



# PMDA Updates

November, 2020

## News

### 1. The 8th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 15, the 8th Joint Conference of Taiwan and Japan on Medical Products Regulation was held, hosted by the Japan-Taiwan Exchange Association and the Taiwan-Japan Relations Association. Considering the global pandemic of COVID-19, this conference was conducted virtually this year. It was attended by more than 480 people from regulatory agencies and industries in Taiwan and Japan. Japanese participants included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), and 11 staff members from PMDA as well as Mr. YASUDA Naoyuki (Director, Office of International Regulatory Affairs) and 2 officers from the Ministry of Health, Labour and Welfare (MHLW). Taiwanese participants attended 56 people including Dr. Hwei-Fang Cheng (Deputy Director-General) from the Taiwan Food and Drug Administration (TFDA) as well as Dr. Ming-Hsun Liu (Executive Director) from the Center for Drug Evaluation (CDE).

In this conference, briefings on the latest regulations in Japan and Taiwan were provided by PMDA's Mr. UZU and TFDA's Dr. Cheng, and the cooperative activities between Japan and Taiwan were introduced. The topics for the pharmaceutical session include overview of the regulatory measures against COVID-19, and health insurance and drug pricing system, and the topics for the medical devices session include the latest regulations for medical devices and the utilization situation of signed MOC (Memorandum of Cooperation) on QMS. The questions for those sessions collected beforehand were answered by session speakers, which led more mutual understanding. The next conference is scheduled to be held in Taiwan in 2021.

Materials including the program of the 8th Joint Conference of Taiwan and Japan on Medical Products Regulation are available at the website shown below.

<https://www.pmda.go.jp/int-activities/symposia/oogo.html>



Group photo of participants. Each venue was connected online.

### 2. PMDA-ATC Japanese Pharmacopoeia Webinar 2020 for Thai FDA

On October 20, PMDA held a seminar entitled "PMDA-ATC Japanese Pharmacopoeia Webinar 2020 for Thai FDA". A total of 20 regulators of Thai Food and Drug Administration (Thai FDA) who are engaged in the review of chemistry, manufacturing and control of pharmaceuticals or pharmacopoeia participated in the webinar.

The webinar opened with remarks by Dr. SATO Junko (Director of Office of International Programs from

PMDA) and by Dr. Suchart Chongprasert (Director of Medicines Regulation Division from Thai FDA). The program of the webinar included lectures and Q&A sessions on the topic of Outline of Japanese Pharmacopoeia (JP), General Methods, Impurity Control and Utilization of the JP. The lecturers were PMDA staff and representatives from "Pharmaceutical and Medical Device Regulatory Science Society of Japan" and "Japan Pharmaceutical Manufacturers Association".

After all the lecture sessions, a round discussion based on questions relevant to the topics of the lectures was held and enhanced understanding.

Please refer to the following web site for the details of PMDA-ATC Japanese Pharmacopoeia Webinar 2020 for Thai FDA.

<https://www.pmda.go.jp/english/symposia/o182.html>



On the top row: Opening ceremony

Picture on the top left: Dr. Suchart Chongprasert (Director of Medicines Regulation Division from Thai FDA)

Picture on the top right: Dr. SATO Junko (Office Director, Office of International Programs from PMDA, left) and Mr Ehara Teruyoshi (International Coordination Officer from PMDA, right)

On the bottom row: Round table discussion

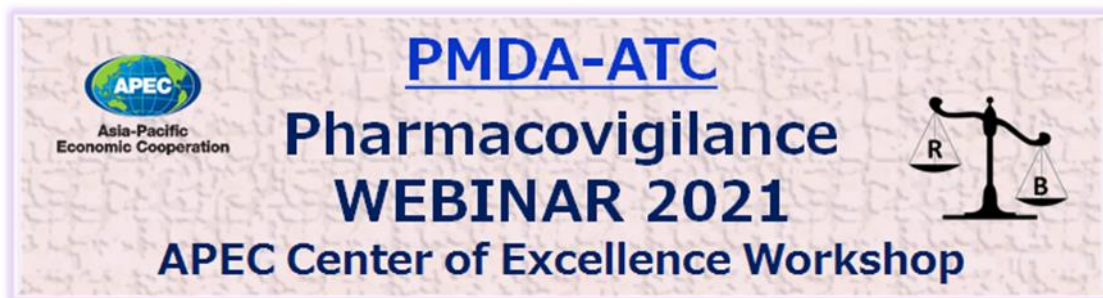
Picture on the bottom left: Lecturers from PMDA

Picture on the bottom center and right pictures: Thai FDA and Department of Medical Sciences(DMSC) participants

### 3. Web conference on Utilization of Real World Data with DKMA

On October 27, 2020, the web conference with the regulatory authority of Denmark, DKMA, was held, which featured DKMA and PMDA's activities on utilization of Real Word Data (RWD). From DKMA, staff of Data Analytics Center, Division of Medical Evaluation & Biostatistics, etc. attended and they presented the activities of the Center. From PMDA, the consideration of RWD and analysis cases were presented by experts of Office of Informatics and Epidemiology. The vigorous discussion including staff of Office of Pharmacovigilance I and II was held after presentations from both sides and constructive opinions for future collaboration were exchanged.

### 4. Call for application to PMDA-ATC Pharmacovigilance Webinar 2021 starts



PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the “PMDA-ATC Pharmacovigilance 2021”, from February 1 to 4, 2021 through web conference system. This webinar is designed for overseas regulatory authority officials who are engaged in pharmacovigilance activities. Participants will be required to join in the live sessions for Q&A and case studies after viewing contents including pre-recorded lectures as self-study, using the e-learning system and acquaint themselves with the topics of the overview of the pharmacovigilance, risk management plan, safety specification, pharmacovigilance plan, pharmacoepidemiology, benefit-risk analysis, labeling, and risk communication. Through the webinar, participants will learn the importance of harmonized regulatory strategy in ICH guideline and regulatory updates to ensure compliance with new pharmacovigilance, risk management, and adverse event reporting, etc.

The webinar is held as a workshop of the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) Center of Excellence (CoE) workshop, however, the webinar is open to non-APEC economies as well.

Please refer to the following website for the details of PMDA-ATC Pharmacovigilance Webinar 2021.

<https://www.pmda.go.jp/english/symposia/o187.html>

### 5. PMDA-ATC e-learning Contents information updated

PMDA has been providing with the PMDA-ATC e-learning system since January 2020. In this system, we are pleased to announce that the new contents on Medical Devices are released and the existing contents are revised in November. E-learning website can be accessed at the following link.

<https://pmda-atclearning.jp/portals>

Contents Category	Last Updated
1. Philosophy	2020.10.31.
2. Organization	2020.10.31.
3. Review	2020.10.31.
4. Safety Measures	2020.10.31.
5. Relief	2020.10.31.
6. International Activities	2020.10.31.
7. Medical Devices	2020.11.04. <b>New</b>

## 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
Tafinlar [Partial Change Approval]	dabrafenib mesilate	October 27
Mekinist [Partial Change Approval]	trametinib dimethyl sulfoxide	October 27



Velexbru [Initial Approval]	tirabrutinib hydrochloride	October 30
Viltepso [Initial Approval]	viltolarsen	November 12

## Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
ZOLGENSMA [Initial Approval]	onasemnogene abeparvovec	October 20
Nepic [Initial Approval]	human (autologous) corneal limbus-derived corneal epithelial cell sheet	November 13

## English Translations of Notifications and Administrative Notices

The following are English version of Notifications and Administrative Notices newly published on PMDA website.

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

Issue Date	Document Type & No.	Title	Posting date
Nov. 17, 2017	PSEHB/MDED Notification No.1117-1 PSEHB/SD Notification No.1117-1	Handling on the Scope of Situations where “Documents related to Clinical Study Results” is Necessary on Medical Devices (Operations based on Measures through Pre- and Post- Marketing Phases	October 20, 2020
Nov. 17, 2017	PSEHB/MDED Administrative Notice	Release of Clinical Trial Guidance to Facilitate the Speedy and Accurate Approval and Development of Medical Devices	October 20, 2020

## Safety Information

### Pharmaceuticals and Medical Devices Safety Information No. 377 (November 4, 2020)

- Summary of the Relief System for Adverse Drug Reactions and Request for Cooperation with the System
- Revision of Dosing Intervals between Different Vaccines
- Important Safety Information
  - Vonoprazan fumarate
- Revision of Precautions (No. 317)
  - Vonoprazan fumarate (and 3 others)
- List of Products Subject to Early Post-marketing Phase Vigilance

<https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0018.html>

### Pharmaceuticals Revisions of PRECAUTIONS (November 5, 2020)

- Glatiramer acetate
- Nivolumab (genetical recombination)

<https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0008.html>

### PMDA Medical Safety Information No.23 Revised version (November)

Precautions in Handling of Insulin Vial Preparations (Ensuring the Use of Insulin Syringes)

<https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html>

## Events

### Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
December 1-2	The 2nd Vietnam-Japan Symposium • PMDA-ATC Pharmaceuticals Review Webinar 2020 for Drug Administration of Vietnam	Virtual
December 15-17	PMDA-ATC Pharmaceuticals Review Webinar 2020	Virtual
January 13-14	8th Thailand – Japan Symposium	Virtual
January 18-21	PMDA-ATC with National Cancer Center MRCT Webinar 2021	Virtual

## Reports from Overseas

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

### The dawning of a new era

Emer Cooke arrived as the fourth Executive Director of EMA on 16th November 2020<sup>1)</sup>. Ms. Cooke has a wide variety of experience in pharmaceutical sector and many stakeholders in Japan may know her well through these activities including the ones of EMA between 2002 and 2016 and WHO between 2016 and 2020.

The response to the COVID-19 pandemic has been regarded as number one priority. In addition, the six areas (Availability and accessibility of medicines, Data analytics, digital tools and digital transformation, Innovation, Antimicrobial resistance and other emerging health threats, Supply-chain challenges, Sustainability of the network and operational excellence) have been introduced as challenges and opportunities at the EMA 25th anniversary meeting on 22nd October 2020 where she spoke in public for the first time as EMA Executive Director Designate<sup>2)</sup>. These areas are also in line with the priority areas identified by the draft European medicines agencies network strategy to 2025<sup>3)</sup>.

In the same period of time, the extension of the mandate of EMA has been proposed by European Commission as one of the recommendations to ensure stronger preparedness and response during the current and future health crises<sup>4)</sup>. To facilitate a coordinated response at the EU level during crisis, the EMA's mandate will be reinforced by granting authority to monitor and mitigate shortages of both medicinal products and medical devices during public health crisis, legislating the current activities of COVID-19 EMA pandemic Task Force<sup>5)</sup> and so on.

In the process of maintaining the strategic plan and further evolving, I, as MHLW/PMDA liaison official, would like to contribute to facilitate the continuing collaboration between EMA and MHLW/PMDA.

- 1) <https://www.ema.europa.eu/en/news/emer-cooke-takes-office-head-ema>
- 2) <https://www.ema.europa.eu/en/events/25-years-ema-building-learning-adapting-new-challenges>
- 3) <https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/european-medicines-agencies-network-strategy>
- 4) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0724&qid=1605690513438>
- 5) [https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-covid-19-ema-pandemic-task-force-covid-etf\\_en.pdf](https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-covid-19-ema-pandemic-task-force-covid-etf_en.pdf)

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