SUPPLEMENT on HEALTHCARE INNOVATION
Visionary Goals and Recommendations
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The R&D-based pharmaceutical and medical device industries continue to play a constructive role in improving the health and welfare of people in the world, including emerging markets, by driving economic growth and job creation, as well as developing innovative healthcare solutions that support the lengthening of the average healthy lifespan and reduction of the economic burden of disease. Accordingly, Japan-U.S. Business Council and the U.S.-Japan Business Council (hereinafter "the Councils") ask both governments to implement healthcare policies that embody the below visionary goals. The Councils recognize and welcome that good progress has been made over the last several years in improving the competiveness and attractiveness of the markets in both countries. In particular the Councils applaud Pharmaceuticals and Medical Devices Agency (PMDA) for steadily decreasing medical device and pharmaceutical approval times as well as Japan's introduction of a pilot program that provides price stability for pharmaceuticals over the patent/exclusivity period. In addition, the Councils welcome the increased levels of cooperation that the two governments have shown on third market issues as well as on free trade initiatives such as the Trans Pacific Partnership (TPP). The Councils offer the following specific recommendations under each visionary goal as a means to advance such progress.

Section I: Pharmaceuticals and Medical Devices

1. R&D Process Visionary Goal - The U.S. and Japanese markets have R&D systems that facilitate collaboration across the private, academic and public sectors and allow for efficient translational, pre-clinical, and clinical development that spurs innovative R&D. The Councils welcome plans to establish a medical research and development control tower function (Japan Agency for Medical Research and Development) to ensure the steady implementation of government efforts to promote and prioritize medical research and development. The Councils also welcome the Forerunner Package Strategy which was published in July by Japan's Ministry of Health, Labor and Welfare (MHLW) and describes significant advances in Japanese pharmaceutical and biotech regulation, approval and recommendations as well as research and development policies.

Pharmaceuticals and Medical Devices Recommendations

- Pursue and support policies that reduce the barriers between the private, academic and public sectors for collaboration globally.
- Make permanent the upper limit of 30% to Japan's R&D tax credit system.
- Introduce a permanent U.S. R&D tax credit system for long-term R&D innovation.

2. Regulatory Approvals Visionary Goal - The U.S. and Japanese markets have regulatory systems that are transparent, predictable, and efficient that foster simultaneous global development and result in first-in-world approvals through a minimization of country-specific requirements and maximization of international standards and common practices.

Pharmaceuticals

The Councils welcome Japanese government plans to promote global harmonization of regenerative medicine regulations. The Councils are also encouraged by Japan's new membership in the Pharmaceutical Inspection Co-operation Scheme (PIC/S), which will result in improvement in harmonization of manufacturing site inspection practices based on the PIC/S Good Manufacturing Practice (GMP) guide. The Councils offer the following recommendations.

- Further improve the expertise of PMDA reviewers, including in the areas of clinical research and practice as well as in new areas of medical specialization.
- Enhance Japan's coordination capacity in the "Tripartite" exercise to promote multinational clinical trials with China and Korea to further facilitate the broader and more flexible use of East-Asian clinical trial data as the basis of establishing safety and efficacy.
- The Councils will cooperate and begin to prepare for PDUFA VI in the U.S.
- Encourage PMDA to focus more on the clinical impact of data as well as to develop the capacity to accept newer statistical methodologies and study designs.
- Increase regulatory efficiency by the U.S. Food and Drug Administration (FDA) and Japan's PMDA more actively sharing GCP inspection reports with the aim of reducing on-site inspections.

Medical Devices

The Councils applaud Japan's passage of the new Pharmaceuticals and Medical Devices Law that establishes a separate chapter for medical devices and appreciate the close consultation with industry facilitated by MHLW and PMDA on the implementing regulations. In addition, the 5-year Action Program for the Speedy Approval of Medical Devices that ended in March of 2014 established performance goals for medical device approvals, tripled PMDA staffing, and substantially improved the approval process. The

Councils offer the following recommendations to both governments:

- Continue FDA consultations with industry on implementation of the U.S. Medical Device User Fee and Modernization Act.
- Establish more efficient regulatory processes in the U.S. to ensure patients have timely access to safe and effective medical devices.
- Establish mutual recognition between the U.S. and Japan of good clinical practices and quality management audit results.

3. Evaluation of Innovation Visionary Goal - The U.S. and Japanese markets have pricing and reimbursement systems that fully recognize the value of innovation in transparent, predictable and efficient processes that maximize patient access and physician choice as well as encourage innovative R&D.

Pharmaceuticals & Medical Devices Recommendations

- Ensure that if any new health technology assessment (HTA) or other pricing/reimbursement approach is introduced in Japan or in the U.S., it promotes innovation without restricting patient access or physician choice, and does not cause a drug or device lag.
- Ensure that the price revision process in Japan is not conducted annually, or in an ad-hoc manner.

Pharmaceuticals

- The Japanese pricing system pilot that provides for price stability over the life of the patent and/or exclusivity period makes the Japanese market more attractive. It should be made standard policy on April 1, 2016. Combined with policies to promote greater use of generic medicines, this is a budget neutral policy that supports innovation and reduction of the drug lag.
- Abolish the anti-innovative application of the "Special Re-pricing for Market Expansion Rule," such as Domino-style price reductions for all other drugs with similar pharmacological modes of action but different safety and efficacy profiles.
- Promote strong language guaranteeing reimbursement and pricing transparency provisions for third countries in TPP.
- Ensure that the Foreign Price Adjustment rule continues to take into consideration the cost of global R&D and rewarding innovation.

Medical Devices

- The Councils appreciate several measures taken in the 2014 price revisions to better reward innovation in Japan's reimbursement system, including targeted improvements

to the C1/C2 premium reimbursement application process, the "single room" system to reward innovative products within existing functional categories, and continuation of the device-lag elimination premium. However, the Councils continue to seek the following fundamental changes to pricing and reimbursement policies in Japan and the U.S.: Eliminate Japan's Foreign Average Price (FAP) rule for medical devices and transition to a product-based, market-oriented pricing system that allows for the full evaluation of innovative medical technologies and enables Japan to effectively execute its Health and Medicine Strategy.

- In line with Japan's Health and Medicine Strategy, consider reimbursement policies that facilitate a stable and predictable environment that encourages investment in the medical device sector.
- Repeal the U.S. "Medical Device Excise Tax" that took effect in 2013 as part of the Affordable Care Act (Obama Care), so that it will not undermine the industry's ability to develop innovative products and therapies.

4. IPR Protection Visionary Goal - The U.S. and Japanese markets have Intellectual Property Rights (IPR) systems that fully provide protections for inventions and data as well as transparent, predictable and effective means of enforcement and redress to ensure full protection of innovators rights and spur further innovations. Furthermore, the U.S. and Japan cooperate to promote the highest possible IPR standards in trade architectures such as TPP by, for example, stressing that IPR is neither a barrier to medicines nor an impediment to economic development.

Pharmaceutical Recommendations

- Adopt a 12-year period of data protection for biologics in Japan.
- Extend the data exclusivity period in the U.S to 8 years (and 10 years for orphan drugs) for small molecules.
- Press for the highest possible IPR standards in TPP.
- Shorten patent approvals in Japan from 2 years 6 months to 1 year 10 months, which is equivalent to that of Korea and China.
- Improve "patent linkage" in Japan by insuring that no generic applications are approved until there is a resolution of any patent issues in the court.
- Apply a "Patent Box" system to reduce the tax rate for royalty income.

Medical Devices

- Establish a harmonized patent term extension system to ensure the same scope of patented inventions subject to the extension.
- Strengthen the IP transfer bridge between academic institutes and companies with

manufacturing and sales capabilities, and restrict patent right enforcement by non-practicing entities.

Section II: Promotion of Healthy Lifestyles

1. Community-based Care Visionary Goal: The U.S. and Japan adopt policies that support and facilitate the optimal utilization of healthcare goods and services within a community-based system for the treatment of chronic and terminal patients. Such an approach will improve patients' quality of life, lower overall healthcare expenditures, leverage recent advances in remote-care, alleviate physician shortages, all while better serving aging populations.

Recommendations

1) Community-care systems should be established that include coverage of not only terminally ill patients but also patients suffering from chronic illnesses.
2) Policies should be adopted to alleviate the financial burden on patients associated with both modifications to and installation of additional capacities in the home needed to facilitate home care.
3) Reimbursement should be increased to fully cover the maintenance costs associated with homecare devices.
4) Treatment of patients using tele-medicine should be encouraged through appropriate reimbursement of healthcare providers for services provided via tele-medicine. Manufacturers also should be rewarded through reimbursement system for the investment associated with the development and servicing of hardware and software tailored for home use.
5) Japan should better integrate its healthcare insurance and nursing care systems so as to ensure seamless provision of quality healthcare to patients as they transition from the hospital or clinical setting to the home.

2. Vaccine Policy Visionary Goal: Eliminate "Vaccine Gap" in Japan and establish infrastructure to accelerate access to innovative and global standard vaccines.
The recent spread of infectious diseases such as dengue fever and ebola across national borders underscores the increasing importance of collaboration among countries on prevention and control measures.

Recommendations:
With this vision in mind, the Councils respectfully recommend that the Government of

Japan takes following actions with a strong leadership to reform the current vaccination system steadily based on the Basic Immunization Plan enforced in April 2014.

1) Develop measurable objective and timeline for the Basic Immunization Plan in order to execute the plan steadily.
2) Fully support the advisory committees on immunizations and relating organizations including National Institute of Infectious Diseases in order to promote science-based discussion and decision-making about vaccination-related issues.
3) Establish a standard process, criteria and timeline for adoption of new vaccines into the National Immunization Program.
4) Set a target vaccination rate of each recommended vaccine and take measures to achieve the target rate.
5) Establish a sustainable financing system for recommended vaccines that designates the federal government as a funding body of vaccination costs in order to promptly achieve uniform vaccination to those wishing to receive vaccines nationwide.
6) Organize an expert team in charge of vaccine communication to enhance risk communication and education of public, healthcare provider and media for promotion of informed vaccine decision-making by conveying detailed and accurate information about risks and benefits of vaccinations.
7) Strengthen collaboration between government, industry and academia for vaccine R&D.
8) Streamline the national testing system to realize flexible vaccine supply.

3. Diagnostics Visionary Goal: The U.S. and Japan recognize the innovative medical diagnostic industry as an important driver of job and export growth, support the use of innovative diagnostics for early diagnosis and treatment to improve patient Quality of Life and help extend the healthy lifespan of the population, and use pricing incentives for the use of innovative diagnostics to improve efficiency in health spending. The Councils welcome the adoption by the PMDA of a new action program in April 2014 to increase the number of reviewers and accelerate reviews of innovative new in-vitro diagnostic (IVD) products. We also applaud the new E3 rule that was introduced to reward innovation based on relative effectiveness and convenience, as well as inclusion in the new Pharmaceutical and Medical Devices Law of a separate chapter for in vitro diagnostic products.

Recommendations

1) In line with this vision, the Councils urge the Government of Japan to take the following steps:

(A) Continue efforts to create a robust regulatory pathway and reimbursement policy suitable for companion diagnostics; and

(B) Implement new E3 rule appropriately by providing pricing incentives for innovation by differentiating among reimbursement prices of various IVD products based on their relative value and quality, including potential for faster and more accurate diagnosis at point of care.

2) The governments of the U.S. and Japan 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.

4. Regional Leadership Visionary Goal

Based on the shared understanding that improved health can lead to increased worker productivity, the U.S. and Japanese governments collaborate in the Asia Pacific region on improving health and welfare as a way to lay a strong foundation for sustainable economic growth and greater international trade. The Councils welcome the strong collaboration between the U.S. and Japanese governments during 2014 in promoting capacity building and best practice sharing in the medical sector among the 21 APEC member economies.

Recommendations

1) Continue collaboration between the FDA and the PMDA in the APEC Regulatory Harmonization Steering Committee to promote regulatory convergence through 2020 based on capacity building and best practice sharing in the areas of biopharmaceuticals and medical devices.
2) Strengthen collaboration between the MHLW and the U.S. Department of Health and Human Services to support the creation of a robust "roadmap" for the implementation of the APEC "Healthy Asia Pacific 2020" vision statement that was endorsed by APEC Ministers in 2014.
3) Continue collaboration on the adoption of codes of ethics by industry associations based on the APEC Kuala Lumpur Principles for the medical device industry and Mexico City Principles for biopharmaceutical industry.