PMDA Updates

September 2023

News

1. PMDA-ATC Pharmaceuticals Review Seminar for JICA trainees 2023

From July 20 to 21 and 24 to 26, the PMDA held a five-day seminar entitled "PMDA-ATC Pharmaceuticals Review Seminar for JICA trainees 2023" in collaboration with the Japan International Cooperation Agency (JICA). Six people from six countries (Bangladesh, Brazil, Egypt, Indonesia, Laos, and Timor-Leste) participated in the seminar. On the first and second days, the trainees visited the Exhibition Room for Remembrance of History of Drug-induced Suffering in the PMDA Tokyo office and were given an overview of the PMDA, approval review in Japan, safety measures, and GCP/GLP inspections. From the third day, they moved to Toyama Prefecture, where the PMDA Hokuriku branch was located, learned about pharmaceutical administration in local governments and GMP management, and went around site tours. The site tour included visits to manufacturing facilities in cooperation with Teika Pharmaceutical Co., Ltd. and TOA Pharmaceuticals Co., Ltd., as well as visits to the Toyama Prefectural Institute for Pharmaceutical Research and Medicinal Plants Center in cooperation with the Toyama Prefectural Government.

The trainees attended the lectures and site tours with great enthusiasm. The PMDA is very pleased to have been able to provide such a good opportunity to trainees.

2. PMDA-ATC Regenerative Medical Products FIH Webinar 2023 for NPRA, Malaysia

On July 26, the PMDA held the "PMDA-ATC Regenerative Medical Products FIH Webinar 2023 for NPRA, Malaysia".

The theme of the webinar was first-in-human (FIH) studies of regenerative medical products. The PMDA staff members from the Office of Cellular and Tissue-based Products shared information on the Japanese regulatory system and PMDA's experiences with 23 National Pharmaceutical Regulatory Agency (NPRA) regulators engaging in the review of biologics, and so on.

The PMDA continues to provide training opportunities and contributes to the capacity building of the NPRA.

3. Call for Application to the APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023" from November 14 to 16 through a web conference system. This webinar is designed for reviewers of medical devices and in vitro diagnostics (IVDs) from overseas regulatory authorities. The objective of the webinar is to provide participants with opportunities to further enhance the regulatory systems in their respective countries and regions by learning the basics of regulations and review and approval processes in Japan, such as quality management

systems (QMS), clinical evaluations, and post-market safety measures, based on the international harmonization of medical device regulations described in the International Medical Device Regulators Forum (IMDRF) documents.

This webinar is offered as a workshop for the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC), APEC Center of Excellence (CoE). However, the webinar is also open to non-APEC economies.

Please refer to the following website for details on the APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023.

https://www.pmda.go.jp/english/symposia/0276.html

4. Call for Application to the PMDA-ATC Medical Devices Seminar 2023

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC Medical Devices Seminar 2023" as inviting overseas regulators to the PMDA Office from December 5 to 7. This seminar is designed for reviewers of medical devices and in vitro diagnostics (IVDs). The objective of the seminar is to provide the participants with opportunities to further enhance the regulatory systems in their respective countries and regions by learning the regulations of IVDs and IVD medical devices, expedited review pathways in Japan as well as review of high-risk medical devices and software as a medical device (SaMD), which are based on the international harmonization of the medical device regulations described in the IMDRF documents.

Please refer to the following website for details on the PMDA-ATC Medical Devices Seminar 2023.

https://www.pmda.go.jp/english/symposia/0275.html

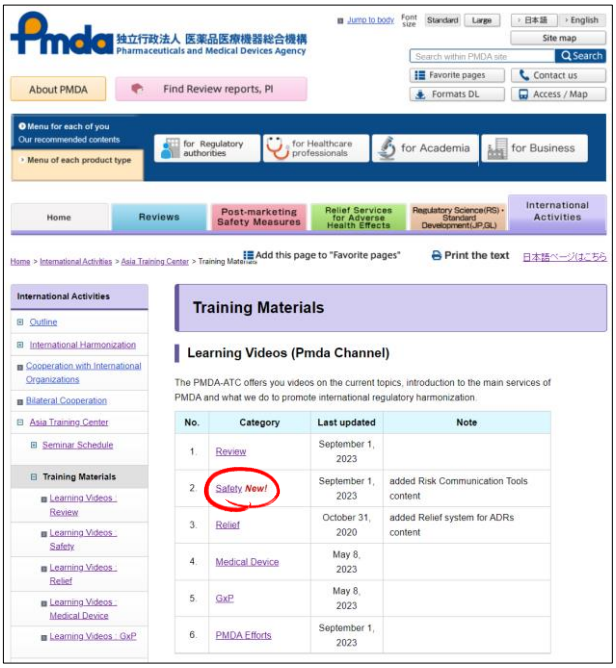
5. PMDA-ATC: Release of new Learning Video Content

The PMDA-ATC provides online learning videos that provide an overview of pharmaceuticals and medical device regulations in Japan and PMDA's services. This month, we are pleased to announce the release of a new content video, entitled "Risk Communication Tools" in the "Safety" category of the PMDA-ATC Learning Videos.

To promote the proper use of medical products, sharing risk information among stakeholders is important. This video introduces the risk communication tools implemented in Japan.

Please follow this link to access the PMDA-ATC 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
Darvias [Initial Approval]	Darinaparsin	August 28, 2023
Kerendia [Initial Approval]	Finerenone	September 5, 2023
Pivlaz [Initial Approval]	Clazosentan sodium	September 5, 2023

Medical Devices

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

Brand Name	Term Name	Posting date
C² Coronary IVL Catheter [Initial Approval]	Atherectomy ablative angioplasty catheter	August 15, 2023
IVL Generator [Initial Approval]	Driving unit for atherectomy angioplasty catheter	August 15, 2023

Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
Vyznova [Initial Approval]	Neltependocel	August 14, 2023

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 403 (August 23, 2023)

1. Safety Measures Against the Risks of Contamination with Nitrosamines in Drugs
2. Important Safety Information
    1. [1] Atorvastatin calcium hydrate, [2] Simvastatin, [3] Pitavastatin calcium hydrate, [4] Pravastatin sodium, [5] Fluvastatin sodium, [6] Rosuvastatin calcium, [7] Amlodipine besilate/atorvastatin calcium hydrate, [8] Ezetimibe/atorvastatin calcium hydrate, [9] Ezetimibe/rosuvastatin calcium, [10] Pitavastatin calcium hydrate/ezetimibe
3. Revision of Precautions (No. 343)
   [1] Atorvastatin calcium hydrate (and 9 others), and 3 others
4. 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 (August 29, 2023)

- Rivastigmine
- Finasteride
- Dabigatran etexilate methanesulfonate
- Peficitinib hydrobromide
- Cefazolin sodium
- Cefazolin sodium hydrate

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
October 5–6	The 11th Joint Conference of Taiwan and Japan on Medical Products Regulation	Taipei
October 28–November 1	ICH meeting	Prague
November 1–2	IPRP meeting	Prague
November 13–16	ICMRA Summit	Melbourne
November 14–16	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023 (Note)	Virtual
November 27–30	GHWP annual meeting	Shanghai

(Note) APEC RHSC CoE Workshop

Reports from Overseas

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

Article about EMA's response to the COVID-19 Pandemic

On 10 August 2023, EMA has published an article titled "EMA's response to the COVID-19 pandemic – putting people's health first." [1)] This article was written by Mr. Noël Wathion. He was a former Deputy Executive Director of EMA from 2016 to 2021 and this is a personal account of EMA's handling of the COVID-19 health crisis. The period covered in this article is from the onset of the pandemic in March 2020 up to early May 2023 when the World Health Organization (WHO) declared the end of COVID-19 as a Public Health Emergency of International Concern.

This article focuses on various aspects of EMA's response to the pandemic, such as level of preparedness to deal with public-health-crisis situations before the start of the pandemic, actions taken during the course of the pandemic to address changing circumstances/unforeseen developments and additional demands requiring EMA to go beyond its formal legal remit. The article also elaborates on steps undertaken for the development support, authorization and supervision of COVID-19 vaccines and treatments as well as transparency and communication measures and finishes with some lessons and subsequent actions already taken.

In this article, it emphasizes the importance of transparency and communication. It says, "to enhanced transparency and targeted, timely and well-balanced communication, engagement with the general public has proven to be another crucial aspect. This required listening to the needs, expectations and any concerns not yet vaccinated persons may have, and providing the necessary assurances." "Making as much as possible use of social media to make EMA´s voice heard was also an important element in ensuring that EMA´s messages could gain traction." Also, it highlights the Preparing for the next health crisis, it says "Monitoring and mitigating shortages of critical medicines and management of major events." "The main new role for EMA consists of monitoring of outbreaks and epidemics that could become serious threats and developing countermeasures; providing scientific advice for medicines with the potential to address future emergencies; maintaining an overview of medicines in development for future emergencies; coordinating activities with other EU institutions such as Directorate-General for Health Emergency Preparedness and Response Authority(DG HERA) and European Center for Disease Prevention and Control(ECDC), as well as with WHO." In conclusion, it states that "EMA will need to get better at explaining how it implements post-marketing tools to manage uncertainty and inform the benefit risk assessment in a public health emergency."

Moreover, in this article, it also discussed the difficulties which EMA faced due to the Brexit in particular with respect to the anticipated loss of in-house staff as well as the loss of the expertise provided by the regulatory authority of the UK which was occurred just before the pandemic.

I am sure that each country has learned many things from this pandemic and is preparing for the future, but once again I felt that the EMA places great importance on transparency from this article.

1) Article: EMA's response to the COVID-19 pandemic – putting people's health first
https://www.ema.europa.eu/en/documents/other/emas-response-covid-19-pandemic-putting-peoples-health-first_en.pdf

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