PMDA Updates

November 2022

News

1. PMDA-ATC GCTP Inspection Training for NPRA, Malaysia

Two Good Manufacturing Practice (GMP)inspectors from the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia, visited Japan from September 14 to 16 to enhance their insight on Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP) Compliance Inspection and joined the inspection conducted by the PMDA. This training was conducted in cooperation with NIPRO CORPORATION to help them learn PMDA inspection methods on regenerative medicine manufacturers. To make the training fruitful, a preliminary briefing by the Office of Manufacturing Quality for Drugs was arranged prior to the inspection, and a conclusive session including lectures on related topics was held after the inspection to deepen their understanding of the GCTP inspection.

The PMDA continues to provide training opportunities and contributes to the capacity building of the NPRA to improve patient access to medical products in Asia.

2. PMDA-ATC First-in-Human Training for NPRA, Malaysia

From September 26 to 30, Dr. Zaril Harza Zakaria (Head, Investigational Product Evaluation and Safety Section) and Ms. Tang Sia Chin (Principal Assistant Director, Evaluation & Safety of Investigational New Product Section) from the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia, visited the PMDA and participated in the training programme regarding the conduct of First-in-Human clinical trials. Members from the relevant PMDA offices (Office of International Programs, Office of New Drug, and Office of Cellular and Tissue-based Products) participated in this training, shared their experiences, and discussed various topics with the participants. The Japan Pharmaceutical Manufacturers Association also cooperated in conducting this training, gave lectures, and arranged an on-site tour to the Ukima Plant of Chugai Pharma Manufacturing Co., Ltd. The PMDA continues to provide training opportunities and contributes to the capacity building of the NPRA.

With Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)

3. Thai FDA staff visited PMDA

On October 13, eight Thai FDA staff members in charge of pharmaceutical review and Good Manufacturing Practice (GMP) inspection visited the PMDA to learn about pharmaceutical regulatory systems in Japan and manufacturing and quality control systems at pharmaceutical manufacturing sites.

This visit was arranged as part of the Japan International Cooperation Agency (JICA) project "Capacity building on drug registration convergence."

The PMDA and Thai FDA have been strengthening their cooperative relationship for a long time through various activities including Thailand-Japan symposia, bilateral meetings, seminars provided by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC), and personnel exchanges.

The PMDA staff members from the Office of Review Management, Office of Cellular and Tissue-based Products, Office of Vaccines and Blood Products, Office of Generic Drugs, Office of Non-clinical and Clinical Compliance, Office of Manufacturing Quality for Drugs, and Office of International Programs shared PMDA's activities and engaged in discourse during the Q&A sessions.

Group photo of Thai FDA staff, JICA staff, and PMDA staff

4. PMDA-ATC Seminar on SARS-CoV-2 Vaccine Review for the Indonesian FDA, Indonesia

On October 24, the PMDA held the "PMDA-ATC Seminar on SARS-CoV-2 Vaccine Review for the Indonesian Food and Drug Authority (Indonesian FDA), Indonesia" in Jakarta, Indonesia. This seminar was resultant of cooperation between the Indonesian FDA and the Ministry of Health Labour and Welfare (MHLW)/PMDA, based on the Memorandum of Cooperation (MoC) between the Indonesian FDA and MHLW signed in August 2021.

The theme of the seminar was "Overview of the consideration of the SARS-CoV-2 vaccine approved in Japan." The PMDA shared its experience in SARS-CoV-2 vaccine review with approximately 80 Indonesian FDA regulators attending online and in person.

PMDA continues to provide training opportunities and contributes to the capacity building of the Indonesian FDA.

5. PMDA-ATC E-learning Updated Content Information

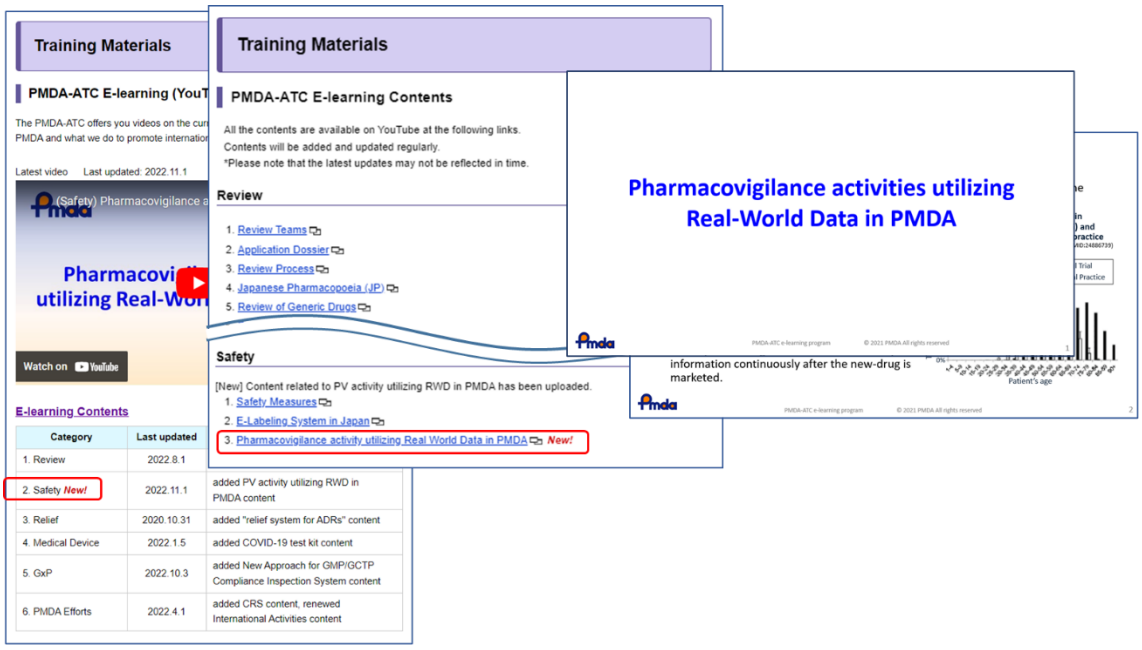
The PMDA-ATC E-learning system has been in operation since January 2020. This month, we are pleased to announce the release of a new content video, entitled "Pharmacovigilance activities utilizing Real-World Data in PMDA" in the "Safety" category.

Conventionally, pharmacovigilance activities have mainly relied on spontaneous adverse drug reaction reports and research reports, among others, in post-market settings. In addition to these data, more data have become available as electronic medical information data collection systems, such as MID-NET, sourcing from the network of partner hospitals and NDB, the national insurance claims database, have been solidified in the recent years in Japan.

The PMDA is conducting pharmacoepidemiological studies utilizing Real-World Data, realizing more accurate drug safety assessment, such as early risk detection, as well as promoting international cooperation in utilizing Real-World Data.

This content introduces PMDA's efforts to promote the utilization of Real-World Data in pharmacovigilance activities.

Please use this link to access the e-learning website:
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
Comirnaty Intramuscular Injection for 5 to 11 years olds [Special Approval for Emergency, Partial Change Approval]	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (active ingredient: tozinameran)	October 27, 2022
Volibris [Partial Change Approval]	ambrisentan	November 4, 2022

Medical Devices

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

Brand Name	Generic Name	Posting date
CureApp HT Digital Therapeutic App for Hypertension Adjunctive Treatment [Initial Approval]	Supporting software for hypertension treatment	October 11, 2022
nodoca [Initial Approval]	Endoscopic telescope Disease characteristic finding detection support software for endoscope	October 20, 2022

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (October 20, 2022)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty RTU intramuscular injection (Bivalent: Original/Omicron BA.1), Comirnaty RTU intramuscular injection (Bivalent: Original/Omicron BA.4-5), Spikevax Intramuscular Injection (Bivalent: Original/Omicron BA.1))
- Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection (Monovalent: Original))
- Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Spikevax Intramuscular Injection (Monovalent: Original))

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Pharmaceuticals and Medical Devices Safety Information No. 396 (November 9, 2022)

1. Summary of the Relief System for Adverse Drug Reactions and Request for Cooperation with the System
2. Revisions of Precautions for Pemafibrate
3. Important Safety Information
   (1) Methotrexate
4. Revision of Precautions (No. 336)
   Loxoprofen sodium hydrate (oral dosage form) (and 9 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0020.html

Pharmaceuticals Revisions of PRECAUTIONS (November 16, 2022)

- Hydrochlorothiazide
- Candesartan cilexetil/hydrochlorothiazide
- Valsartan/hydrochlorothiazide
- Losartan potassium/hydrochlorothiazide
- Roxadustat
- Imatinib mesilate
- Amoxicillin hydrate
- Potassium clavulanate/amoxicillin hydrate
- Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- Rabeprazole sodium/amoxicillin hydrate/clarithromycin
- Rabeprazole sodium/amoxicillin hydrate/metronidazole

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
December 6-8	PMDA-ATC Pharmaceuticals Review Webinar 2022	Virtual
December 8	ICH Fund Training Forum	Tokyo
December 8-11	14th DIA China Annual Meeting	Suzhou
January 16-19	9th Thailand - Japan Symposium	Bangkok
January 16-19	PMDA-ATC with National Cancer Center MRCT Webinar 2023	Virtual

Reports from Overseas

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

Quality of the data that support decision-making on the benefits and risks of medicines in the European Union

The joint Heads of Medicines Agencies (HMA)/EMA Big Data Steering Group began its work in May 2020. The group advises the EMA Management Board and HMA on prioritisation and planning of actions, to implement the ten priority recommendations [1)] in the Big Data Task Force final report. Recently, the joint Big Data Steering Group has endorsed two documents for public consultation.

The first one is related to the Data Quality Framework for medicine regulation [2)]. This public consultation will end on 18 November 2022. The main objective of the Data Quality Framework is to improve consistency in the evaluation of the quality of the data used by regulators, enable the development of a standardized approach for data quality across all data sources, and facilitate a more systematic use of data for regulatory decision-making. It also provides considerations on data quality, definitions for data dimensions and sub-dimensions, as well as their characterisation and related metrics.

EMA held a multi-stakeholder webinar [3)] to support public consultation on the Data Quality Framework for EU medicines regulation on 18 October 2022. The main objective of the webinar was to explain the draft Data Quality Framework and having Q&A session to collect feedback from the stakeholder.

The second one is related to the discoverability of real-world data. A draft good practice guide for use of the EU metadata catalogue of real-world data sources [4)] is open for public consultation until 16 November 2022. This is the first guide produced worldwide to focus on metadata to empower systematic integration of real-world evidence in medicines regulation. The guide provides recommendations on how to use the catalogue of real-world metadata that is currently being built and, in late 2023, will replace the existing catalogue of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The guide will help to identify suitable real-world data sources for studies and describes the metadata elements that will be used.

Medicines regulators will increasingly use insights derived from big data to assess the benefit-risk of medicines across their lifecycle in the future. This requires accurate and concise data, and to establish consistent and standardized criteria. I will continue to monitor this activity carefully.

1) Priority Recommendations of the HMA-EMA joint Big Data Task Force
https://www.ema.europa.eu/documents/other/priority-recommendations-hma-ema-joint-big-data-task-force_en.pdf
2) A draft of the Data Quality Framework for medicine regulation
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf
3) Webinar on the draft Data Quality Framework for EU medicines regulation
https://www.ema.europa.eu/en/events/webinar-draft-data-quality-framework-eu-medicines-regulation
4) A draft good practice guide for the use of the EU metadata catalogue of real-world data sources
https://www.ema.europa.eu/documents/regulatory-procedural-guideline/good-practice-guide-use-metadata-catalogue-real-world-data-sources_en.pdf

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