Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

Toward the Earlier Marketing of Innovative Medical Devices

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Medical devices come in many different shapes and forms, such as from scalpels and tweezers to MRIs and artificial organs. Moreover, they differ from pharmaceuticals in that they undergo repeated improvements and modifications even after they are placed on the market. This characteristic is particularly noticeable in Software as a Medical Device (SaMD), which is often upgraded post-market. The performance, of medical devices that use artificial intelligence (AI) are expected to change constantly. Establishing review processes for the approval of medical devices that are sensitive to this characteristic, to ensure the quality, efficacy, and safety of products, while assuring access for the medical front lines to innovative, safe and effective medical products as quickly as possible is, we emphasize, one of the most significant roles of the Pharmaceuticals and Medical Devices Agency (PMDA).

In Japan, the regulation of medical devices varies according to the risks involved. For example, low-risk products (Class I) require prior marketing notification, medium-risk products (Class II and some Class III) require third party certification, and high-risk products (some Class III and Class IV) must obtain the Minister's Approval through PMDA review. In recent years, 506 medical devices were newly approved in fiscal 2019 (April 2019–March 2020). That number includes 11 new medical devices, 211 improved medical devices, and 283 generic medical devices. Japan recently became the first

country in the world to approve a smoking cessation treatment support system (behavior modification app)[1], a neutron irradiation system for boron neutron capture therapy[2], and a treatment planning program for boron neutron capture therapy.[3]

Since PMDA's establishment in April 2004, the PMDA has enhanced and strengthened reviewers who undertake approval reviews of medical devices. We have also worked to improve our review capabilities and restructure organizational frameworks for the review of medical devices. As a result, the total review period for medical devices is now on a par with that of Western countries. In fiscal 2019, the review period was 11.1 months for normal devices and 7.3 months for priority new devices including orphan devices. In this way, the respective targets of 14 months and 10 months were achieved, and the device lag that had previously been a problem in Japan has become the past issue. In April this year, the PMDA set up a new review office that specializes in Software as a Medical Device (SaMD) using AI, etc. By enhancing and strengthening our review framework in this and other ways, the PMDA will continue in its efforts to speed up the approval review process for more advanced medical devices with higher medical needs.

With recent advances in science and technology, the speed at which innovative technologies will be adapted and applied to medical devices continues to increase. On the other hand, the fact remains that there are some medical devices whose development is challenging to promote, despite their high degree of medical necessity. The Amended Pharmaceuticals and Medical Devices Act (PMD Act) was promulgated in December 2019 and is being enforced stepwise from September 2020. Predictability of medical device approval review has been improved even further as a result of the following systems newly enforced.

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1 https://www.pmda.go.jp/files/000238855.pdf
2 https://www.pmda.go.jp/files/000237993.pdf
3 https://www.pmda.go.jp/files/000237994.pdf

(1) SAKIGAKE Medical Device Designation System

In this system, medical devices that display potential for marked efficacy in the early phases of clinical trials are designated as SAKIGAKE (Pioneering) Medical Devices with the aim of accelerating the regulatory approval process so that patients can be provided with innovative medical devices using breakthrough technologies ahead of the rest of the world. The advantages of designation as a SAKIGAKE Medical Device include prioritized consultation, enhanced pre-submission consultation, and priority review (target review timeframe: 6 months).

(2) Designation System for Medical Devices for Specific Applications

Medical devices that are used for the treatment of pediatric diseases whose medical needs remain significantly unmet and that offer particularly outstanding value for use are designated as Medical Devices for Specific Applications. Such devices are able to take advantage of priority review and other benefits of designation. Medical devices for fewer than 50,000 patients in Japan are eligible for research grants for promotion of research activities and preferential treatment such as tax exemptions.

(3) Conditional Early Approval System

This system allows for the approval with limited clinical data of medical devices that are particularly necessary for the treatment of serious diseases and diseases that lack effective treatments, but for which it is difficult to conduct new confirmatory clinical studies for reasons such as the rareness of the disease, although certain clinical data are available for evaluation. Such approval is subject to conditions including the implementation of post-market risk management measures. In particular, PHOENIX (PHysical OpEratioN of Intelligible eXtrapolation approval) applies to medical devices that are designed to physically affect the human body, such as cauterization and irradiation, and for which there are clinical data for specific disease areas (e.g., organs, sites) that can be extrapolated to other areas.

(4) Improvement Design within Approval for Timely Evaluation and Notice (IDATEN[4])

In light of the nature of medical devices that undergo ongoing modifications and improvements during their post-market lifecycles, and AI-based programs and software whose performance is constantly changing and improving, change plans will be confirmed during the approval review process so that partial amendments to approvals can be made promptly within the scope of such plans during the devices' post-market lifecycles.

As a form of regulatory agility during the COVID-19 pandemic, the PMDA is working to ensure that product development for COVID-19-related medical devices proceeds smoothly. This includes conducting priority reviews of such products and providing consultation for developers from the early stages of development. To date, a total of 16 COVID-19-related medical devices, including ventilators and a COVID-19 Pneumonia Image Analysis Program, have been approved in a short period of time.

In conclusion, the PMDA is promoting the development of innovative medical devices with high medical needs and their early introduction into clinical settings by enhancing and strengthening our organizational structure, the appropriate implementation of the Amended PMD Act, and the active promotion of regulatory agility. As our philosophy states, we will strive to be the bridge between patients and their wishes for faster access to safer and more effective medical devices.

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Pharmaceuticals and Medical Devices Agency

4 "IDATEN", originally the name of a member of the guardians of Buddha who has the episode of running very fast, is a title for a very fast runner in Japan.