PMDA Updates

January, 2020

News

1. Chief Executive Dr. Fujiwara's New Year Message for 2020

Dr. Fujiwara

I would like to wish you all a Happy New Year.

A year has almost passed since I took office as a new chief executive of PMDA. I have been promoting Regulatory Science and making efforts to realize my priority, "4Fs" (Patient First, Access First, Safety First, Asia First).

Regarding "Patient First", I actively exchanged opinions with stakeholders at sessions of this topic in various conferences. PMDA is also promoting by creating the "Patient Centricity Working Group" and make a guidance to advance it. I think it is indispensable that innovative technology will be incorporated into product development and patient's opinion from development to post-marketing phase will become more important than ever.

As for "Access First", "Sakigake Designation System" and "Conditional Early Approval System" were legalized in December 2019. In addition, PMDA has advanced the utilization and application of Real World Data in the process of marketing approval.

In terms of "Safety First", PMDA has been providing Safety information including "Dear Healthcare Professional Letters" with stakeholders in abroad as well as Japanese ones. PMDA has also been focusing on Precision Medicine and working on enhancement of the department that reviews in vitro diagnostics. A gene panel testing system that was approved under "Sakigake Designation System" enables health professionals to select anti-cancer drugs properly for individual patient. This leads to protect patients from unnecessary side effects. This product is now has been reimbursed by public insurance after its approval.

As of international activities, PMDA not only promotes international regulatory harmonization, but also cooperates with China, India and Singapore within the framework of "Asian Network Meeting" as co-leads in order to realize regulatory harmonization among Asian countries/regions. PMDA also contributes to capacity building for other regulatory agencies through "Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs". In addition, in June 2019, Japanese government decided a "Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization" so that we will strengthen "Asia First".

Based on my priority, "4Fs", I will devote myself to make PMDA become the agency that contributes Health and Welfare of people of the world as well as Japanese, by reviewing applications for marketing approval of medical products, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions/regenerative products.

Once again, I wish you all health, prosperity, and happiness in the year 2020.

2. PMDA-ATC e-learning system

PMDA-ATC started to provide Online Learning System, "PMDA-ATC e-learning system" on January 6, 2020 to make the training seminars more efficient and effective. The system is open to public, so that not only seminar participants but also other people including other regulatory authorities' staff can learn about the services of PMDA, PMDA-ATC activities, basics of pharmaceutical and medical devices regulations, and so on. The contents of the e-learning system will be updated and expanded thereafter.

Please access the e-learning system using the following link;
https://pmda-atclearning.jp/portals

3. Data Analytic Workshop with DKMA

A look of Data Analytic Workshop

On December 2, 2019, 8-person delegation from DKMA, the regulatory authority of Denmark including Pierre Quartarolo (Director of Division for Pharmacovigilance & Medical Device), visited PMDA for an information-sharing-and-discussion workshop. In this workshop, both parties presented their use of real world data and real world evidence. Members from the relevant PMDA offices (Office of International Programs, Office of Pharmacovigilance I, Office of Informatics and Epidemiology) attended this workshop and gave presentations on PMDA's recent work on the Japanese legal structures for post-marketing surveillance and utilization of real world data. DKMA representatives gave presentations on a system that is unique to Denmark in which individuals are registered, and on data analysis methods. Both sides had information exchange and discussion through these presentations. Based on this discussion, both parties agreed to have staff exchange in 2020 for topics of interest to each party.

4. PMDA-ATC Quality Control (Herbal Medicine) Seminar 2019

Group photo of participants and PMDA directors
Front row from right to left, Ms. Akiko Ogata (Deputy Director, Office of International Cooperation), Dr. Yoshikazu Hayashi (Director, Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs)

From December 10 to 12, PMDA held a seminar entitled "PMDA-ATC Quality Control (Herbal Medicine) Seminar 2019" in Toyama. This seminar was designed for officials of overseas regulatory agencies engaged in pharmaceuticals reviews, and participated by 14 regulators from Bangladesh, Bhutan, Brazil, Cuba, India, Indonesia, Lao PDR, Malaysia, Philippines, Saudi Arabia, Singapore, Taiwan, and Thailand.

In the seminar, lectures were delivered by PMDA staffs, representatives from Toyama prefecture, Institute of Natural Medicine of Toyama University, National Institute of Health Sciences, and The Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ). The lectures covered the outline of PMDA, overview of regulations on herbal medicines in Japan, quality evaluation of crude drugs (herbal medicine), regulation and review process of OTC drugs, current status of Japanese traditional medicines (herbal medicine), evaluation process and GMP inspection by prefectural authorities, Japanese Pharmacopoeia (JP), Japanese standards for non-pharmacopoeial crude drugs (non-JP crude drug standards), standards and guidelines for crude drug/kampo medicine marketing approval, quality management and manufacturing management of crude drugs and herbal medicines and forefront of herbal medicines in modern medical care.

Besides these lectures, the program included the on-site tour to visit the Center for Medicinal Plant Resources (cultivation and processing of medicinal plants) and a manufacturing facility of herbal medicine (manufacturing process of herbal medicine preparations and their quality control).

At the end of the seminar, the course completion certificates were handed to each participant by Dr. Eriko Fukuda (Office Director, Office of International Cooperation).

Please refer to the following website for the details of PMDA-ATC Quality Control (Herbal Medicine) Seminar 2019.

https://www.pmda.go.jp/english/symposia/0157.html

5. Japan-US HBD East 2019 Think Tank Meeting

HBD East 2019 Think Tank Meeting was held in Tokyo on December 11. Harmonization By Doing (HBD) is a regulatory harmonization activity for medical devices, launched in 2003 by regulators, academia, and the medical device industries in the U.S. and Japan. HBD has been discussing and examining ways to identify and resolve issues due to differences in medical device regulations and evaluation methods in both countries. HBD holds regularly Think Tank Meetings to inform the stakeholders of the results of the HBD activities widely and to identify issues to be addressed in the future.

Group photo

Approximately 170 people from the FDA, academia and industries from the U.S. and Japan participated in the HBD East 2019 Think Tank Meeting. At the meeting, lively discussions were held on topics of high interest, such as efforts to improve patient access to medical devices in both countries, promotion of the development of pediatric medical devices, and the utilization of Real World Evidence.

Please refer to the following website for details of the meeting.
https://www.pmda.go.jp/english/int-activities/int-harmony/0004.html

English translations of review reports

The followings are current information about English version of review reports on PMDA website.

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Non-proprietary Name	Posting date
Yervoy [Partial Change Approval]	ipilimumab (genetical recombination)	December 17
Opdivo [Partial Change Approval]	nivolumab (genetical recombination)	December 17
Smyraf [Initial Approval]	peficitinib hydrobromide	December 23
Bavencio [Initial Approval]	avelumab (genetical recombination)	January 10
Empliciti [Initial Approval]	elotuzumab (genetical recombination)	January 10
Istodax [Initial Approval]	romidepsin	January 10

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 369 (January 9, 2020)

1. Safety of Influenza Antiviral Drugs
2. Suspected Adverse Reactions to Influenza vaccines in the 2018 Season
3. Important Safety Information

1. Atezolizumab (genetical recombination)
2. Osimertinib mesilate
3. Bilastine

4. Revision of Precautions (No. 309) Mecasermin (genetical recombination) (and 3 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0017.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
February 3-6	PMDA-ATC Pharmacovigilance Seminar 2020	Tokyo
February 5-6	4th Japan-India Medical Products Regulatory Symposium	Tokyo
February 7-8	APEC-LSIF-RHSC meeting	Putrajaya
February 13-14	PMDA-ATC Pharmaceuticals Review Seminar 2020 in Jakarta, Indonesia	Jakarta
March 16	ICMRA Plenary Meeting	Brussels
March 17-19	IMDRF Management Committee Meeting	Singapore
March 17-19	32th DIA Euro Meeting	Brussels
March 19-20	ICH Management Committee Interim Meeting	Brussels

