PMDA Updates

November 2021

News

1. PMDA-ATC Pharmacovigilance Webinar for NPRA, Malaysia

On October 4, the PMDA held the "PMDA-ATC Pharmacovigilance Webinar for the National Pharmaceutical Regulatory Agency (NPRA), Malaysia."

The theme of the webinar was pharmacovigilance. The PMDA shared information on the Japanese regulatory system and PMDA's experiences with 41 NPRA regulators engaging in pharmacovigilance and related areas.

The PMDA continues to conduct seminars and strengthen collaboration with NPRA.

2. The 9th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 14, the 9th Joint Conference of Taiwan and Japan on Medical Products Regulation was held, hosted by the Taiwan-Japan Relations Association and the Japan-Taiwan Exchange Association. Considering the global pandemic of COVID-19, this conference was conducted virtually, similar to last year's conference. It was attended by more than 800 people from regulatory agencies and industries, among others, from Taiwan and Japan. Japanese participants included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), and nine staff members from PMDA, as well as Mr. YASUDA Naoyuki (Director, Office of International Regulatory Affairs), and three officers from the Ministry of Health, Labour and Welfare (MHLW). Taiwanese participants included Dr. Shou-Mei Wu (Director-General) with 45 staff members from the Taiwan Food and Drug Administration (TFDA) as well as Dr. Ming-Hsun Liu (Executive Director) with eight staff members from the Center for Drug Evaluation (CDE).

In this conference, PMDA's Mr. UZU and TFDA's Dr. Wu provided briefings on the latest regulations in Japan and Taiwan, including the cooperative activities between Japan and Taiwan. The topics for the pharmaceutical session included an overview of the regulatory actions against COVID-19, orphan drug regulations, and recent drug pricing system, and the topics for the medical devices session included the latest regulations for medical devices. The questions for these sessions, collected beforehand, were answered by each session speaker, which furthered the mutual understanding. The next conference is scheduled to be held in Japan in 2022.

Materials including the program of the 9th Joint Conference of Taiwan and Japan on Medical Products Regulation are available on the website shown below:

https://www.pmda.go.jp/int-activities/symposia/0105.html

Group photo of partcipants. Each venue was connected online.

3. Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) Meeting

The Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) web conference was held on October 26, 2021. Key participants from Japan included Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), Mr. KOGA Daisuke (Division Director, Asia 2nd Division, PMDA), and a staff member of the Ministry of Health, Labour and Welfare (MHLW).

The APEC-LSIF-RHSC aims to promote a strategic framework for regulatory convergence of medical products regulation, and is co-chaired by Dr. NAKASHIMA, along with Dr. Michelle Limoli from the US FDA. Regulatory authorities of APEC economies, representatives from industry coalitions (pharmaceuticals, biopharmaceuticals, and medical devices), and academia participated in the meeting. APEC-LSIF-RHSC has established Centers of Excellence (CoEs) focusing on seven Priority Work Areas (PWAs) to offer workshops for regulatory capacity building to regulators and relevant personnel. PMDA is endorsed as the CoE on MRCT/GCP Inspection PWA, Pharmacovigilance PWA, and Medical Device PWA.

At the meeting, the PMDA reported that PMDA-ATC webinars, as CoE workshops on Medical Device PWA, MRCT/GCP Inspection PWA, and Pharmacovigilance PWA, will be held in November 2021, and January and February 2022, respectively.

Further, it was reported by a co-chair that CoEs whose Memorandum of Understanding (MoU) with LSIF will expire in 2022, including PMDA, were subject to CoE assessment to renew the MoU.

4. IMDRF Domestic Debriefing Meeting in Japan 2021 (Virtual)

The International Medical Device Regulators Forum (IMDRF) Domestic Debriefing Meeting in Japan 2021 was held on November 2. Participants included Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. TANISHIRO Hiroyuki (International Coordination Officer), 10 other staff members from the PMDA, Ms. YAMAMOTO Fumi (Councilor for Pharmaceutical Affairs, Minister's Secretariat), and a staff member from the Ministry of Health, Labour and Welfare (MHLW).

This debriefing meeting was hosted by MHLW, 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 latest IMDRF activities for domestic industries, academia that has innovation seeds, and the public who are interested in medical devices.

After Dr. FUJIWARA and Ms. YAMAMOTO gave the opening remarks, Dr. TANISHIRO and the MHLW staff member, who are the Japanese management committee (MC) members of IMDRF, presented the current and future IMDRF activities, including an overview and strategic plan for IMDRF. Following the presentation, PMDA staff members presented the recent activities of eight working groups (WGs) including Good Regulatory Review Practices, Artificial Intelligence Medical Devices (AIMD), Personalized Medical Devices, Medical Device Cybersecurity Guide, Medical Device Clinical Evaluation, Principles of In Vitro Diagnostic (IVD) Medical Devices Classification, Adverse Event Terminology, and Regulated Product Submission. As an industrial perspective, JFMDA and JIRA presented their recent activities relating to IMDRF, and Mr. YAMAMOTO Akio (Vice Chairman, JFMDA and Chairman, JIRA) gave the closing remarks as a representative of the industrial groups.

Approximately 500 people participated in the meeting, showing the high interest in international regulatory convergence activities of medical devices from the stakeholders. Although this domestic debriefing meeting was the first attempt, it confirmed the importance of sharing recent activities with the public through the meeting. The presentation materials are on the following PMDA website:

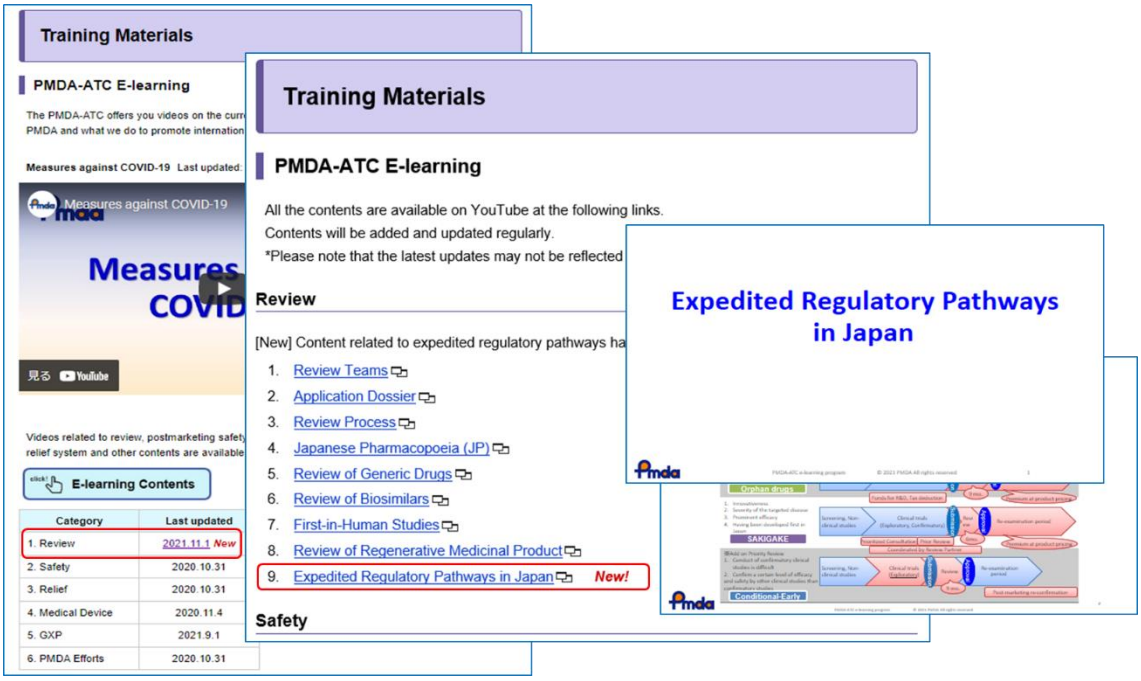
https://www.pmda.go.jp/int-activities/symposia/0107.html

From the left, Ms. YAMAMOTO Fumi (MHLW), Dr. FUJIWARA Yasuhiro (Chief Exective, PMDA), and Mr. YAMAMOTO Akio (Vice chairman, JFMDA and Chairman, JIRA)

5. PMDA-ATC E-learning Updated Content Information

The PMDA has been providing PMDA-ATC E-learning system since January 2020. This month, we are pleased to announce the release of content entitled "Expedited Regulatory Pathways in Japan." This content introduces the expedited pathways, namely, priority review, orphan drugs, SAKIGAKE, and conditional-early pathway.

The e-learning website can be accessed through the following link:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



English Translations of Review Reports

The following link provides the latest information on the English version 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
Ronapreve [Special Approval for Emergency]	casirivimab (genetical recombination) and imdevimab (genetical recombination)	October 13, 2021
COVID-19 Vaccine Moderna [Special Approval for Emergency]	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2)	October 14, 2021

English Translations of Notifications and Administrative Notices

The following link provides the latest information on the English versions of the Notifications and Administrative Notices newly published on the PMDA website:

https://www.pmda.go.jp/english/review-services/regulatory-info/0003.html

Issue Date	Document Type & No.	Title	Posting Date
Sep 14, 2021	PSEHB/PED Administrative Notice	English Translations of Guidelines for Bioequivalence Studies of Generic Products	Oct 21, 2021

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 387 (November 9, 2021)

1. Summary of the Relief System for Adverse Drug Reactions and Request for Cooperation with the System
2. Acute coronary syndrome accompanying allergic reaction (Kounis Syndrome)
3. Important Safety Information
   (1) Cefoperazone sodium/sulbactam sodium
4. Revision of Precautions (No. 327)
   Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection) (and 5 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/0019.html

Pharmaceuticals Revisions of PRECAUTIONS (November 16, 2021)

- Atezolizumab (genetical recombination)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Events

Conferences/Meetings that the PMDA will host or participate in

Date	Title	Location
December 1-2	ICMRA Summit	Virtual
December 6-8	PMDA-ATC Pharmaceuticals Review Webinar 2021	Virtual
December 14	ICH Fund Training Quality Forum	Virtual
January 18-21	PMDA-ATC with National Cancer Center MRCT Webinar 2022	Virtual

Reports from Overseas

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

EU strategy on COVID-19 therapeutics

As EMA news in November has highlighted many progress on COIVD-19 therapeutics, this issue introduces the EU's measures around COVID-19 therapeutics.

In May 2021, the European Commission (EC) has proposed the Strategy on COVID-19 therapeutics [1)] to support the development and availability of COVID-19 therapeutics. The strategy is modelled on the successful EU Vaccines Strategy [2)] and the "end to end" approach to support research, development, manufacturing and deployment of therapeutics. For example, the EC has hosted two matchingmaking events to enhance the connection between organisations and companies and help in production planning.

On 22nd October, based on the strategy the EC has established portfolio of 10 most promising treatments for COVID-19 in order to guide the work [3)]. Of these, in November one monoclonal antibody combination therapy has been authorized; one monoclonal antibody has been submitted for the marketing authorisation; two oral

antivirals has come under review to support national decision-making on the possible use of these medicines before a formal authorisation is issued, under Article 5(3) of Regulation 726/2004 [4], subsequently EMA has issued the advice on the use of one product later in the month. It should be noted that the selection of the 10 candidates is independent from and does not replace the scientific assessment by the EMA or the authorisation of the medicines by the EC. A selected product may not be authorised, if the available scientific evidence does not meet the regulatory requirements [3]. Indeed, the EMA has ended the rolling review for the product initially identified as a promising candidate therapeutic.

The COVID-19 pandemic is still raging in many regions including EU. I expect these COIVD-19 therapeutics as well as COIVD-19 vaccines will contribute to help solve the current situation.

1) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0355R(01)&from=EN
2) https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en
3) https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5366
4) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-article-53-reviews

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