PMDA Updates

June 2023

News

1. ASEAN–Japan Risk Management Plan Symposium 2023

The ASEAN–Japan Risk Management Plan Symposium 2023 was held on May 24 in Jakarta, Indonesia. It was co-hosted by the Indonesian Food and Drug Authority (Indonesian FDA), the PMDA, and the University of Indonesia.

The symposium was supported by the Japan–ASEAN Integration Fund (JAIF) to deepen the knowledge of the Risk Management Plan (RMP) for regulators in ASEAN Member States (AMS). The target audience of the symposium comprised regulatory authorities, industry, and academia in AMS, and there were 271 people in the venue and 248 participants online, totaling 519 people that participated in the symposium.

The symposium began with opening remarks by H.E. KIYA Masahiko, Ambassador of the Mission of Japan to the ASEAN, Dr. Agustin Kusumayati, Secretary of the University of Indonesia, and Dra. Togi Junice Hutadjulu, the Acting Deputy Chairperson of the Indonesian FDA. Following the opening remarks, Dr. UZU Shinobu, Senior Executive Director of the PMDA, and representatives from the Japan Pharmaceutical Manufacturers Association (JPMA); the Indonesian FDA; the Office of Pharmacovigilance II, PMDA; and the Japanese Society of Hospital Pharmacists delivered lectures on the RMP and engaged in a question and answer (Q&A) session. A panel discussion was held at the end of the symposium, thus providing an opportunity to deepen the understanding regarding the RMP.

In closing the symposium, Prof. Arry Yanuar, Dean of Faculty of Pharmacy of the University of Indonesia, delivered the closing remarks.

The details of symposium are available at the following link:
https://aseanrmp.ui.ac.id

Guests, speakers, and secretariats

2. ASEAN–Japan Risk Management Plan Seminar 2023

The ASEAN–Japan Risk Management Plan Seminar 2023 was held on May 25 and 26, in Jakarta, Indonesia, and was co-hosted by the Indonesian Food and Drug Authority (Indonesian FDA), the PMDA, and the University of Indonesia.

The target audience of the seminar comprised the regulators of the ASEAN Member States (AMS). Thirty-nine participants attended the seminar. This seminar was also supported by the JAIF as was the ASEAN–Japan Risk Management Plan Symposium 2023.

At the seminar, a PMDA staff from the Office of Pharmacovigilance I delivered a lecture on how to evaluate the Risk Management Plan (RMP), and a representative of the Japan Pharmaceutical Manufacturers Association (JPMA) provided group work guidance. After these lectures, group work on RMP development was conducted. The participants actively exchanged opinions and deepened their understanding of pharmaceutical risk management. At the end of the seminar, Dr. UZU, Senior Executive Director of the PMDA, awarded a certificate of participation to the participants.

The details of the seminar are available at the following link:
https://aseanrmp.ui.ac.id

Seminar participants and facilitators

3. IMDRF Domestic Debriefing Meeting (Japan 2023, Virtual)

The 2023 International Medical Device Regulators Forum (IMDRF) Domestic Debriefing Meeting in Japan was held on May 25. This debriefing meeting was co-hosted by the Ministry of Health, Labour and Welfare (MHLW), the PMDA, the Japan Federation of Medical Devices Associations (JFMDA), and the Japan Medical Imaging and Radiological Systems Industries Association (JIRA). It aimed to share the information on latest IMDRF activities with domestic industries, academia that has seeds of innovation, and the public who are interested in medical devices. This meeting is the second of its kind since the initial meeting of 2021.

The participants included Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. KUSAKABE Tetsuya (International Coordination Officer), 13 other staff members from the PMDA, Ms. YAMOTO Fumi (Councilor for Pharmaceutical Affairs, Minister's Secretariat), and a staff member from the MHLW.

After Dr. FUJIWARA, Ms. YAMAMOTO, and Mr. YAMAMOTO Akio (Vice Chairman, JFMDA, and Chairman, JIRA) gave the opening remarks, Dr. KUSAKABE and the MHLW staff member, who were the Japanese management committee members of the IMDRF, presented the overview of the IMDRF. Following the presentations, staff members from the PMDA who belongto the IMDRF working groups (WGs) presented the newly published documents about Artificial Intelligence Medical Devices, Medical Device Cybersecurity, Post Market Safety Measures, Good Regulatory Review Practices and Collaboration with Other Standards Groups, and Personalized Medical Devices and their implementation to domestic regulation. In addition, a staff member from the PMDA, who is the Chairman of the Medical Device Single Audit Program, gave a presentation about the single audit program in connection to the quality management system (QMS) requirements in multiple countries. Moreover, other PMDA staff members that belong to WGs gave presentations on the WG activities and what was to come about Software as a Medical Device, Regulated Product Submission, Process Validation, and Controls of Products and Services Obtained from Suppliers on QMS. The Q&A sessions were conducted based on the questions taken from the participants before the event. As an industrial perspective, the JFMDA and JIRA presented their recent activities relating to the IMDRF.

Approximately 560 people participated in the meeting online, showing the high interest in international regulatory convergence activities of medical devices from the stakeholders. It confirmed the importance of sharing recent activities with the public through the debriefing meeting.

The presentation materials are on the following PMDA website:
https://www.pmda.go.jp/int-activities/symposia/0135.html

4. Call for Application to PMDA-ATC Pharmaceuticals Review Webinar 2023

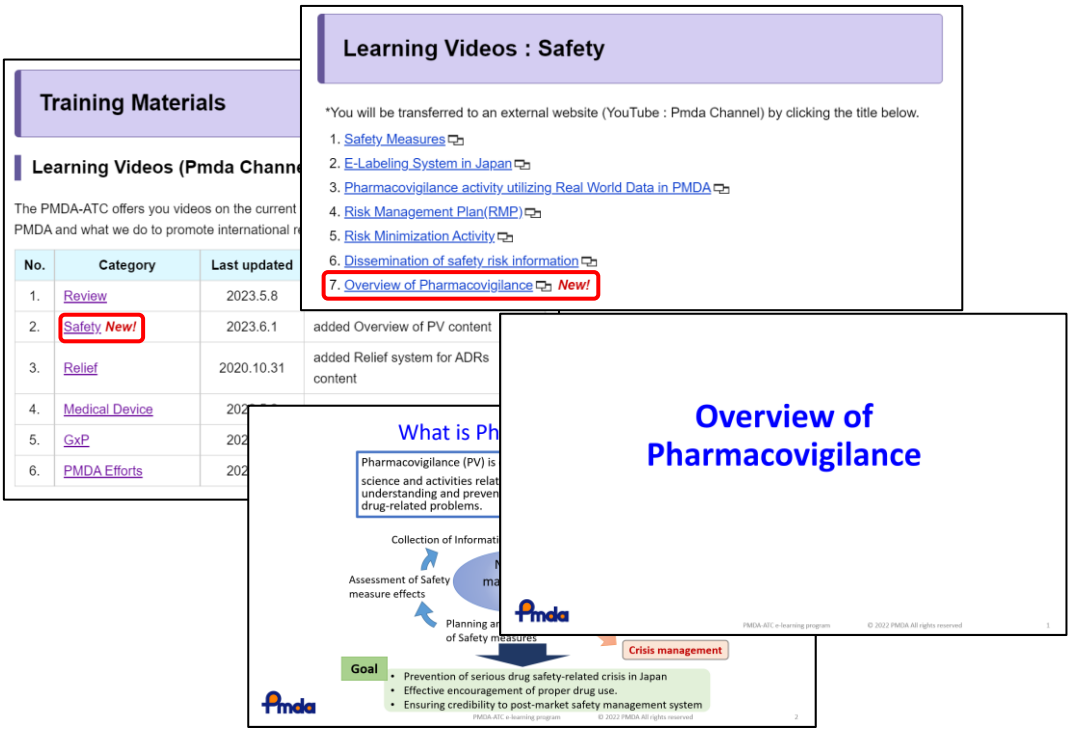
The PMDA-ATC is pleased to inform you of the "Pharmaceuticals Review Webinar 2023" to be held from September 26 to 28 through a web conference system. This webinar is designed for pharmaceuticals reviewers from overseas regulatory authorities. The objective of the webinar is to provide the participants with opportunities to acquire knowledge and perspectives on the review process for new drugs, biosimilars, and generic drugs, and consequently apply them to enhance the regulatory system in the participant's own organization.

Please refer to the following website for the details of PMDA-ATC Pharmaceuticals Review Webinar 2023.
https://www.pmda.go.jp/english/symposia/0270.html

5. 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 "Overview of Pharmacovigilance" in the "Safety" category of the Learning Videos.

The main goal of pharmacovigilance is to minimize the risks related to drugs use and maximize their benefits. This video introduces the basic concept of pharmacovigilance and the system 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
Thaled [Partial Change Approval]	Thalidomide	May 17, 2023
Vyvgart [Initial Approval]	efgartigimod alfa (genetical recombination)	May 26, 2023
Dysval [Initial Approval]	valbenazine tosilate	June 5, 2023

Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
Carvykti [Initial Approval]	ciltacabtagene autoleucel	May 25, 2023
Kymriah [Partial Change Approval]	tisagenlecleucel	June 6, 2023

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 401 (May 30, 2023)

1. Revision of Precautions for Drugs Inhibiting the Renin-angiotensin System
2. The Survey Results on the Status of Acquisition, Communication, and Use of Drug Safety Information at Hospitals and Pharmacies and Desirable Directions
3. Important Safety Information
    1. ・Angiotensin-converting enzyme inhibitors ([1] Alacepril and 9 others)
       ・Preparations containing angiotensin II receptor blocker([1] Azilsartan and 19 others)
       ・Direct renin inhibitor ([1] Aliskiren fumarate)
    2. ・Angiotensin receptor-neprilysin inhibitor
       ([1] Sacubitril valsartan sodium hydrate)
    3. Mesalazine
    4. Zinc acetate hydrate
4. Revision of Precautions (No. 341)
   [1] Azilsartan (and 30 others) and 7 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/0021.html

Pharmaceuticals Revisions of PRECAUTIONS (May 30, 2023)

- *Haemophilus influenzae* type b conjugate vaccine (tetanus toxoid conjugate)

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

Pharmaceuticals Revisions of PRECAUTIONS (June 13, 2023)

- Ipilimumab (genetical recombination)
- Nivolumab (genetical recombination)

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
July 10–13	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023	Tokyo
August 22–24	PMDA-ATC Quality Control (Herbal Medicine) Seminar 2023	Toyama

Reports from Overseas

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

Digital health initiative

On 5th June 2023, the European Commission and the World Health Organization (WHO) have announced the launch of a landmark digital partnership [1]. This is the first building block of the WHO Global Digital Health Certification Network (GDHCN) that will develop a wide range of digital products to deliver better health for all. This initiative is based on the "EU Global Health Strategy [2]" and "WHO Global Strategy on Digital Health [3]" which follows the December 2022 agreement and it will enhance strategic cooperation on global health issues. This also robust a multilateral system with WHO at its core, powered by a strong EU.

This partnership will include close collaboration in the development, management and implementation of the WHO system, benefitting from the European Commission's ample technical expertise in the field. A first step is to ensure that current EU digital certificates continue to function effectively. In June 2023, WHO will take up the European Union system of digital COVID-19 certification to establish a global system that will help facilitate global mobility and protect citizens across the world from on-going and future threats.

These are also lessons learned from the pandemic, and I believe that the establishment of such a system will ensure that citizens are quickly protected in the event of future health emergencies.

1) Press release: Commission and who launch landmark digital health initiative to strengthen global health security https://ec.europa.eu/commission/presscorner/detail/en/ip_23_3043
2) EU Global Health Strategy https://health.ec.europa.eu/system/files/2023-03/international_ghs-report-2022_en.pdf
3) WHO Global Strategy on Digital Health https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf

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