PMDA Updates

August 2023

News

1. The DIA 2023 Global Annual Meeting

The Drug Information Association (DIA) 2023 Global Annual Meeting was held in Boston, US, from June 25 to 29. Dr. UZU Shinobu (Senior Executive Director, PMDA), Dr. SATO Junko (Director of the Office of International Programs, PMDA), Mr. KOGA Daisuke (Division Director of the Office of International Programs, PMDA), two PMDA staff members, and one officer from the Ministry of Health, Labour, and Welfare (MHLW) attended the meeting in person.

Dr. UZU highlighted the importance of patient engagement in the fields of pharmaceutical administration and development in a forum titled "What's in the Future for Global Advancements in Patient Engagement and Patient-Focused Medical Product Development?"

Dr. SATO chaired the "PMDA Town Hall" session, while Dr. UZU, Mr. KOGA, and the MHLW officer delivered presentations on the PMDA's efforts and latest initiatives in the light of changes in pharmaceutical research and development, PMDA's activities to promote regulatory cooperation in Asia, and accelerated regulatory pathways and Japanese pharmaceutical regulatory updates from the MHLW, respectively. The session, where approximately 130 individuals participated, facilitated the understanding of pharmaceutical regulations in Japan.

In the "Asia Town Hall" session, also chaired by Dr. SATO, Mr. KOGA presented the PMDA's efforts to harmonize regulations in Asia. Along with representatives from the National Pharmaceutical Regulatory Agency, Malaysia; Ministry of Health, Malaysia; and Health Sciences Authority, Singapore, the importance of close collaboration through the Asian Network Meeting and other efforts was discussed in the session, where approximately 80 individuals participated.

In the "Emerging Therapies and Technologies: Leveraging Opportunities for Engaging in Pre-Competitive Research and with Medicine Regulators to Support Innovation" session, one of the PMDA staff delivered a presentation on the use of the PMDA's consultation service in early stage of drug development and shared the importance of information sharing between pharmaceutical companies and regulators in early-stage research and development.

The next DIA Global Annual Meeting will be held in San Diego, US, from June 16 to 20, 2024.

Photo from "PMDA Town Hall" session
From left : Dr. SATO Junko (Director of the Office of International Programs, PMDA), Dr. UZU Shinobu (Senior Executive Director, PMDA), Mr. KOGA Daisuke (Division Director of the Office of International Programs, PMDA)

2. PMDA-ATC Regenerative Medicinal Products Review Webinar 2023 for CDSCO, India

On June 28, the PMDA held a webinar titled "PMDA-ATC Regenerative Medical Products Review Webinar 2023 for CDSCO, India." This webinar is a course for regulatory agencies such as the Central Drugs Standard Control Organization (CDSCO). 30 regulators from India (CDSCO) participated in the webinar which provided opportunities for the active exchange of opinions on the themes of regulations on Regenerative Medicinal Products through the sharing of two case studies on regenerative medicinal products, as well as a lecture on the regulations on Regenerative Medicinal Products in Japan.

Feedback was collected through webinar evaluation forms, and digital certificates (open badges) were given to the participants.

3. Minister, Ministry of Health, Vietnam, calls on the PMDA

On July 4, Ms. Dao Hong Lan (Minister, Ministry of Health (MoH), Vietnam), and five executives including Mr. Vu Tuan Cuong (Director General, Drug Administration of Vietnam (DAV), MoH), and two staff members from the MoH, and Dr. SHOBAYASHI Tokuaki (Health Policy Advisor, MoH and JICA), visited the PMDA and met Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. UZU Shinobu (Senior Executive Director), Mr. YASUDA Naoyuki (Associate Executive Director for International Programs), Mr. TANAKA Daisuke (Director of the Office of International Programs), and other officers.

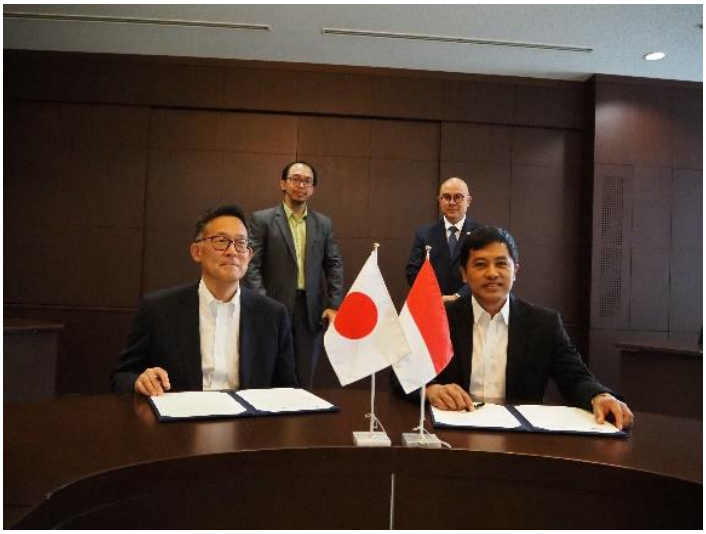
The PMDA explained its organization and activities, outlined Japanese regulatory affairs to the delegation, and communicated about the bilateral cooperation between Vietnam and Japan. Ms. Lan expressed her mission to learn the Japanese review system and accumulate experience in building an organizational structure to reflect it on future policies in Vietnam. Dr. FUJIWARA assured of PMDA's cooperation by sharing experiences of the organizational structure and expressed his expectations of the next symposium between the DAV and PMDA.

4. The Ministry of Health of the Republic of Indonesia and the PMDA signed a Letter of Intent on Long-term Training Program

On July 5, the Ministry of Health of the Republic of Indonesia (MoH) and the PMDA signed a Letter of Intent on a long-term training program on the occasion of the visit of Dr. Dante Saksono Harbuwono (Vice Minister of the MoH) to Japan.

Since the MoH and PMDA have been collaborating in medical devices regulatory program, the MoH and PMDA have agreed to conduct a long-term training program in the field of medical device regulation under the framework of the "Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs" for one year from April 2024.

The PMDA continuously promotes collaboration with the MoH for international regulatory convergence and makes efforts to strengthen the relationship between the two countries.



(State of signature) Front row from left to right： Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. Dante Saksono Harbuwono (Vice Minister, MoH)

5. PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023

The PMDA held a seminar titled "PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023," from July 10 to 13. This seminar was intended for officials from overseas regulatory agencies involved in reviewing pediatric clinical trials and new drug applications for pediatric indications. Notably, 25 regulators from Hong Kong, Indonesia, Lao PDR, Malaysia, the Philippines, Saudi Arabia, Taiwan, and Thailand participated in the seminar.

In addition to the PMDA, lecturers from the U.S. FDA and the European Medicines Agency (EMA) were invited.

The lectures covered a brief overview of the organization as well as the pediatric regulation update of the PMDA, U.S. FDA, EMA, physiology and clinical pharmacology in pediatric populations, extrapolation of efficacy from other population data, and ethical considerations for clinical trials among children. In addition to the lectures, the attendees collectively explored case studies on topics such as the reviews of pediatric applications, ethical issues in pediatric clinical trial design, and modeling and simulation. The participants also presented information on the pediatric drug development programs from their respective countries/regions. They actively engaged in all the discussions.

Front row from left to right; 3rd Ms. ENDO Ayumi (Director, Office of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), 4th Dr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), 5th Dr. Shetarra Walker (U.S. FDA), 6th Dr. John Alexander (U.S. FDA). And lecturers and all the participants

Please refer to the following website for details on the PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023.
https://www.pmda.go.jp/english/symposia/0274.html

6. The 2nd ARISE-PMDA Joint Symposium for Asian Clinical Trials

On July 20, the 2nd ARISE-PMDA Joint Symposium for Asian Clinical Trials was held and co-hosted by the National Center for Global Health and Medicine and PMDA. The speakers from the PMDA included Dr. ARAI Hiroyuki (Executive Director), Dr. SATO Junko (Associate Executive Director for Non-clinical and Clinical Compliance), and Ms. KANEMATSU Miwa (Principal Coordinator of the Office of International Programs).

A variety of speakers, including regulatory authorities from Japan and other Asian countries and representatives from academia and industries in Asian countries, exchanged information and engaged in discussions at the symposium, where approximately 380 individuals participated.

In the keynote speech, Dr. SATO presented the PMDA's efforts related to cooperation for patients in Asia. In the session "First patient in (FPI) in Asian clinical trials," Ms. KANEMATSU presented the efficient process for Investigational New Drugs (IND) review in Japan.

Dr. SATO and Dr. SUGIURA Wataru (Director, Center for Clinical Sciences, National Center for Global Health and Medicine) chaired the panel discussion, "How academia, regulators and industry can work together to

address barriers to accelerate FPI and approval in Asia." Speakers from regulatory authorities, including the PMDA, academia, and industries in Asian countries, discussed obstacles and barriers to promoting clinical trials in Asia and their expectations regarding the development of medical products based on their experiences with COVID-19.

The program is available on the following website:
The 2nd ARISE-PMDA Joint Symposium for Asian Clinical Trials (event info.jp)

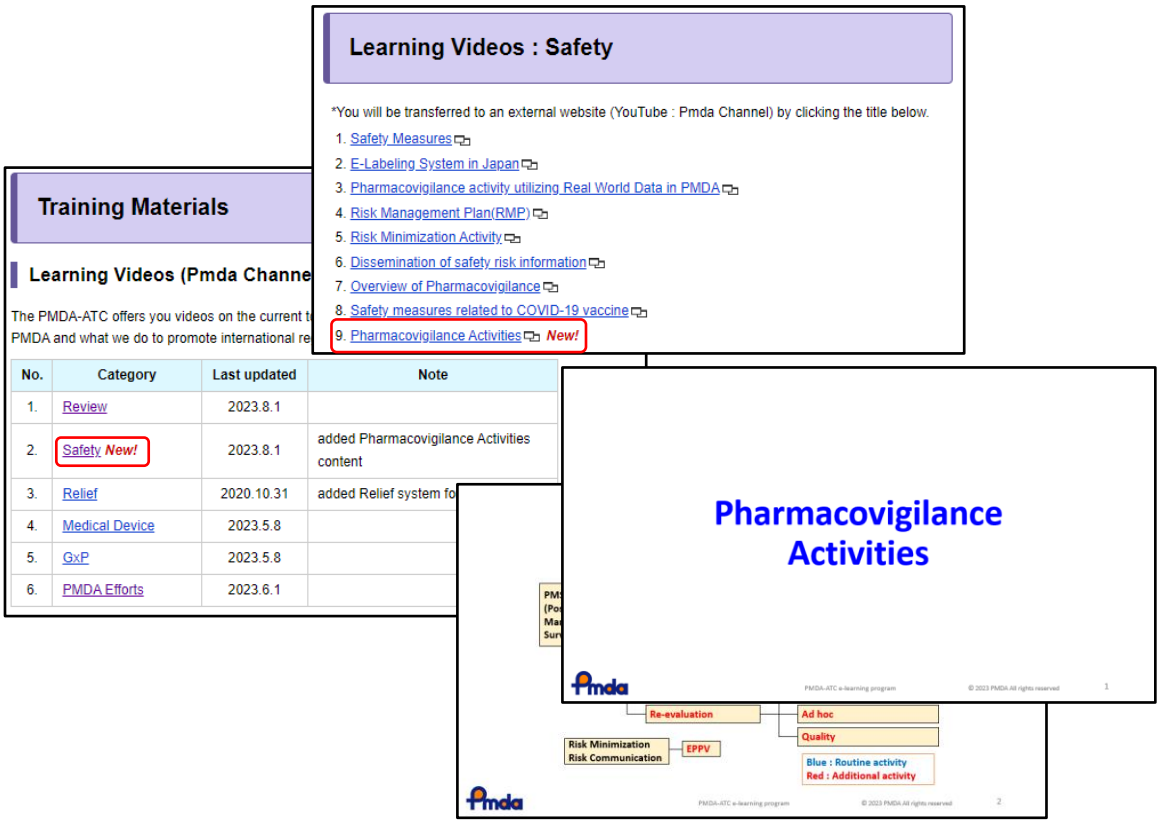
Photos from the symposium
From left: Dr. ARAI Hiroyuki (Executive Director, PMDA), Dr. SATO Junko (Associate Executive Director for Non-clinical and Clinical Compliance, PMDA), and Ms. KANEMATSU Miwa (Principal Coordinator of the Office of International Programs, PMDA)

7. PMDA-ATC E-learning: Updated Learning Video Content Information

The PMDA-ATC E-learning system has been in operation since January 2020. This month, we are pleased to announce the release of a new content video, entitled "Pharmacovigilance Activities" in the "Safety" category of the Learning Videos.

The video introduces the collection of drug safety information and monitoring systems in Japan.

Please follow this link to access the learning video contents:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



English Translations of Review Reports

The following links provide the latest information on the English versions of the review reports on the PMDA website.

Pharmaceuticals

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

Brand Name	Non-proprietary Name	Posting Date
Lyfnua [Initial Approval]	Gefapixant citrate	July 11, 2023
Perjeta [Partial Change Approval]	Pertuzumab (genetical recombination)	July 28, 2023
Herceptin [Partial Change Approval]	Trastuzumab (Genetical Recombination)	July 28, 2023

Medical Devices

https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Brand Name	Term Name	Posting date
AutoloGel System [Initial Approval]	Platelet-rich plasma gel preparation kit	July 18, 2023
Zephyr Endobronchial Valve System [Initial Approval]	Endobronchial valve	July 18, 2023

Regenerative Medical Products

https://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html

Brand Name	Generic Name	Posting date
YESCARTA [Partial Change Approval]	Axicabtagene ciloleucel	July 11, 2023

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (July 20, 2023)

- Atorvastatin calcium hydrate
- Ezetimibe/atorvastatin calcium hydrate
- Ezetimibe/rosuvastatin calcium
- Simvastatin
- Pitavastatin calcium hydrate
- Pitavastatin calcium hydrate/ezetimibe
- Pravastatin sodium
- Fluvastatin sodium
- Rosuvastatin calcium
- Amlodipine basilate/atorvastatin calcium hydrate

- Tirzepatide
- Minocycline hydrochloride (oral dosage form)
- Minocycline hydrochloride (injections)
- Ensitrelvir fumaric acid

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0011.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
September 25–29	IMDRF Management Committee Meeting	Berlin
September 26–28	PMDA-ATC Pharmaceuticals Review Webinar 2023	Virtual
October 28–November 1	ICH meeting	Prague

Reports from Overseas

Our officers deliver lively reports of their activities at their stationed overseas authorities.

Use of Artificial Intelligence in the lifecycle of medicines

On 19 July 2023, EMA has published a draft reflection paper on the use of artificial intelligence (AI) in the lifecycle of medicines [1)] for public consultation [2)]. The public consultation is open until 31 December 2023. This paper outlining the current thinking on the use of AI to support the safe and effective development, regulation and use of human and veterinary medicines. This paper reflects on potential use cases relevant to the application of AI and machine learning (ML) at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting. The second part of this draft paper focus on technical aspects for consideration in using AI in the lifecycle of medicinal products including concerns, risks and other factors: data acquisition and the training/validation/test of datasets, model development that will take use of the datasets, considerations on performances assessment of the model, its interpretability, deployment, governance and with an extra focus on data protection and ethical aspects.

In the conclusion of this draft paper, it indicated that "the quickly developing field of AI and ML shows great promise for enhancing all phases of the medicinal product lifecycle. In several aspects such as data management, governance, and statistical stringency, currently established regulatory principles, guidelines, and best practices are directly applicable to AI/ML and efforts should be made in all organisations to reciprocally integrate data science competence with the respective fields within medicines development and pharmacovigilance." In addition to that it indicates "the use of AI in the medicinal product lifecycle should always occur in compliance with the existing legal requirements, by considering ethics and its underlying principles and with due respect of fundamental rights. A human-centric approach should guide all development and deployment of AI and ML."

Overall, this draft paper outline risks of AI/ML including potential bias and ethics requirements, calling for active measures to avoid integration of bias into AI/ML applications and developing standards for trustworthy AI. This draft paper does not endorse a specific AI/ML approach, but rather provides an initial communication with stakeholders and encourages discussions early in the process. EMA also puts weights on the MAH's responsibility to ensure that all algorithms, models, datasets, and data processing pipelines used are fit for purpose and are in line with ethical, technical, scientific, and regulatory standards.

I think this topic will need to be considered in Japan in the future. This topic will be further discussed during a joint HMA/EMA workshop scheduled for November 2023. The feedback from stakeholders will be analysed and considered for the finalisation of the reflection paper and future development of guidance as relevant.

1) Draft reflection paper on the use of artificial intelligence (AI) in the lifecycle of medicines
https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-

intelligence-ai-medicinal-product-lifecycle_en.pdf

2) Related Website https://www.ema.europa.eu/en/news/reflection-paper-use-artificial-intelligence-lifecycle-medicines

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