

IV.-4 Healthcare Innovation

Overview

The National Health Insurance (NHI) system is a backbone of the longevity of the Japanese. Its sustainability is the challenge facing the government in a stagnating economy with a declining working-age population, and increasing healthcare spending in a rapidly ageing society. Meanwhile, the life science industry, an economic growth driver, is facing increasing global competition. To date, the government's focus on controlling social security expenses has been achieved primarily through price reduction of medicines and medical supplies. However, to maintain the NHI system, the government should secure fiscal savings in other areas of the healthcare system.

In addition to the sustainability of the NHI system, the government should also promote innovation from viewpoint of establishing a social security system for all generations as well as promoting a '100-year life era.' New industry platforms are being developed along with diverse healthcare modalities (e.g. small molecules, middle molecules, and large molecules). The advancements of new digital technologies like AI, big data, and telemedicine have set off a new wave of innovation in the health care industry. The application of such technologies will enable us to increase the precision of diagnosis and treatments that can significantly contribute to the sustainability of the NHI.

To maintain the sustainability of the NHI, it is necessary to promote healthy life expectancy, reform incentive and reimbursement systems, secure alternative or supplementary finance sources, and incorporate the latest healthcare technologies, including biopharmaceuticals, biomarkers, gene therapy, regenerative medicines, medical devices, advanced radiation therapy and proton therapy techniques, real world data, etc., in our medical practice. It is also necessary to improve the regulatory and reimbursement environments for advanced healthcare technologies to ensure that that patients get timely access to innovation with appropriate prices. Toward these goals the Councils make the following recommendations.

Build a Sustainable Healthcare System and Enhance Innovation

Delivering innovations that contribute to an extension of healthy lifespans and that help people to remain active throughout their lives under comprehensive NHI reform.

1. It is necessary that the government and stakeholders recognize the value of innovation as a key investment in achieving a healthy and productive society. In order to achieve this goal, the US-Japan Business Council and the Japan-US Business Council (hereafter, the 'Councils') recommend that all stakeholders should work to build a social health care system that properly values innovative medicines, medical devices and preventive care.
 - The Councils believe pro-innovation policies that are transparent and predictable need to be restored, including meaningful consultation with industry in advance of future policy changes and fair and predictable rules that appropriately reward innovation. These include repeal of the revised Price Maintenance Premium company and product criteria, as well as the implementation of any annual repricing mechanism. For medical devices, annual price revision must be avoided. Maintaining the overall stability in the current rules governing the biennial revision process (because of the large number and complexity of medical devices that are often used with other products and services) is important, with an openness

to consider targeted improvements in support of existing and new medical devices that deliver value to the health care system.

- The Councils believe that careful deliberation with stakeholders and rigorous testing are necessary for the implementation of value assessment tools such as Health Technology Assessment (HTA). Such value assessments should be based on rigorous post-launch evidence from the entire healthcare system, including the impacts on various stakeholders, the overall healthcare system and the economy. It is necessary to ensure that any HTA assessment and recommendation do not restrict patient access and treatment outcomes or physician choice, and do not delay drug or medical device regulatory approval and/or patient access.
 - Progress is needed on the Council on Economic and Fiscal Policy (CEFP) reforms for rebuilding better social security system that do not deal with drug pricing system. The government should carry out reforms to other parts of healthcare system, such as optimization of medical service allocation and co-payment reform, by developing more concrete goals and action plans.
2. It is necessary to adopt a longer-term strategy to ensure both the stability of the healthcare system and promotion of innovation in coordination with key stakeholders. There have been several vision papers put out by the government and by industry that have very constructive suggestions on how Japan can move forward with a pro-innovation policy agenda that helps address key concerns. These include *Japan Healthcare Policy*. For the next revision of the Healthcare Policy, the Councils recommend that the government should take into consideration the *JPMA Industry Vision 2025*, the *PhRMA Vision Report of the Innovative Biopharmaceutical Industry*, the *JFMDA Industry Vision Report 2018*, and the Economist Intelligence Unit's *Medtech and a Vibrant Japan Study*.

Promoting cutting-edge technology and investment to achieve sustainable promotion of innovation and timely patient access.

3. Strengthening translational research: Overcoming the ongoing issues in the area of Japanese translational research so that Japan can capitalize on its strengths to become a world leader in medicines discovery and global provision. The Councils recommend the further establishment of a public-private collaboration between AMED, academia, bio-ventures and the pharmaceutical industries in Japan to tackle barriers to translational research in Japan and to accelerate research and development of new medicines to address Japan's specific health needs as well as to improve global health.
4. Improving the competitiveness of Japan by leveraging advanced regulatory science, like expedited approval pathways, as a regional and global leader:
- The Councils would like to ensure that multi regional clinical trials are conducted under common international practices and guidelines, especially ICH E-17.
 - The Councils would like to ensure that patients have early access to innovative medical products through the *Sakigake* system, or through the conditional approval which are being scrutinized for legislation. These measures should be implemented as soon as possible. Product eligibility criteria should be equivalent to the U.S. and EU systems to ensure global competitiveness. All innovative products that meet the requirements or eligibility should be designated to reduce costly and time-consuming clinical trials.

5. Establishment of a data protection system in Japan: Examine introducing a new rule that would achieve the highest global standard of protection of clinical data for biologic medicines to enhance Japan's global competitiveness, which will be a main source of future medical innovations.

Optimizing expenditure through an increase in efficiency

6. The Japanese Government should comprehensively examine overall healthcare spending with the aim of optimizing expenditures, and consolidate the vast number of dispersed medical centers.
7. A sustainable pro-innovation environment could be achieved through re-investing some of the savings available through off-patent reforms. Further reforms of the off-patent sector, including policies to encourage and promote the use of generics/biosimilars, could release savings to support the broader health care budget, cover pro-innovation policies and remove the need for additional cost-cutting measures.

Encouraging preventive measures/preemptive medicines that contribute to an extension of healthy lifespan - Developing new policies that encourage and reward primary and secondary prevention measures that contribute to an extension of healthy lifespan.

8. To realize a goal of achieving healthier lifespans through prevention, the Councils believe that the government should adopt pro-vaccination policies and give greater recognition to the value of innovation relating to prevention. Of particular importance would be policies that incentivize innovations where their acquisition cost is less than cost-savings for the total health system and to the broader economy.
9. The government should set a goal and policies for infectious disease control, taking into consideration potential threat of infectious diseases coming from inside/outside of the country and burden of the diseases. Laying out the basic principle that many diseases are preventable by immunization and vaccination, the government should prepare for immunization and vaccination program as well as treatment program.
10. Sustainability should be the most important forces driving industrial innovation on vaccine development with a sense of urgent against global health threats caused by pandemic influenza and imported infectious disease with emerging & re-emerging infectious diseases. It is important to initiate governmental initiatives for increasing public funding and promoting public-private partnership, which includes the preparedness of emergency use from practical and legal perspective, and the promotion of universal health coverages across different countries and regions through delivery of vaccines.
11. Regular use of dietary supplements can have substantial health benefits, thus reducing healthcare expenditures. The Councils suggest that the governments recognize the evidence-based health benefits of functional foods, such as health foods and dietary supplements, so that the benefits can be communicated to promote public health.

Promote the use of Digital Health

Enact new public policies that support the delivery of health care through promising new digital health technologies, e.g., AI, Big Data and practical use of Real World Data, as soon as possible

12. Encourage investment in, and development of, digital health products; establish coverage and payment policies that encourage technology innovation and patient access; and ensure regulatory paradigms for digital health products are transparent, predictable, consistent, timely, and science-based.
13. The early approval review system for the next generation of medical devices should not review the content of the algorithm but consider the evaluation of performance and safety by real world data after marketing. Similarly, the Councils encourage the two governments to work together to prevent such preconditions in other markets.
14. Allow private industry to utilize real world data in order to create innovative medical devices and innovative medicines, such as cancer genomic medicine, medical imaging diagnostics assisted by AI. Therefore, the Councils recommend that industry, academia, government and medical institutions collaborate to develop real world data bases of sufficient quantity and quality to assist industry in the development of innovative and medical devices and pharmaceuticals.
15. Create networked specialty centers: Facilitate remote care and improved efficiencies through creation of networked specialty centers (i.e., cancer) that utilize a common IT platform to support integrated care across diagnosis, treatment planning & delivery, patient follow-up, and management of patient data.

Utilizing Information and Communication Technology (ICT) data infrastructure to streamline the drug development and pharmacovigilance processes

16. The Councils consider that introducing a unique Medical ID number, the government should promote ICT data infrastructure to streamline the drug development and pharmacovigilance processes. The government should improve the existing system which has been uniquely developed in Japan, to align to the global standards, and if necessary conduct necessary change of related regulations. The Councils recommend Japan maintain the highest safety standards, by integrating similar large-scale medical information databases which link data of diagnosis, medical checkup, nursing, and genomic information through ICT usage.

Safety of medical institutions as social infrastructure in the digital age

17. Medical devices are changing the way we manage chronic health conditions, improve quality of life and health care, and save lives. Governments and industry stakeholders should enhance public and private collaboration to advance innovation and smart risk management policies to realize the promise these connected devices have for public health. Cyber Security is not only the medical device manufacturers' responsibility, but medical institutions also share such responsibilities as clearly stated and defined under the "Safety Management Guidelines" written in the "Guidance on Securing Cyber Security of Medical Device (July 24, 2018)". The guidance also reviews the importance of conducting maintenance contracts. In response to this, medical institutions and medical device manufacturers cooperate to promote cyber security compliance. The Councils recommend enacting the following three things in order to enhance

cooperation between device manufacturers and medical institutions to strengthen the security of connected medical devices:

- Enact a new regulation having medical institutions comply with the "Safety Management Guidelines" and conclude a mandatory maintenance contract with the medical device manufacturers.
- Make an exemption clause in the modification application in the case of changes regarding the compliance of the cybersecurity section of the already certified equipment's to provide quick and prompt application and approval.
- Define the roles and responsibilities of the medical device manufactures and the medical institution regarding on how to provide information safely and in security to users of implantable medical devices.