GHM Open. 2023; 3(1):1-6.

POLICY FORUM

DOI: 10.35772/ghmo.2022.01008

Seven steps in the value chain of health products for equitable access and delivery in low- and middle-income countries

Eiichi Shimizu*, Yuta Yokobori, Kazuki Miyazaki, Kaori Ohara, Megumi Fujii, Tomoko Nishioka, Noriko Fujita

Bureau of International Health Cooperation, National Center for Global Health and Medicine, Tokyo, Japan.

Abstract: The introduction of health products to low- and middle-income countries (LMICs) is hindered by several barriers. Even when these barriers are overcome, improper use of health products can have a negative effect on health outcomes. Health products may go unused due to a mismatch of product needs as well as a lack of public infrastructure, spare parts and consumables, or trained technicians. This study presents a comprehensive framework of the essential steps for effectively delivering quality health products to people in need based on our document reviews and case studies. We divide the value chain of health products into seven steps: 1) situation analysis, 2) research and development, 3) regulatory authorization, 4) selection and prioritization, 5) public procurement, 6) distribution and storage, and 7) health service delivery. We find that the practice of undertaking one step at a time leads to enormous costs in terms of time and resources, often with little success. Failed attempts sometimes necessitate starting over from the beginning. Therefore, it is important to attempt each step while looking ahead to the end through the entire chain of seven steps. More in-depth analysis and lessons from best practices for each of the seven steps may need to be investigated further to consider possible interventions.

***Keywords*:** access and delivery, health products, developing countries, medical devices, universal health coverage

Introduction

As Goal 3 of the Sustainable Development Goals states, "access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all" are critical to achieving universal health coverage (UHC) (*1*). Nevertheless, many low- and middle-income countries (LMICs) lack access to quality vaccines, medicines and medical devices (hereafter "health products"), health technologies, and health services (*2*), a situation that impacts the health of the population.

One reason for this challenge is that health products are not always delivered in a manner appropriate for the country (*3*). In addition, improper use of health products can have a negative impact on health outcomes (*4*). Health products may go unused due to a mismatch of product needs as well as a lack of public infrastructure, spare parts and consumables, or trained technicians (*5*).

Equitable delivery of health products and services is becoming more complex due to pharmaceutical regulations and geographic disparities, as seen in the delivery of vaccines and related supplies for countering COVID-19 (*6,7*). LMICs have limited access to safe and high-quality health products and must rely heavily on donor support, exceeding 80% of supply in some cases (*8*). In LMICs where regulatory authorization is weakly functioning, public procurement is a major means to secure access to and delivery of safe and affordable health products (*9*).

Several conceptual frameworks exist but there is no universal framework for effectively improving access to and delivery of health products in LMICs (*10*). Thus, this study attempts to create a series of steps that correspond to the existing value chain of health products by conducting a document review and case studies.

The following three cases describe the experiences of the National Center for Global Health and Medicine (NCGM; Tokyo, Japan) in promoting access to and delivery of health products in LMICs. Each case is presented in the order of context, actions, outcomes, and lessons learned. Based on these cases, we propose a comprehensive framework for describing characteristics, with a view to enhance access to and delivery of health products in LMICs.

Case 1. Development of health products for LMICs

Working in hospitals and health centers in LMICs, we have often observed situations where health products, manufactured in high-income countries and provided by international agencies, were kept unused. In some cases,

products were never distributed from central storehouses. For those that were distributed to health facilities, many went unused or unopened because they did not suit the local context and actual needs.

To ensure safe and quality health products are used appropriately and continuously in LMICs, NCGM, as part of advising the provision of health products by Japanese grant aid and other Official Development Assistance (ODA) agencies, launched a program in 2016 called "Supporting business plan of Medical Equipment Development for Overseas based on local needs" (SMEDO) with funding from the Tokyo Metropolitan Government (*11*). The program targets small and medium-sized Japanese manufacturers aiming to develop health products for LMICs, helping them to increase their understanding of the on-the-ground reality through lectures and site visits to health facilities in Vietnam and Cambodia. Manufacturers also receive expert advice on financing and business plans for overseas deployment.

The needs for health products vary from country to country due to country-specific factors such as the educational and technical level of the health workforce, economic conditions, the health insurance system, infrastructure development, lifestyles, and customs. Through visits to facilities where their products are actually used, manufacturers can better understand the actual needs of the local health workforce, how equipment is maintained, and local business customs and distribution methods.

Through this program, participating manufacturers found that LMICs need low-cost, easy-to-use, and easy-to-maintain products, leading them to reconsider subsequent product development. This case demonstrates the importance of conducting situational analyses of local contexts and actual needs and incorporating the results in the research and development (R&D) of health products for use in LMICs.

Case 2: Installation of radiological equipment in Zambia

In 2015, the Zambian Ministry of Health purchased computed tomography (CT) and interventional radiology (IVR) equipment for the University Teaching Hospital (UTH) in order to improve the treatment of cardiovascular disease (CVD). However, the hospital staff lacked the training to operate the equipment and it went unused. Consequently, UTH continued to send patients in need of testing and treatment to health institutions in neighboring countries.

Because the equipment was manufactured by a Japanese company, UTH requested that NCGM provide technical support to their physicians, radiology technologists, and nurses involved in diagnosing and treating CVD. From 2017 to 2019, NCGM provided hands-on technical assistance, including not only how to use the equipment but also how to make the best use of the equipment in medical procedures. In addition, NCGM established an equipment management system and provided comprehensive in-service training, including radiation protection, to ensure provision of safe healthcare. The training also covered "*Setsugu*" (*12*), Japanese-style patient hospitality.

Subsequently, under the supervision of the NCGM team, the UTH team successfully performed Zambia's first coronary CT in February 2018, coronary angiography (CAG) and percutaneous coronary angiography (PCI) in November 2019. In addition, the number of CT scans performed at the hospital increased by 129.6% from 2017 to 2019 (*13*). However, an unexpected CT equipment failure in 2019 prevented us from performing coronary CT. In response to this, UTH signed a maintenance contract with the manufacturer for its sustainable use. Consumables such as stents and catheters are needed to perform CAG and PCI; thus, a distribution system for these supplies was established between UTH and local distributors.

This case study yields three lessons from the perspectives of access and delivery. First, the capacity of the local health workforce should be evaluated when delivering equipment. It is important to determine whether there are enough trained technicians to operate the equipment. If not, it will be necessary to provide training. Second, it is important to ensure proper equipment management, including daily inspections and regular maintenance. Third, the introduction of new technologies might necessitate the procurement of consumables that were not previously required.

Case 3. Introduction of health products for blood safety in Myanmar

From 2005 to 2015, NCGM and the Ministry of Health and Sports (MOHS) in Myanmar worked together to improve blood transfusion services in Myanmar. Then, to further improve the quality and safety of blood transfusions for advanced therapies such as transplantation, NCGM and the Myanmar National Blood Center (NBC) launched a new four-year project in collaboration with Japanese medical equipment manufacturers in 2015 (*14*).

In this project, an infectious disease control advisor from NCGM coordinated between Japanese doctors, nurses, and laboratory technicians and Myanmar government officials and the NBC. The Japanese team visited the NBC and local hospitals to understand the local conditions. Recognizing the need for further safety improvements, the Japanese team provided training to local doctors, laboratory technicians, and nurses in blood typing and clinical transfusion therapy. Simultaneously, Japanese manufacturers provided equipment and consumables, including refrigerators for blood packs, centrifuges for component blood preparation, and leukocyte filters.

High-ranking officials from the Myanmar government and the NBC visited Japan to learn about the Japanese blood transfusion system. To improve safety, an annual blood transfusion seminar for policymakers and clinicians was launched in Myanmar in collaboration with the NBC. Furthermore, the infectious disease control advisor assisted with the creation of Myanmar's national blood transfusion guidelines. Through these activities, Japanese blood transfusion-related products were procured and distributed by the MOHS.

This case exemplifies technical cooperation that met local needs and led to successful product procurement. First, the relationship of trust fostered by long-term cooperation with MOHS and the NBC made it possible to perform a more practical situation analysis that led to technology transfers and training as well as R&D of products that reflected actual needs. Second, involving stakeholders facilitated coordination within the MOHS, enhancing awareness of the importance of safety. Consequently, Japanese products were procured by the Myanmar government. Third, providing appropriate training in collaboration with the NBC improved service quality and led to nationwide product distribution. Finally, Japanese manufacturers shifted their mindset toward investing in the future, illustrating an effective marketing strategy for expanding overseas.

Framework of essential steps for better access to and delivery of health products

By reviewing the barriers and success factors in the above cases, we concluded that the entire value chain can be divided into seven steps to accelerate equitable access to and delivery of health products in LMICs: 1) situation analysis, 2) research and development, 3) regulatory authorization, 4) selection and prioritization, 5) public procurement, 6) distribution and storage, and 7) health service delivery (Figure 1). Below, we describe the characteristics of each step.

Step 1. Situation analysis

This step involves thorough market research to identify the end users, their needs, the circumstance in which the intended product would be used, and prices in the existing market. Critical questions include *i*) Can health products be distributed to rural clinics? *ii*) What is the status of infrastructure such as water, electricity and telecommunications? *iii*) What is the maintenance capacity of local suppliers and service providers who use health products? *iv*) What testing and medication costs are affordable for residents? *v*) What health issues are specific to the region? And *vi*) What are the projections for demographic characteristics, emerging diseases, socioeconomic status, and so on? It is also important to study competing products and examine related trends. The SMEDO and Myanmar cases illustrated situational analyses that led to effective interventions. In contrast, the Zambia case demonstrated an inadequate analysis of the situation regarding trained technicians capable of accurately using and managing the product.

Step 2. Research and development (R&D)

In this step, it is important to find appropriate partners that can help collect data and verify the utility of the product in LMICs. Some manufacturers may take advantage of the financial and technical support

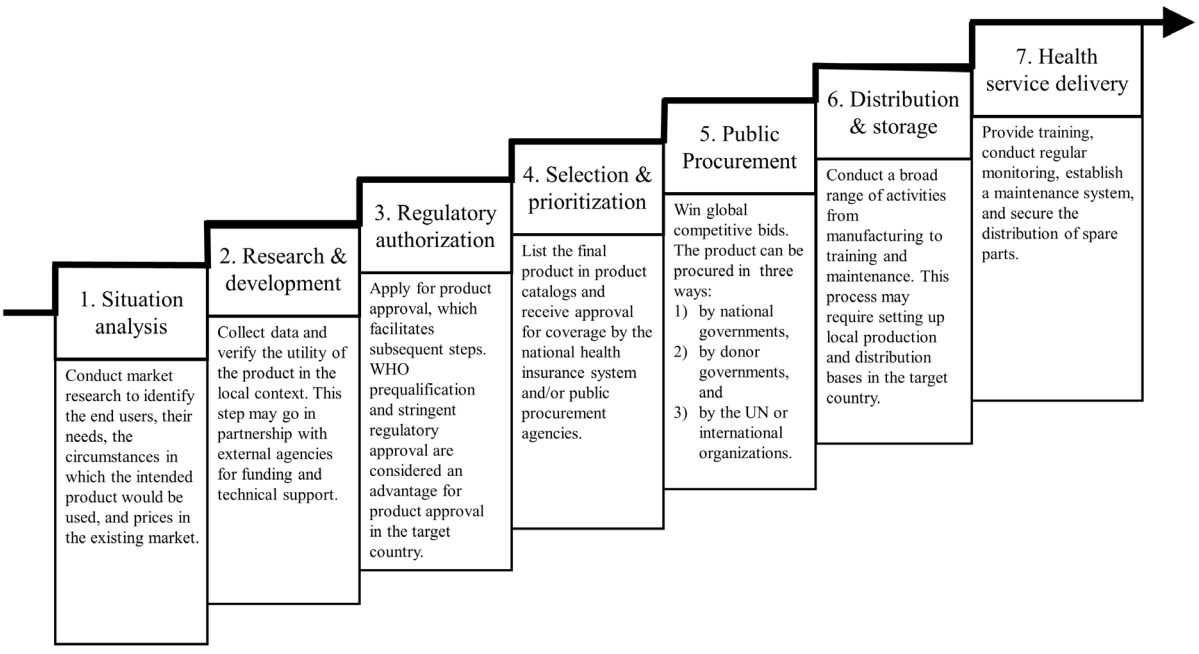

Figure 1. Seven steps for equitable access to and delivery of health products. This framework represents the entire value chain of health products divided into seven steps. The characteristics of each step are described in the box below.

provided by academia, international organizations, and governments as they design and develop products suitable for LMICs. In the case of Myanmar, the Japanese team collaborated with the NBC from the beginning, and the Japanese manufacturer was able to obtain the necessary information to adapt its products to local conditions.

Step 3. Regulatory authorization

The World Health Organization (WHO) and national governments use their regulatory authority to assure the safety and quality of health products. This step involves confirming the WHO's prequalification and obtaining national regulatory approval in the target country. Manufacturers can apply for product approval, which facilitates subsequent steps, especially Steps 4 and 5. However, this time-consuming and costly step requires strategic planning (*15*). The abovementioned activities in Myanmar were influential in obtaining regulatory authorization. High-ranking government officials were involved in the training and therefore played a crucial role in the public procurement of Japanese products because they understood their necessity and practical applications.

Step 4. Selection and prioritization

Obtaining product approval does not necessarily mean the product should be selected for local usage. This step involves efforts to list the final product in product catalogs and to be covered by the national health insurance plan of the target government. National governments may require a track record of sales results in different countries and examples of product use on English-language websites. Among approved products, those that should be used at the local health facility level will tend to be prioritized. In some countries, a health technology assessment is conducted for selection and price-setting (*16*). In the Myanmar case, the national transfusion guidelines created through the project indicated the need for quality and safety standards. Because the products met those standards, they were selected and prioritized.

Step 5. Public procurement

This step can occur in three ways: *i*) direct procurement by national governments in LMICs, sometimes with funding provided by international organizations (or procured by international organizations on behalf of the government); *ii*) procurement by donor governments for the purpose of assisting LMICs; and *iii*) procurement by United Nations agencies or other international organizations for the purpose of supporting LMICs. Challenges for manufacturers include establishing an adequate supply chain for mass production and setting affordable prices to win global competitive bids. Products that are already pre-qualified by the WHO and listed in global product catalogs have an advantage. In the case of Myanmar, the government directly procured the products. The Japanese manufacturer's shift toward investing in the future was an essential component of cultivating the target country's market.

Step 6. Distribution and storage

This step refers to the entire supply chain in the provision of products and services. This involves a broad range of activities from manufacturing including local production, distribution, and storage, to user training and maintenance. Manufacturers may need to set up local production and distribution bases in the target country. In the case of Myanmar, the NBC coordinated the nationwide distribution of the products. In the case of Zambia, the ability to provide a new kind of examination service led to increased demand for consumables, which opened up further sales opportunities.

Step 7. Health service delivery

To deliver and maintain health products locally, it is essential to provide local technicians with proper training and guidance. It is also helpful to establish a maintenance system, secure distribution of spare parts, and provide a monitoring system to receive feedback from local health facilities. In Myanmar, provision of practical training improved the quality of service, while the involvement of stakeholders facilitated the creation of national guidelines. The Zambia case suggested the importance of keeping maintenance contracts and user training.

Perspectives in setting a universal framework for access and delivery

There are several existing conceptual frameworks that describe the factors related to access to and delivery of health products in LMICs. The United Nations proposed a pharmaceutical value chain, from the development of medicines to their appropriate use by patients, to ensure access to safe, effective, and quality-assured medicines, including controlled medicines (*17*). This framework is characterized by the "Manufacturing" step and by dividing "Health service delivery" into several practical steps, which were modified by the WHO to expand the focus to health products as a whole, with post-marketing surveillance added at the end (*18*). In addition, the UN Development Programme Access and Delivery Partnership (UNDP-ADP) suggested another framework of steps to help manufacturers deliver health products to people in need (*19*). As shown in Table 1, these frameworks are similar to ours in that they cover the steps from R&D to health service delivery. However, there are some differences, including "Situation

Table 1. Comparison of relevant frameworks for access to and delivery of health products

Items	NCGM 7 steps	UNDP-ADP	UN pharmaceutical value chain	WHO value chain of health products
Target	Health products	Health products	Medicines	Health products
Number of steps	7	6	8	9
Steps				
Situation analysis	① Situation analysis			
R&D	② R&D	① New medicines, vaccines, diagnostics	① R&D and innovation	① R&D and innovation
Manufacturing	*Included in step ⑥		② Manufacturing	② Manufacturing
Accreditation	③ Regulatory authorization	② Regulatory authorization	③ Marketing registration	③ Marketing registration
Selection	④ Selection and prioritization	③ Selection, prioritization and resource allocation	④ Selection/pricing/ reimbursement	④ Selection/pricing/ reimbursement
Procurement	⑤ Public procurement	④ Public procurement	⑤ Procurement and supply	⑤ Procurement and supply
Distribution	⑥ Distribution and storage	⑤ Storage and distribution		
Service provision	⑦ Health service delivery	⑥ Health service delivery	⑥ Prescribing, ⑦ Dispensing, and ⑧ Use	⑥ Prescribing, ⑦ Dispensing, and ⑧ Use
Monitoring				⑨ Post market surveillance

*NCGM seven steps include "Manufacturing" in step of ⑥ Distribution and storage. NCGM, National Center for Global Health and Medicine; UNDP-ADP, United Nations Development Programme Access and Delivery Partnership; R&D, Research and development.

analysis," which was incorporated into our framework as the first step.

As stated in Cases 1 and 2, better understanding of local conditions is needed to ensure access to and delivery of health products to people in need in LMICs in order to achieve UHC. In particular, the following perspectives should be considered at the "Situation analysis" step: the distribution system of health products to local health facilities; the status of basic infrastructure, including water, electricity, and telecommunications; the maintenance capacity of local suppliers; the affordability of services for local people; and compatibility with local needs and demographic prospects. Although the "R&D" step in other frameworks may include the investigation of local conditions, our framework places more emphasis on "Situation analysis," which is the first and most important step in supporting access to and delivery of health products in LMICs. By analyzing local needs, it might be possible to modify existing health products for local markets without a long and costly R&D process.

In addition, analyzing the needs of marginalized and vulnerable populations can facilitate the promotion of equitable access to healthcare in light of UHC. For example, mobile X-ray equipment is a good example of how a product developed for home healthcare in Japan was adapted for use in remote settings, leading to market expansion and better access for disadvantaged populations in LMICs (*20*). No matter how innovatively products are developed, if they do not contribute to mediating health equity issues, they will only create health disparities.

Our seven-step approach serves as a road map for a diverse range of stakeholders by clarifying core principles at each step in the value chain and services to be delivered to the population, with the aim of realizing UHC. However, further research is required to strengthen the evidence base for accurate conceptualization of the topic. For example, our framework does not include a "Manufacturing" step, which is incorporated into the "Distribution and storage" step instead. This is because we developed our framework based mainly on our experience that manufacturing was included in a series of activities by manufacturers under distribution and storage. However, the location, method, and cost of manufacturing are important aspects in the value chain of health products. Therefore, it remains to be determined whether the "Manufacturing" step should be emphasized more in our framework.

Lastly, our framework incorporates several activities into the "Health service delivery" step. In contrast, the UN has three separate steps ("Prescribing," "Dispensing," and "Use"), while the WHO added "Post market surveillance" as the final step after health service delivery. The need to monitor the progress of access to and delivery of health products should also be investigated in future research. We wish to explore more case studies in order to identify challenges and lessons learned in addressing how best each step should take place in the deliberation of accessible health products in LMIC settings.

Conclusion

Our goal should be to provide people in LMICs with equitable access to safe, affordable, and reliable products that are suitable for local conditions and needs, with the aim of improving health outcomes. Instead of a narrow approach that aims only to achieve WHO prequalification or product approval, it is important to view the entire value chain of health products comprehensively, following the seven steps proposed in this article. Such a comprehensive, forward-thinking perspective would be helpful in ensuring that the end user is always considered. Our seven-step approach offers considerations that may

be useful for all stakeholders involved in access to and delivery of health products. The approach will also contribute to improving global health disparities.

Acknowledgements

The authors would like to thank Drs. Masahiko Hachiya, Yuriko Egami, Masami Fujita, Mari Nagai, and Shinsuke Miyano as well as our colleagues who supported the work of the Bureau of International Health Cooperation at NCGM to promote access to and delivery of health products in LMICs by providing insight and technical expertise, which greatly assisted this research.

Funding: This work was supported by a research grant from the Ministry of Health, Labour and Welfare (MHLW) of Japan (Grant No. 21BA1001).

Conflict of Interest: The authors have no conflicts of interest to disclose.

References

1. The United Nations. Sustainable development goals. Goal 3: Ensure healthy lives and promote well-being for all at all ages. *https://www.un.org/sustainabledevelopment/health/* (accessed September 9, 2022).
2. Compton B, Barash DM, Farrington J, Hall C, Herzog D, Meka V, Rafferty E, Taylor K, Varghese A. Access to medical devices in low-income countries: addressing sustainability challenges in medical device donations. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. *https://doi.org/10.31478/201807a* (accessed September 9, 2022).
3. Malkin RA. Barriers for medical devices for the developing world. Expert Rev Med Devices. 2007; 4:759-763.
4. World Health Organization. Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action. *https://apps.who.int/iris/handle/10665/43918* (accessed September 9, 2022).
5. Diaconu K, Chen YF, Cummins C, Jimenez Moyao G, Manaseki-Holland S, Lilford R. Methods for medical device and equipment procurement and prioritization within low- and middle-income countries: findings of a systematic literature review. Global Health. 2017; 13:59.
6. Wakabayashi M, Ichimura Y, Shimizu E, Nishioka T, Kono Y, Doi M, Egami Y, Kadowaki T, Iso H, Fujita N. Global extension of Japanese medical products related to COVID-19: a survey of WHO Emergency Use Listing. GHM Open. 2022; 2:59-62.
7. World Health Organization. Assessment of the COVID-19 supply chain system: full report. *https://www.who.int/publications/m/item/assessment-of-the-covid-19-supply-chain-system-report* (accessed September 9, 2022).
8. World Health Organization. Medical devices: managing the mismatch. https://apps.who.int/iris/bitstream/handle/10665/44407/9789241564045_eng.pdf (accessed September 9, 2022).
9. World Health Organization. The Global Health Observatory - Procurement of medical devices carried out at the national level. *https://www.who.int/data/gho/data/indicators/indicator-details/GHO/procurement-of-medical-devices-carried-out-at-the-national-level* (accessed September 9, 2022).
10. Kuupiel D, Bawontuo V, Drain PK, Gwala N, Mashamba-Thompson TP. Supply chain management and accessibility to point-of-care testing in resource-limited settings: a systematic scoping review. BMC Health Serv Res. 2019; 19:519.
11. Tokyo Metropolitan Government. Supporting business plan of medical equipment development for overseas based on local needs. *https://smedo.tokyo/english.html* (accessed September 9, 2022).
12. Shimada H. Consideration of patient care from point of view of radiological technologist. Iryo. 2007; 61:26-29. (in Japanese)
13. Kono Y, Shimizu E, Matsunaga F, Egami Y, Yoneda K, Sakamoto K, Mubita M, Sichizya VS, Wakamatsu K, Terashima M, Fujita N. Enhancing the use of computed tomography and cardiac catheterization angiography in Zambia: A project report on a global extension of medical technology in Japan. Glob Health Med. 2021; 3:52-55.
14. Nozaki I, Aung T, Oo NN, Kodoi H, Ito Y, Inaba T, Shiratori K. Enhancing the blood safety program in Myanmar: Report on projects of global extension of medical technologies of Japan. Glob Health Med. 2021; 3:48-51.
15. Vaz A, Roldão Santos M, Gwaza L, Mezquita González E, Pajewska Lewandowska M, Azatyan S, Saint-Raymond A. WHO collaborative registration procedure using stringent regulatory authorities' medicine evaluation: reliance in action? Expert Rev Clin Pharmacol. 2022; 15:11-17.
16. Oortwijn W, Broos P, Vondeling H, Banta D, Todorova L. Mapping of health technology assessment in selected countries. Int J Technol Assess Health Care. 2013; 29:424-34.
17. The United Nations. The pharmaceutical value chain. *https://syntheticdrugs.unodc.org/syntheticdrugs/en/access/pharmaceutical/index.html* (accessed September 9, 2022).
18. World Health Organization. Realizing equitable global access interfaces between public health, innovation and intellectual property. *https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_who_wto_gc_covid_19_21/wipo_who_wto_gc_covid_19_21_3.pdf* (accessed September 9, 2022).
19. The Access and Delivery Partnership. Strengthening national health systems. https://adphealth.org/strengthening-national-health-systems/ (accessed September 9, 2022).
20. National Center for Global Health and Medicine. Learning from domestic and overseas cases on the global expansion of medical products: development, regulatory approval, and global public procurement. *https://kyokuhp.ncgm.go.jp/library/tenkai/2021/tenkaiseminar202203_light.pdf* (accessed September 9, 2022). (in Japanese)

Received September 9, 2022; Revised October 13, 2022; Accepted October 19, 2022.

Released online in J-STAGE as advance publication November 4, 2022.

**Address correspondence to*:
Eiichi Shimizu, Bureau of International Health Cooperation, National Center for Global Health and Medicine, 1-21-1 Toyama, Shinjuku-ku, Tokyo 162-8655, Japan.
E-mail: eshimizu@it.ncgm.go.jp