

Approach of Medical Excellence JAPAN to create platforms of collaboration in Asia

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Abstract: Medical Excellence JAPAN (MEJ) is a general incorporated association established in 2011 in Japan. It aims to serve as a central hub and a platform to promote international health business jointly with governments, medical communities, academic organizations, and healthcare industries. This article introduces the works of MEJ in the broader context of Japan Revitalization Strategy. The Act on Promotion of Healthcare Policy (2014 Act No. 48) established the Headquarters for Healthcare Policy, chaired by the Prime Minister and supported by dedicated secretariats in the Cabinet Office. The Headquarters aimed at policy coordination across ministries but learned hard lessons from COVID-19, such as delay of domestic vaccine production. This highlights our systematic weakness of the trajectory from R&D to public availability, and this is the field in which MEJ can play further roles. The value and feasibility of developing MEJ-like mechanisms in Asia with a rapidly growing healthcare sector is discussed.

Keywords: healthcare business, Medical Excellence JAPAN, Asia Health and Wellbeing Initiatives, international collaboration

Introduction

The COVID-19 pandemic has not shown signs of abating since its start in January 2020. More than 186 million people have been infected worldwide, and nearly four million have lost their lives (1). This pandemic of "once-in-a-life-time" scale brings large implications to every corner of the globe. Japan is not exempted. Although the impact in Japan caused by the pandemic is relatively small in terms of mortality and morbidity, our over-reliance on foreign production of essential health goods such as surgical masks created consumer panics in March 2020. The insufficient decade-long investment in vaccines left Japan in a situation entirely dependent on vaccines from foreign manufacturers. The pandemic (a health problem) threatens to trigger an economic crisis and even pose a national security challenge (2). In the globalized world, countries are interconnected, and people move rapidly on a massive scale. The final report of the Independent Panel for Pandemic Preparedness warns that new pathogens with pandemic potential could emerge at any time. The Panel urges us to take COVID-19 as a wake-up call to move jointly and robustly to make COVID-19 the last pandemic (3). How

can we take advantage from globalization and mitigate the negative impact of future global challenges? We believe we need to strengthen international collaboration to solve domestic and common international challenges while expanding business opportunities simultaneously.

Medical Excellence JAPAN (MEJ) is a general incorporated association established in 2011 to serve as the central organizational hub to facilitate overseas expansion in the health/medical care sector (4). MEJ promotes international health cooperation jointly with governments, medical communities, academic organizations, and healthcare industries. MEJ also provides a business development platform in response to the needs of collaborating countries. In this article, the authors review the past and present works of MEJ and propose the next step to create platforms of collaboration in the post-COVID-19 era.

Concept and creation of MEJ

Japan suffered from economic stagnation caused by the asset price bubble's collapse in late 1991, and economic revitalization has been the top national agenda for many years. Japan has strong research capability,

universal access to quality healthcare services, high-morale personnel, and industries such as pharmaceutical companies that ranked third in originating country of top-selling drugs in the world (5). On the other hand, low economic growth and population ageing result in high dependence of Japan's medical expenditures on public resources (6). From the international perspective, healthcare markets in neighboring economies are growing at a higher rate than Japan. Given these conditions, international collaboration especially with Asian countries would yield a triple-win situation; specifically, improving health in other countries, achieving business development in Japan, and consequently contributing to sustainability of Japan's social security system.

However, it has proven difficult to create synergy that allows the fragmented actors to work together for more efficient and effective health services delivery, R&D, regulation, production, national economy, and health diplomacy, which are all interlinked. For example, the perspectives and mindsets of the major actors and relevant ministries are diversely different. Healthcare providers and their professional associations prioritize patients and their families at the community level, whereas health-related industries are primarily concerned about shareholder interests. Ministry of Health, Labor and Welfare (MHLW) aims to protect the people's health through stringent regulations. Ministry of Economy, Trade, and Industry (METI) emphasizes industrial development. Ministry of Education, Culture, Sports, Science and Technology (MEXT) focuses on R&D for advancement of science. Ministry of Foreign Affairs (MOFA) and Japan International Cooperation Agency (JICA) address health as a part of development problems in low-income countries. Such diversities make it challenging to set a common agenda for action. However, the other side of the coin is that different stakeholders' self-defined positioning may bring unexpected leverage if mutual complementarity among stakeholders can be achieved.

With the above background, a concept emerged to create at the Cabinet level (1) a platform of "pragmatic"

collaboration among key players and (2) a central coordination body across the ministries. Creation of a platform was realized by establishing the MEJ in 2011. This initiative was further activated by the second Abe Cabinet (from December 26, 2012) that emphasized healthcare as one of the Japan Revitalization Strategies (7). The mission of the MEJ is shown in Table 1. The initial works were concentrated around the promotion of acceptance of foreign patients by domestic medical institutions (inbound activities) and support of business development of Japanese medical care and related industries overseas (outbound activities).

Regarding strategic coordination at the Cabinet level for seamless stimulations, from R&D to practical application of innovations, products and health systems domestically and internationally, the existing mechanism was reorganized and strengthened by the Act on Promotion of Healthcare Policy (2014 Act No. 48) [unofficial translation under the title "Act to Advance Health and Medicine Strategy" (8)]. The Act established the Headquarters for Healthcare Policy, chaired by the Prime Minister, and supported by dedicated secretariats in the Cabinet Office. The Headquarters' official briefing (9) listed four specific works including "measures related to the promotion of creation and overseas expansion of new industry activities related to healthcare and medical care" as well as its organizational structure (10). This Act together with the Act on Japan Agency for Medical Research and Development (AMED) (11) were designed to enhance our research and, consequently, industrial competitiveness under the broader Japan Revitalization Strategy. The Headquarters approved the Healthcare Policy (12), which was adopted in 2014 and updated in 2017, 2019 and 2021, as well as the Plan for Promotion of Medical Research and Development (13) adopted and updated together with the Policy. The Headquarters also approved the Basic Principles of the Asia Health and Wellbeing Initiative (AHWIN) in 2016 (revised in 2018) (14). Under this initiative, the exchange of long-term care-related personnel and collaboration of long-term care services with overseas countries have expanded.

Table 1. Mission statement of MEJ

Medical Excellence JAPAN (MEJ) aims to contribute to the health, social welfare and economic improvement of people around the world through the provision of medical services and technologies provided through cooperation between the governments of Japan and other nations as well as these nations' respective medical and business/industrial communities.

- Contributing to Global Healthcare

MEJ aims to contribute to the development and improvement of medical services around the world through the provision of medical services and technologies appropriate for the characteristics of each individual country and region.

- Contributing to Health Care in Japan

MEJ aims to contribute to the development of medical services in Japan by supporting improvements in Japan's capacity to provide international medical services.

- Contributing to Economic Development

MEJ plans to contribute to economic growth in Japan around the world by supporting the growth of medical institutions and medical-related industries.

Consequently, business activities in related fields are becoming active. Also, the Basic Principles of the Africa Health and Wellbeing Initiative (15) were adopted in 2019.

Various initiatives and lessons of vaccine defeat

As discussed above, under the Abe Cabinet, attempts to enhance coordination among ministries made progress. However, these organizational changes did not bring a substantial outcome in Japan's response to the COVID-19 pandemic. It is unfortunate that we did not observe the warp speed R&D, clinical trials, approval, production, and access for COVID-19 vaccine. Various systems have policy objectives reflecting the originating ministries, and the barrier was difficult to overcome. Attempting to visualize the involvement of different ministries and providers in each process of pharmaceutical R&D, the authors have constructed a matrix as shown in Figure 1.

There are various steps before medical products can become widely accessible. The first step is to find the seed compound through basic research. Then the safety and effectiveness of the compound are verified. This is followed by approval through various regulatory procedures. After the developer's intellectual property is protected, the product is produced and marketed based on business strategies according to market demand such as price setting. In reality, these steps may proceed in parallel.

Next, the above steps will be examined more carefully regarding the various arrangements provided by different sectors. From the health sector, AMED

offers basic and applied research funding, and MHLW provides a legal framework and incentives for promotion of domestic and overseas clinical trials. To encourage innovative medical products uniquely from Japan, a special measure for regulatory approval called the Sakigake Designation System (16) is provided by the Pharmaceuticals and Medical Devices Agency (PMDA). In addition to quicker approval, indirect support is provided by the investment of the Japanese Government in Gavi (vaccine), Global Fund (AIDS, tuberculosis, malaria drugs, and diagnostics), and UNITAID (AIDS, tuberculosis, malaria, hepatitis drugs, and diagnostics) that support procurement of medical products for low income countries. However, the middle part of the process; business and production, is handled by companies and manufacturers. This part could be "the valley of death".

Also, it is worth reviewing other support schemes provided by ministries and MEJ in development of international health business. MOFA and JICA support local activities involving the initial project development in collaborating countries, such as private sector cooperation projects and model projects, through technical cooperation. To strengthen collaboration with low and middle-income countries, they offer assistance in developing relevant infrastructure through grants-in-aid, loans, and technical cooperation. This surely enhances the absorption capacity of new products and technologies.

METI supports the stage of project formation, and a typical project is "Development of International Healthcare Hubs" (17). Also, METI in collaboration

	Basic Research	Applied Research/ Clinical Trial	Approval by Regulatory Agency	IP Protection	Business Plan and Price Setting	Production	Procurement
Role	Exploring Seeds	Verification	Legal Procedure	Protection of IP	Business Plan	Production Capability	Provision of Services and Goods
Main Providers	Researchers, Companies and Institutions		Regulatory Agency	Company	Company + Consultants	Company Grants/Investments	Service Beneficiaries and Gov.
Health Approach by MHLW	Strengthening Clinical Trials by MHLW		Strengthening PMDA and Harmonization of Regulations				Insurance Coverage
Development Approach by MoFA/JICA		Private Sector Coordination Project and Technical Cooperation by JICA				Loan to Companies by JBIC	Contribution to International Organizations (GAVI, GF, UNTAID)
Industry Approach by METI	Next Generation Health Care Project/ outbound service providers and their infrastructure building	Hub Creation Initiative	JH/Certified Medical Visitor Supports				Grants/Loan/Technical Assistance
Approach by MEJ	Secretariats Function		Encouragement of Inbound/outbound service providers and their infrastructure building		Business Model of MEJ/Mexx (One-stop Shop)		

Figure 1. Mapping of broadening international health care products and business at various stages of pharmaceutical research and development.

with Japan External Trade Organization (JETRO) and MEJ supports the development and promotion of new services, service providers, enlightenment, training, and infrastructure development for next-generation medical/inbound/outbound businesses. The Japan Bank for International Cooperation (JBIC) provides loans to overseas projects undertaken by Japanese companies willing to expand overseas.

Policy dialogues are conducted between governments, resulting in MOUs with countries such as India and Vietnam. However, there is a wide perception that these mechanisms are not optimally functioning in developing the COVID-19 vaccines in Japan and some perceive this as the "lost war in vaccine competition". Meanwhile, the world is moving towards preparing for the next pandemic, as symbolized by the G7 summit and G7 Health Ministers' agreement in boosting international clinical trials to address the bottleneck of evaluating the efficacy and safety of the needed medical products (18).

What is the position of MEJ? As shown in Figure 1, MEJ is currently serving the function as secretariat and the role as the executive agency of the METI industrial policy approach, which is indicated by the red dotted line in the figure. On the other hand, for any business entity, it is undoubtedly desirable to have one-stop support and advice during the entire R&D process from seed-finding to getting on track with business. Until now, support options are concentrated in the upstream part of the flow. However, it will be necessary to provide assistance for the middle part; business and production, where many business entities struggle. This is the part where accumulated experience and knowledge are unfortunately not shared effectively. In the future, MEJ should make a business plan on how to overcome this "valley of death" and to develop activities by obtaining funds in the form of sustainable investments from corporate business entities.

Future development

Medical care in Asia is expected to grow in volume and in quality through market expansion and mutual exchange. New efforts are required to further promote the international business development of Japanese-style medical care. In this respect, the vision of MEJ is to speedily introduce a "patient-centered rational medicine initiative" to like-minded countries, to substantiate this initiative in absolute terms to improve medical care quality, and to create a new mutually beneficial arrangement for health security through international medical care.

At the same time, as shown in ASEAN Economic Community Blueprint 2025 (19), cooperation in the medical field is progressing steadily in Asia. To take advantage of such momentum in ASEAN countries, we need an environment in which industry, government, academia, and health care providers can discuss on

the same platform. As mentioned above, in industry-government-academia-medicine collaboration, each ministry has its own unique policy objectives. The perspectives, mindsets, interests, and priorities of major stakeholders are diverse. Therefore, comprehensive coordination is essential and is a common challenge for both Japan and other Asian countries. One possible measure to alleviate these bottlenecks is to create MEJ-like forums (tentative name, ME_{xx}) in countries with large market sizes, such as India, Vietnam, the Philippines, and Indonesia. In the future, when these forums collaborate mutually at each platform, health improvement and competitiveness of the Asian health care industry can be expected to improve further. With this background, the Economic Research Institute for ASEAN and East Asia (ERIA) (20) has set up a secretariat for coordination, and full-scale activities will start from the latter half of 2021. The MEJ aims to facilitate this next generation of collaboration for health and economic prosperity for all countries involved.

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