A UHC Approach to Harmonizing Asian Pharmaceutical and Medical Device Regulations

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Task Force for Promoting Pharmaceutical and
Medical Device Regulatory Harmonization in Asia

Executive Committee on Global Health and Human Security

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JAPAN CENTER FOR INTERNATIONAL EXCHANGE

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Recommendations of the Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia

1. A UHC-Focused Approach to Implementing the Grand Design

The United Nations 2030 Sustainable Development Agenda seeks to create a world where no one will be left behind. Advancing universal health coverage (UHC) is a vital component of efforts to achieve that ideal. In Asian countries and regions, however, this requires initiatives across multiple fields because the social environments are undergoing significant change, primarily as a result of economic development and population growth. Japan, as a country that is seeking to contribute to global health through the promotion of UHC, should share its own experience with achieving and sustaining UHC in order to assist other Asian countries in reaching that goal as well.

On June 20, 2019, the Headquarters for Healthcare Policy of Japan approved the Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization (hereafter, Grand Design). Built upon the Basic Principles of the Asia Health and Wellbeing Initiative (AHWIN) that were previously adopted by the Headquarters, the Grand Design was aimed primarily at concretizing regulatory harmonization in the fields of pharmaceuticals, medical devices, and regenerative medicine products (hereinafter "pharmaceuticals and medical devices") in order to contribute to the health of people in Asian countries through improved access to these products.

The basic approach of the Grand Design consists of four components: (1) shared principles and values through regulatory science, (2) close cooperation that respects the positions of regulatory authorities in Asian countries/regions, (3) coordination and cooperation with the business community's activities in and outside of Japan, and (4) development of hard and soft infrastructure. Based on these components, the Grand Design proposed that Japan take the following actions to improve patient access to pharmaceuticals and medical devices in Asian countries: (1) establish systems and frameworks in Japan for promoting regulatory harmonization in Asia, (2) establish the infrastructure for clinical development, and (3) promote regulatory harmonization. It also suggested priorities in the pharmaceuticals, medical device, and in vitro diagnostics fields.

Setting its sights on 2030, the United Nations adopted the Sustainable Development Goals (SDGs) and proposed a wide range of policy initiatives to achieve them. Of these, Target 3.8 reads, "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all." As reflected in this target, ensuring access to essential healthcare services, pharmaceuticals, and vaccines is regarded as an important factor in achieving the SDGs. As described in the Grand Design, improving access to high-quality pharmaceuticals and medical devices through the promotion of regulatory harmonization and raising the quality of healthcare services by establishing the infrastructure for clinical development will help all countries/regions in Asia achieve UHC.

Accordingly, this report examines and summarizes specific areas that Japan should tackle in order to promote regulatory harmonization and establish clinical development systems as proposed in the Grand Design. As many Asian countries/regions are poised to undergo population aging and demographic changes in the coming years, the types of diseases that will threaten those respective societies will change as well, resulting

in an anticipated increase in the incidences of cancer, cardiovascular disease, dementia, and similar disorders. To address this, clinical development systems should be established within these countries to promote multinational clinical trials; achieving this will lead to the provision of cutting-edge pharmaceuticals and medical devices, as well as advanced medical care.

The current outbreak of the novel coronavirus disease, COVID-19, is a stark reminder of the importance of establishing organizational infrastructure in advance that enables the development of pharmaceuticals and medical devices to address emerging infectious diseases. In the current globalized society, once an infectious disease breaks out, it will quickly spread throughout the Asian region. Creating an organizational infrastructure that will work in times of crisis as well will enable the development of therapeutic medicines, diagnostics, and other products to address such a disease.

The implementation of the recommendations contained in this report is expected to help improve the health of people in Asian countries.

Also, in order to respond to the coming healthy longevity society in Asian countries/regions and to develop an ecosystem conducive to better access to healthcare throughout the region, Japan's industry, academia, and government, including relevant ministries, should work collaboratively, in a way that is open to civil society as well, to achieve that goal.

2. Promoting Regulatory Harmonization

We live in an era in which innovative products are being developed one after another and are swiftly supplied to people around the world. Given that context, in order to improve access to pharmaceuticals and medical devices in Asian countries/regions, it is important that international regulations be applied consistently throughout Asia, thereby creating a borderless market for those products.

By d oing so, outstanding products will be accepted and swiftly supplied to patients regionwide. As such, regulatory harmonization plays a major role in ensuring access to pharmaceuticals and medical devices.

(1) Measures for regulatory harmonization

In accordance with the Grand Design, the following measures are scheduled to be undertaken in FY2020 to promote regulatory harmonization:

i. Designate specialized personnel in Japan's Pharmaceuticals and Medical Devices Agency (PMDA) to handle priority countries/regions in Asia in order to accelerate regulatory harmonization.

ii. Enhance personnel training in response to the needs of individual countries/regions through PMDA's Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC).

iii. Hold an Asian Network Meeting comprising the heads of regulatory authorities of Asian countries/regions to enable their close collaboration and coordination.

These measures are expected to strengthen the framework for promoting international regulatory harmonization. In addition, further concrete measures as outlined below should be implemented.

Incorporation of international standards

- Japan should further encourage Asian countries/regions to more actively incorporate international standards, develop guidelines, and take other necessary measures, in particular by sharing its own experience through training programs at the PMDA-ATC and through bilateral symposia.

- The World Health Organization (WHO) has been advocating the concept of "reliance"[1] in recent years. The PMDA and other Japanese regulatory authorities should collaborate with the WHO to further encourage Asian countries/regions to recognize this concept. In addition, to help manufacturers obtain WHO prequalification and so forth, the PMDA and relevant organizations should strengthen cooperation with the WHO's prequalification department.

Capacity-building (human-resource development) of Asian regulatory authorities

- With the enhancement of regulatory systems, it is necessary that countries/regions improve the capacity of their regulatory officials engaged in inspections, quality control surveys, compliance investigations, and post-market safety measures. For that purpose, effective training programs should be provided via PMDA-ATC, for example, by conducting Good Manufacturing Practice mock inspections at actual manufacturing sites.
- In this regard, a framework whereby the PMDA dispatches personnel overseas should be considered. If so requested by the government of another Asian country, mechanisms of the Japan International Cooperation Agency (JICA) and other bodies can be utilized to provide necessary training programs and to dispatch Japanese experts to cooperate with and work for the host country on-site.

Sharing of safety information among Asian countries/regions

- Support should be given to help Asian countries/regions strengthen their capacities and to share information in the area of safety measures. Improved access to innovative products must be accompanied by post-market safety measures. Japan should work with other Asian countries/regions to consider collaborative industry-academia-government approaches to strengthen the capacity of regulatory authorities and enhance the reporting capabilities of frontline medical personnel.
- Japan should play a leading role in creating a framework for utilizing real-world data in the Asian region, including from the perspective of ensuring database quality and setting rules for data collection and management.

Measures in individual fields

- Efforts must be made to implement the measures contained in the Grand Design regarding the fields of pharmaceuticals, medical devices and in vitro diagnostics, and regenerative medicine products.

If the measures described above are implemented simultaneously through collaboration among the industry, academia, and governments of Japan and other Asian countries/regions, it will facilitate the acceptance of Japan's drug approvals, inspection outcomes, and regulatory systems by those Asian countries/regions. These measures should be implemented to achieve improved patient access to innovative pharmaceuticals and medical devices in those locations.

It is also crucial for the regulatory harmonization measures above to be implemented in conjunction with measures to enhance the infrastructure for clinical development, as outlined below.

1. *Reliance* in this context means that when a regulatory authority of one country conducts approval reviews or inspections, it considers, attaches importance to, and utilizes in its own regulatory activities, the outcomes of assessments made by its counterparts in other countries.

3. Measures to Enhance the Infrastructure for Clinical Development

Forming a network of clinical trial sites in Asia will enable pharmaceuticals and medical devices to be developed faster and at a lower cost. To that end, Japan and other Asian countries/regions should work hand in hand to build the soft and hard infrastructure needed to conduct clinical studies in a manner compliant with Good Clinical Practice guideline of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH-GCP). They should also cooperate in having core clinical research institutes serve as academic research organizations (AROs)[2] by establishing or strengthening clinical research promotion departments at those centers. To build such infrastructure, government, industry, and academia need to work together and, when so requested by the government of anther Asian country/region, seek assistance from the Asian Development Bank (ADB), JICA, or other international cooperation bodies.

To form sites and networks in Asian countries effectively and more concretely, it would be helpful to begin by identifying an area of disease and then form a provisional network based on work that is already underway. Specifically, we recommend beginning with two fields of disease. First, given that the ratio of older persons will be rising in Asian countries, the number of cancer cases is expected to rise as well, and thus measures to combat cancer will be essential. It will be important that work in the field of oncology reflect the needs of the business community as well as the results of investigator-initiated multinational clinical trials to date. Second, given that the burden of infectious disease remains high in Asia, this is another field that requires regionwide efforts. Measures in these two initial fields can serve as a model when expanding to additional fields in the future.

In implementing these measures, a phased approach should be taken according to the needs of each country while fully utilizing the knowledge and experience Japan has amassed. To benefit both Japan and other Asian countries alike, it is advisable, for example, to start with trials for new indications of pharmaceuticals and medical devices that have been in use in Japan.

(1) Oncology

Specifically, it is recommended that the following measures be taken in this field:

Develop soft infrastructure (training and educational materials) in Asia

To advance multinational clinical trials, it is essential to develop core clinical research hospitals and establish a structure in individual Asian countries/regions that enables the implementation of clinical trials on a regular basis. Hence, the following measures should be undertaken:

- Translate the educational syllabi, manuals, and other materials used in Japan into English and use those materials to train the physicians, research nurses (RNs), study coordinators (SCs), and clinical research coordinators (CRCs) engaged in clinical trials at core research institutes in other Asian countries/regions.
- Share the educational materials used for those training programs with other local core research institutes in Asian countries/regions to enable those centers to train personnel on their own.

Develop hard infrastructure in Asia

To advance multinational clinical trials, it is essential to develop core clinical research hospitals in individual Asian countries/regions and strengthen the infrastructure to enable the implementation of clinical trials on a regular basis. Hence, the following measures should be undertaken:

- At each core clinical research hospital, create or strengthen a clinical research promotion

2. An ARO chiefly refers to an organization in a university to assist with implementing trials and coordinating with relevant parties utilizing the capabilities of research and medical centers, in the course of pharmaceutical development.

department consisting of physicians, RNs, SCs, and CRCs and establish infrastructure for conducting clinical trials.

- Strengthen the capacity of individual core hospitals to provide clinical trials by installing the necessary equipment for clinical testing and diagnosis, equipping them with freezers to store trial drugs and specimens, and establishing a system for the continued maintenance of such equipment. At the same time, help these hospitals obtain ISO 15189 accreditation, the international standard for medical laboratories.
- Enhance the functionality of the Asian Oncology Early Phase 1 Consortium (Asia One), an existing network of major Phase 1 centers in East Asian developed countries, with the aims of encouraging implementation of more multinational clinical trials initiated by pharmaceutical companies and stimulating early-phase new drug development throughout Asia.

Strengthen the infrastructure in Japan to stimulate multinational research conducted by researchers in Japan and other Asian countries

In addition to developing the soft and hard infrastructure at core clinical research hospitals in other Asian countries/regions, each Japanese core research institution/hospital should be strengthened to enable them to promote greater cooperation with Asian counterparts, and a permanent network should be created to enable the rapid, high-quality, and low-cost implementation of investigator-initiated clinical trials.

- Develop personnel who are versed in ICH-GCP and other clinical trial practices and are proficient in English, and strengthen the capacity to support international research projects in Japan's core clinical research hospitals.
- Station personnel in other Asian countries/regions to have them liaise with the government and core clinical research hospitals in those countries.
- Encourage Japan's core research institutes and businesses to interact with and visit their counterparts in Asian countries/regions in order to identify the needs of the core clinical research hospitals there and match them up with Japanese counterparts upon their request.

(2) Infectious disease

For certain infectious diseases, it is impossible to conduct clinical trials in Japan owing to the insufficient number of domestic patients. With regard to such diseases, it is crucial that the necessary infrastructure (clinical trial platform) be constructed in Asia to conduct the clinical trials required to develop new drugs and diagnostic agents, among other products. This includes creating networks of epidemiological studies and medical facilities, developing human resources, and forging ties with central and local governments. Such a platform will allow high-quality clinical development data to be obtained for the practical application of innovative Japanese technologies (referred to as "seeds" in Japanese). This type of platform is essential to achieve UHC because it not only improves access to pharmaceuticals needed to diagnose and treat infectious diseases that are locally prevalent in other Asian countries/regions, but also raises the quality of clinical trials—and therefore of treatment—in those locations.

The current outbreak of COVID-19 is a stark reminder of the importance of establishing a structure in advance that enables the development of pharmaceutical and other products for emerging infectious diseases. In the present globalizing society, therapeutic medicines, diagnostics, and other products for fast-spreading infectious diseases should be developed through constant collaboration and information-sharing with each country's institutions and with international organizations around the

world. To make that possible, collaborative arrangements with other Asian countries/regions should be established in advance to ensure that these functions can continue even in times of crisis.

Develop soft infrastructure (select facilities and create training systems)

Based on the circumstances of each country, facilities should be selected to carry out clinical trials and research and local cooperation offices should be set up or strengthened. This should be done by utilizing and enhancing existing projects, such as those of Japan's National Center for Global Health and Medicine (NCGM). At the selected clinical trial and research facilities, insufficiencies in terms of personnel or equipment should be identified, and those insufficiencies should be eliminated by providing training to healthcare professionals and staff engaged in clinical trials and research. If needed, assistance should be sought from Japanese pharmaceutical and other companies, and, if so requested by the government of another Asian country/region, from JICA and the ADB.

Create an environment conducive to business operations (addressing regulations and local data collection)

In order to provide Asian countries/regions with Japanese pharmaceuticals and medical devices in a timely manner to address infectious disease, obtaining WHO prequalification and recommendation is also useful. However, there is a possibility that few Japanese companies understand the usefulness of, or have pursued, that process. This issue should be addressed by the secondment of personnel to WHO's prequalification department, training the personnel necessary, or more closely collaborating with relevant organizations.

In the infectious disease field, it is imperative that clinical trials of pharmaceuticals and medical devices be conducted with symptomatic patients in the relevant countries/regions and that those products be made available for those patients, but in addition, approaches to asymptomatic infected individuals are also important. In light of this, surveillance of infectious diseases including asymptomatic patients is another important measure to undertake. Moreover, introducing pharmaceuticals and medical devices for asymptomatic infected patients in Asian countries/regions is particularly critical when the objective is to eradicate that infectious disease in those places, and in such cases, conducting epidemiological cohort studies is important as the basis of clinical trials for that purpose. Going forward, if and when a candidate compound for asymptomatic infected patients is developed, it is expected that prior to clinical trials, an epidemiological study will be conducted utilizing a research team or the existing projects of the NCGM, which will contribute to a market survey and patient recruitment. The feasibility of such epidemiological studies needs to be examined in detail, and it will be useful to investigate and examine such factors as which diseases should be the focus of such efforts, what pharmaceutical and medical devices candidates there are for development, which geographical areas should be the focus, and necessary cohort size.

Match specific projects

Shedding light on the diseases that are rampant in each Asian country/region and the corresponding pharmaceuticals and medical devices needed to address them will be informative for the future development of pharmaceuticals and medical devices. In that process, accurately identifying local needs is critical. The employment of local staff in those countries/regions will facilitate coordination with their home governments and core clinical research hospitals as well as propose necessary actions to those relevant organizations. In securing individuals capable of serving as that type of liaison, the frameworks of existing projects of the NCGM and other organizations should be utilized. Also, if so requested by the government of another Asian country, the use of JICA's assistance will be considered.

Develop an industry-government-academia platform

Industry, government, and academia stakeholders should be united in their purpose to enhance the infrastructure for clinical development in the infectious disease field in Asia. This requires that they build the platform in Japan to discuss which pharmaceutical or medical device clinical trials should be performed and when, and to deliberate on activities to be conducted at clinical trial sites. That platform would also be expected to monitor the activities at the sites.

It must be noted that the recommendations herein on establishing the infrastructure for clinical development in the area of infectious disease should be reviewed as needed based on the experience gained in addressing the current COVID-19 outbreak and on the results of assessments of measures taken.

4. An All-Government Approach and Systems

To effectively implement the measures recommended above requires an all-government approach and the following systems should be established to move that forward:

(1) Establish a government-led system in Japan

To encourage unified efforts by the relevant government ministries, interministerial coordination and systems should be created or strengthened. In doing so, it is essential to engage organizations capable of working across all industries.

(2) Develop clinical trial sites and train personnel to conduct trials

Japan should work to create a framework for enhancing infrastructure in other Asian countries/regions while respecting local deliberations and ownership regarding the areas of disease that interest them, their healthcare systems, and related matters. To encourage united efforts by the relevant government ministries in these processes, coordination and system strengthening should be carried out across ministries. In doing so, it is essential to involve organizations capable of working across all industries.

Access to pharmaceuticals and medical devices entails complex aspects in which various factors intertwine, such as research and development, regulations, and intellectual property protection. Addressing these factors will require industry, academia, and government to cooperate and work hand in hand.

The Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization represented a new Japanese initiative to help address the aging of populations in Asia and achieve healthy longevity societies. As outlined above, it is recommended that the measures contained in the Grand Design be further developed in detail and that an institution be designated to play a leadership role in coordinating and spearheading these efforts.

APPENDIX

Members of the Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia

(alphabetical order)

Masatomi Akana	Chair of the International Affairs Committee, Japan Pharmaceutical Manufacturers Association (JPMA)
Hirofumi Inoue	Chair of the International Affairs Committee, Federation of Pharmaceutical Manufacturers' Association of Japan (FPMAJ)
Yasuhiro Fujiwara	Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)
Kunihiro Funakoshi	Member of Asia Subcommittee, International Policy & Strategy Committee, Japan Federation of Medical Devices Associations (JFMDA); Member of the Communicable Disease Working Group (CDWG)
Hiroshi Kasanuki	University Professor and Adviser, Waseda University Medical Regulatory Science Institute
Norihiro Kokudo	President, National Center for Global Health and Medicine
Tatsuya Kondo	Chief Executive Officer, Medical Excellence JAPAN [Chair]
Akira Kuba	Senior Managing Director, JFMDA; Member of the Noncommunicable Disease Working Group (NCDWG)
Satoshi Kunitada	Chair of the Drug Evaluation Committee, JPMA; Member of NCDWG
Kenichi Matsumoto	President, JFMDA
Daikichi Monma	Member, Board of Directors, Global Health Innovative Technology Fund (GHIT)
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Hiroki Nakatani	Project Professor, Senior Researcher, Keio Global Research Institute (KGRI), Keio University
Akio Okawara	President and CEO, Japan Center for International Exchange (JCIE); Director, Executive Committee on Global Health and Human Security
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Catherine Ohura	CEO and Executive Director, GHIT
Shigeru Omi	President, Japan Community Healthcare Organization (JCHO); Regional Director Emeritus, World Health Organization for Western Pacific Region; Chair of CDWG
Tomoyuki Otsuka	Deputy Chair of the International Affairs Committee (Asia Region), JPMA
Masakazu Susaki	Chair of the Regulatory Affairs Committee, JPMA
Keizo Takemi	Member, House of Councillors; Senior Fellow, JCIE; Chair, Executive Committee on Global Health and Human Security
Norio Tamura	Member of the International Affairs Committee, FPMAJ

* Representatives from the Office for Healthcare and Medical Strategy of the Cabinet Office, Ministry of Health, Labour and Welfare (MHLW), and Ministry of Foreign Affairs (MOFA) also joined the meetings. Tomoko Suzuki and Momoko Abe of the Japan Center for International Exchange (JCIE) served as the secretariat for the Task Force.

* Two working groups were created under the Task Force to provide more specific input on communicable and noncommunicable diseases. In addition to the members listed below, participants included representatives from the relevant departments of the Ministry of Health, Labour and Welfare and from the Office for Healthcare and Medical Strategy of the Cabinet Office. In addition, representatives from MOFA and the Ministry of Finance attended meetings of both working groups as observers, while representatives of JICA and GHIT observed meetings of the Communicable Disease Working Group.

  Communicable Disease Working Group: Mari Ariyasu (Senior Director, Project Management Dept., Shionogi & Co., Ltd.), Tatsuo Iiyama (Director, Department of International Trial, National Center for Global Health and Medicine—NCGM), Hajime Inoue (Director General, Bureau of Strategic Planning, NCGM), Kiyoshi Kita (Dean, School of Tropical Medicine and Global Health, Nagasaki University), Yasunori Tawaragi (Director, International Affairs, Japan Pharmaceutical Manufacturers Association), Yasuyoshi Mori (Director, 2nd Research Laboratory in Biochemistry, Eiken Chemical Co., Ltd.), Yasuhiro Yasutomi (Director, Tsukuba Primate Research Center, National Institutes of Biomedical Innovation, Health and Nutrition)

  Noncommunicable Disease Working Group: Tatsuo Iiyama (Director, Department of International Trial, NCGM), Kenichi Nakamura (Division Chief, Research Management Division, National Cancer Center Hospital).

* The Task Force members acknowledge and agree that this recommendation was compiled independently from any business transactions and decisions in relation to the supply or purchase of goods or services from specific member companies and that the provision of support has in no way influenced the content.

Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia

In December 2018, the Task Force for Promoting Pharmaceutical and Medical Device Regulatory Harmonization in Asia was created under the Executive Committee on Global Health and Human Security. It is comprised of nearly two dozen experts from industries, academia and government. Japan is committed to promoting universal health coverage (UHC) as part of its contribution to the global health field, but as Asia undergoes economic expansion, population increases, and the aging of its societies, the inadequate access in the region to pharmaceuticals and medical devices—including products that utilize innovative technologies—poses a serious obstacle to that objective. In 2019, the first phase of the task force's work culminated in a proposal, "Recommendations on Formulating a Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization—A Four-Wheel Drive Approach to Promoting Regulatory Harmonization in Asia," which was published under the name of EC.

Executive Committee on Global Health and Human Security

The Executive Committee on Global Health and Human Security is a high-level, public-private platform that facilitates the Japanese government's policymaking on global health and public-private collaboration in that field. Under the chairmanship of Professor Keizo Takemi, the committee holds quarterly meetings to provide a venue for unofficial exchanges of views and information-sharing among senior representatives from government ministries, academia, private companies, and civil society organizations in Japan. Relevant global health experts are invited to speak at the meetings to offer their knowledge and advice. The committee is an integral part of the Global Health and Human Security Program of the Japan Center for International Exchange (JCIE), which manages all aspects of the committee's work.

Japan Center for International Exchange (JCIE)

Founded in 1970, JCIE is one of Japan's leading foreign policy institutes. With offices in Tokyo and New York, it organizes legislative exchanges and policy dialogues that bring together key figures from diverse sectors of society, both in Japan and overseas. During the 1990s, it played a leading role in encouraging the adoption of human security as a pillar of Japanese foreign policy, and this led to the launch of a series of major initiatives on global health. The Friends of the Global Fund, Japan, was created in 2004, the Global Health and Human Security Program in 2008, and the Healthy and Active Aging in Asia in 2017 to strengthen public-private partnership and Japan's role in global health.

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