

## **To Boost Japan-first Medical Product Approvals ~ PMDA Now Looks at Next Steps ~**

24th November, 2020

Medical products need to be reviewed and approved in a timely manner with securing their efficacy, safety and quality in order to enable early patient access to necessary treatments. In this process, the PMDA plays a key role and has great responsibility in Japan. A few decades ago, there existed drug lag, but now we resolved this issue with measuring such as implementation of new systems.

Between 2008 and 2019, a total of 400 new pharmaceutical products, i.e. drugs that contain new active substances, were approved in Japan. Important finding is that 80 products (20.0%) among them were the first-in-world approval (including those only approved in Japan). Further looking at 355 new drugs approved both in Japan and other regions, 35 (9.9%) were first approved in Japan. While this number of Japan-first approvals has slightly been increasing over recent years, there still exists room for improvement. From other aspects, in the period of 2016-2019, the median of drug lag such as the delay of approval in Japan from the first-in-world approval was found to be decreased by more than 2.5 years compared to that of 2008-2011. In addition, by looking at the frequency of post-marketing cautions for drug safety and that of discontinued products, the PMDA's review for new drugs firstly approved in Japan was shown to be at the same level of excellence as those firstly approved outside of Japan. The details of

these numbers are [published](#) by our staff<sup>i</sup>. Overall, these results show that the PMDA has made a big step forward for achieving earlier patient access to new pharmaceutical products in Japan.

All this progress was made not just in one day but from every tireless effort made for more than a decade. The most significant contributor is the infrastructural improvement including strengthened staffing of reviewers. The number of PMDA staff engaging in product review is now over 560, after a large increase by more than 400 from 154 at the time of PMDA's establishment in 2004. This is a result of proactive recruitment carried out to address the drug lag. More human resources enable us to shorten the product review time expectedly.

In addition to those initiatives to shorten the review time, the PMDA and the Ministry of Health, Labour and Welfare (MHLW) also introduced many initiatives for the product development and regulatory submission. One example is the partnership agreement that PMDA concluded with the Japan Agency for Medical Research and Development (AMED) in 2015. This encourages earlier interactions between the researchers and the PMDA reviewers and enables strategic and speedy product development. Furthermore, accelerated approval pathways such as SAKIGAKE Designation and Conditional Early Approval enabled efficient product development thus rapid regulatory submission. With the formal legislation of these approval pathways in 2019, further utilization of these processes is highly expected.

To achieve 'access first', which is one of my priorities '[4 Firsts](#)', facilitating patient and public involvement (PPI) in product development is also a key. I established "Patient Centricity Working Group" in May 2019, and a guidance document to promote PPI is under development. I believe that we will see positive outcomes from these new approaches in near future. Now as one of the regulatory agencies to contribute to bringing innovative medical products into practice promptly, the PMDA is just amid the next stage

to further promote patient access with more Japan-first approvals by nurturing cooperative and efficient environment for product development working with all stakeholders.

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<sup>i</sup> [Evolving landscape of new drug approval in Japan and lags from international birth dates: retrospective regulatory analysis.](#)

Mototsugu Tanaka, Mayumi Idei, Hiroshi Sakaguchi, Ryosuke Kato, Daisuke Sato, Kenji Sawanobori, Shuichi Kawarasaki, Toshiyuki Hata, Asako Yoshizaki, Miki Nakamura, and Mutsuhiro Ikuma.

Clin Pharmacol Ther. 2020 Oct 13. doi: 10.1002/cpt.2080. Online ahead of print.

PMID: 33048367