the value of innovative pharmaceutical R&D by not excluding or diminishing the U.S. price in the “Foreign Price Adjustment.”
- Expand incentives for the development of innovative stem-cell and regenerative therapies through adequate reimbursement policies.

Medical Devices

- Repeal the currently suspended U.S. Medical Device Excise Tax that took effect in 2013 as part of the Affordable Care Act.
- Implement stable and predictable reimbursement policies in Japan that align with Prime Minister Abe’s focus on the medical device sector as a driver of economic growth and job creation.
- Ensure that the medical devices prices revision in Japan is not conducted every year.
- Careful introduction of health technology assessment (HTA) system in consideration of the characteristics of medical devices.
- Ensure that, new functional classification can be reapplied in case additional clinical experiences are shown even after the first reimbursement in consideration of the characteristics of medical devices.
- Better reward innovation in Japan’s reimbursement system by reconsidering the FAP revision formula (see below); making targeted improvements to the C1/C2 premium reimbursement application process; continuing the “single room” system to reward innovative products within existing functional categories including, if appropriate, establishing functional category subdivisions for innovative products; and continuing the device lag elimination premium.
- Reimbursement for special treatment materials is utilized by functional category system but not by brand as pharmaceuticals. For that reason, there might be a case where products with a large difference such as actual usage status, structure, or market price would be mixed in the same functional category. It is expected to accelerate the innovation by further expanding the subdivision of the functional category.
- Abolish Japan’s Foreign Average Pricing system and replace with a market-oriented, data-driven, transparent reimbursement scheme that welcomes and rewards innovation. Until the system is abolished, maintain – and increase for certain C1 products - the current Foreign Average Price (FAP) multiplier; adjust the reimbursement upward for products with FAP ratio lower than 0.75; apply the outlier rule to the lowest price; and exempt certain C1 products from reductions over at least two revision cycles.

Diagnostics

- Develop pricing incentives for companion diagnostics that can improve efficiency in healthcare spending.

4. IPR Protection

Biopharmaceuticals and Medical Devices

- Strengthen the IP transfer bridge between academic institutes and companies with manufacturing and sales capabilities for both biopharmaceuticals and medical devices.

Biopharmaceuticals

- Continue to further strengthen IPR standards in the U.S. Japan and globally, including data protection to continue fostering innovation.
- Increased collaborative efforts between the U.S. and Japan to minimize the use of compulsory licenses in other regions, which by World Trade Organization design should be used only in specified circumstances (i.e., to meet a health crisis or emergency) rather than being applied as tools for price control.
- Ensure that IPR systems in Japan and the U.S. fully recognize and offer robust, comprehensive protection for next generation innovative therapies, such as gene , stem-cell , and regenerative therapies.
- Maintain early resolution mechanisms to ensure that generic products do not enter the market when the originator product has still valid IP protection.
- Extend patent term restoration to address untimely pricing and reimbursement approvals in third country markets.
- Consider the introduce Patent Box system in US and Japan to further promote innovation.
- In TPP 11, remaining member countries are inclined to agree on the suspension of the data protection discussion until the return of US. The Councils urge Japan to pursue the highest standard of data protection for biologics to promote innovation.

Medical Devices

- Establish a harmonized patent term extension system to ensure the same scope of patented inventions subject to the extension.
- Restrict patent right enforcement by non-practicing entities.
- Ensure that IPR systems in Japan and the U.S. fully recognize and offer robust, comprehensive protection for next generation medical devices associated with innovative therapies, such as gene, stem-cell, regenerative therapies, etc.

Section II: Maintaining Workforce Health and Productivity, Reducing Economic Burdens of Diseases, and Extending Healthy Life Expectancy

2. Promote Preventive Care and Health and Productivity Management

The Councils recommend that both governments advance ongoing health policy reform discussions of on preventive care and wellbeing promotion. Such policies, once properly developed and implemented, could help mitigate healthcare-related economic challenges in both countries.

Specifically, the Councils offer the following suggestions to Japan and U.S. government policy makers:

- Collaborate with healthcare professionals to develop public education programs on preventive health measures, including programs to improve awareness on vaccinations, early diagnosis of disease, and slowing disease progression. Such programs should also include education on possible treatment options when relevant.
- Accelerate Japan’s vaccine policy reform efforts through increased collaboration between government, industry, academia, medical societies and patient advocacy organization to promote sustainable vaccination programs.
- Speed efforts to recognize the health benefits of functional foods, such as health foods and dietary supplements.
- A systematic Process Management and encouraging behavioral change of employees for improving their quality of life is needed for the organizations to strengthen Health and Productivity Management. The Councils thus recommend both governments to set up a strategic planning committee or taskforce of Healthcare Society, and encourage international standardization and possible disclosure system.

3. Healthcare System Efficiency

- Health Management should be based on clinical value and clinical outcome, not solely on frequency or numbers of clinical measures in Japan.. To make an effective universal coverage healthcare system like Japan’s sustainable, able to account for various innovative products and services to be provided within the system, evaluation standards for healthcare expenditures should be evolved from volume-based to value- and outcome-based calculations. The Councils support the initiatives proposed by the “Next Generation Healthcare Information and Communication and Technologies(ICT)” Infrastructure Council in Japan, which promotes the use of real-world data (RWD) through ICT databases for disease prevention, evaluation of health technologies, and to foster research & development.
- Incentive models should be built to facilitate ICT investment through medical and long-term care funding and reimbursement. Advanced medical technologies and innovative approaches, such as remote healthcare service (Tele-Health), should be utilized to reduce the physical and economic burdens created by chronic and terminal illness. A community-based approach should be adopted that educates patients and their families on resources available from both private and public providers. Well defined and transparent insurance models should be promoted that enables patients to receive

consistent, high-quality care as they transition from hospitals and other skilled nursing facilities to their homes.

- Regulatory evaluation criteria and reimbursement rules specific to medical devices used at home should be developed.
- It should be acknowledged that the foreign caregivers are an essential component of sustainable community-based care system, providing training and certification programs to accelerate recruitment of foreign caregivers.

4. Global Leadership

The Councils recommend the U.S. and Japanese governments continue to collaborate on improving health and welfare globally (and in particular in the Asia Pacific Region) to lay a strong foundation for sustainable economic growth and greater international trade. This continued collaboration allows both countries to lead healthcare promotion and reform initiatives not only in APEC markets, but also in other emerging regions and countries.

- Recognizing the leading contributions by the U.S. and Japan to providing biomedical innovation to the rest of the world, they should collaborate to ensure that regulatory review and approvals in other countries, particularly in leading emerging markets, are conducted in a transparent, fair, and expeditious manner.
- Collaborate on the adoption of codes of ethics based on APEC Kuala Lumpur Principles for medical devices Declaration of Helsinki as well as the Mexico City Principles for biopharmaceutical industry. The Councils support collaborative global health initiatives such as “U.S.-Japan Cooperation for a More Prosperous and Stable World,” “G7 Ise-Shima Vision for Global Health” as well as APEC “Healthy Asia Pacific 2020” vision. The Councils welcome the positive trend of strengthening collaboration among industry, governments, academia and global organizations to effectively prevent and control global crisis and develop sustainable and high performing health systems. The Councils will contribute by actively investing in R&D and voluntarily supply necessary medicines during pandemic outbreaks.
- Request Japan and U.S. to take leadership in accelerating the research, and development of and access to innovative therapies for rare, pediatric and infectious diseases in APEC markets, by creating an incentive mechanism for the creation of cross-border, seamless-innovation platforms, consisting of a seed database and patient registry using real world data, where industry, academia and government can collaborate closely for drug discovery and development.
- Request that US and Japan partner effectively to advance Digital Health, recognize their leading role in the development of cutting-edge medical and digital technologies
- Health and social care policy reforms in Japan to address the challenges of and support a super-aging society (with the smaller birth rate) could provide the global standard to drive healthcare system reforms in other countries in the world. Collaboration between the Japanese and U.S. governments to implement ideal measures to challenge these issues should become best practices in other Asia Pacific regions, which will eventually face similar situations in the future.