PMDA Updates

September 2021

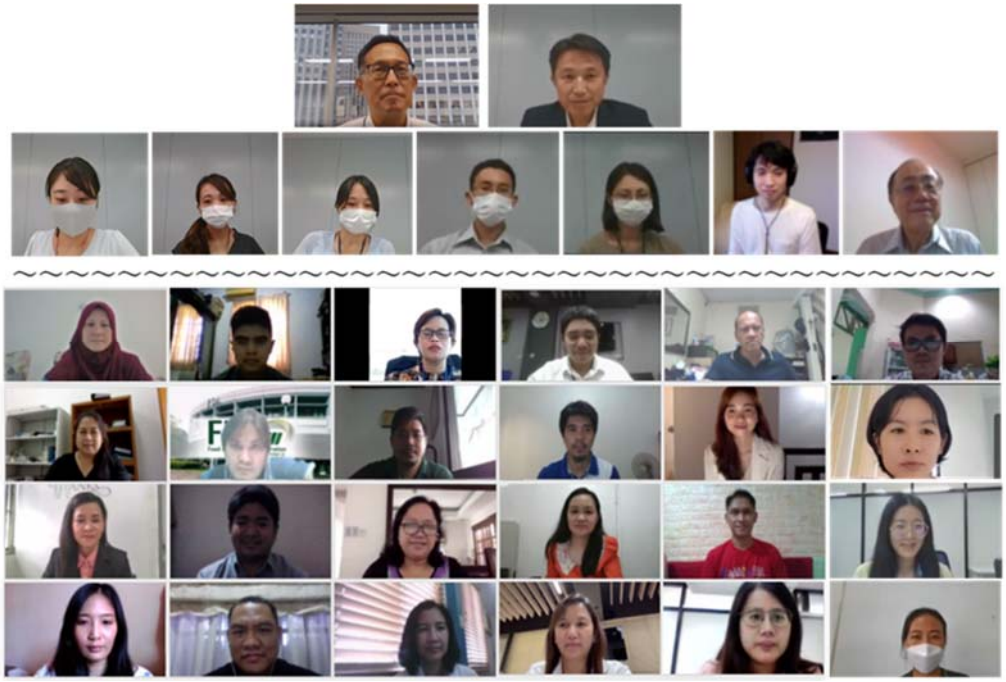
News

1. PMDA-ATC/AMDC Medical Devices Webinar 2021

On August 25 to 26, the PMDA, in collaboration with the ASEAN Medical Device Committee (AMDC), held the "PMDA-ATC/AMDC Medical Devices Webinar 2021" aimed at providing an opportunity for medical device regulators in the ASEAN Member States to deepen their knowledge of the medical devices regulatory system by sharing experiences between ASEAN Member States and Japan. A total of 100 regulators who engaged in review and post-market safety measures for medical devices participated in the webinar.

The webinar was opened with remarks from Dr. FUJIWARA Yasuhiro, the Chief Executive of PMDA. Subsequently, the PMDA staff shared information on the regulatory framework and PMDA's experiences in medical device review and post-market safety measures based on international standards and documents by the Global Harmonization Task Force (GHTF) / International Medical Device Regulators Forum (IMDRF).

At the end of the webinar, Mr. UZU Shinobu, the Director of the Asia Training Centre for Pharmaceuticals and Medical Devices Regulatory Affairs of the PMDA, gave the closing remarks.



Top row, from left：Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA)
Second row：Lecturers
Third and subsequent rows：Some of the participants in the webinar

2. Indonesian Food and Drug Authority and Ministry of Health, Labour and Welfare Signed a Memorandum of Cooperation on Medical Products

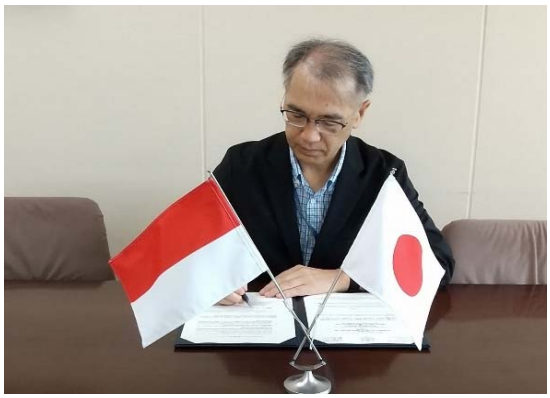
On August 27, 2021, the Indonesian Food and Drug Authority (Indonesian FDA) and the Ministry of Health, Labour and Welfare (MHLW) of Japan signed a "Memorandum of Cooperation between the Ministry of Health, Labour and Welfare of Japan and the Indonesian Food and Drug Authority of the Republic of Indonesia on Medical Products Regulation Dialogue and Cooperation Framework."

Due to the impact of COVID-19, the signing ceremony was not held face-to-face, but each side signed the memorandum.

Areas of cooperation in the memorandum included "The exchange of information and cooperation in the areas of medical products and relevant administrative and regulatory matters"; "The cooperation in pharmaceutical products, biological products, and traditional medicines"; "The cooperation in scientific collaboration, personnel training, and multilateral fora."

The MHLW/PMDA and the Indonesian FDA have established cooperative relationships through joint symposiums and other meetings. The conclusion of the memorandum is expected to further strengthen this relationship among regulatory authorities in both Japan and Indonesia.

The MHLW and the PMDA continuously promote collaboration with the Indonesian FDA for the international regulatory convergence and make efforts to strengthen the relationship between the two countries.



(State of signature) Left: Mr. KAMATA Mitsuaki, Director General of the Pharmaceutical Safety and Environmental Health Bureau, MHLW
Right: Dr. Penny K. Lukito, MCP Chairperson, Indonesian FDA

The MHLW's press release is available at the following link:
https://www.mhlw.go.jp/stf/houdou/0000202344_00002.html (in Japanese)

3. PMDA-ATC Reprocessed Single-Use Medical Devices (R-SUD) Webinar 2021 for MDA

On September 1, the PMDA held the "PMDA-ATC Reprocessed Single-Use Medical Devices (R-SUD) Webinar 2021 for Medical Device Authority (MDA), Ministry of Health Malaysia".

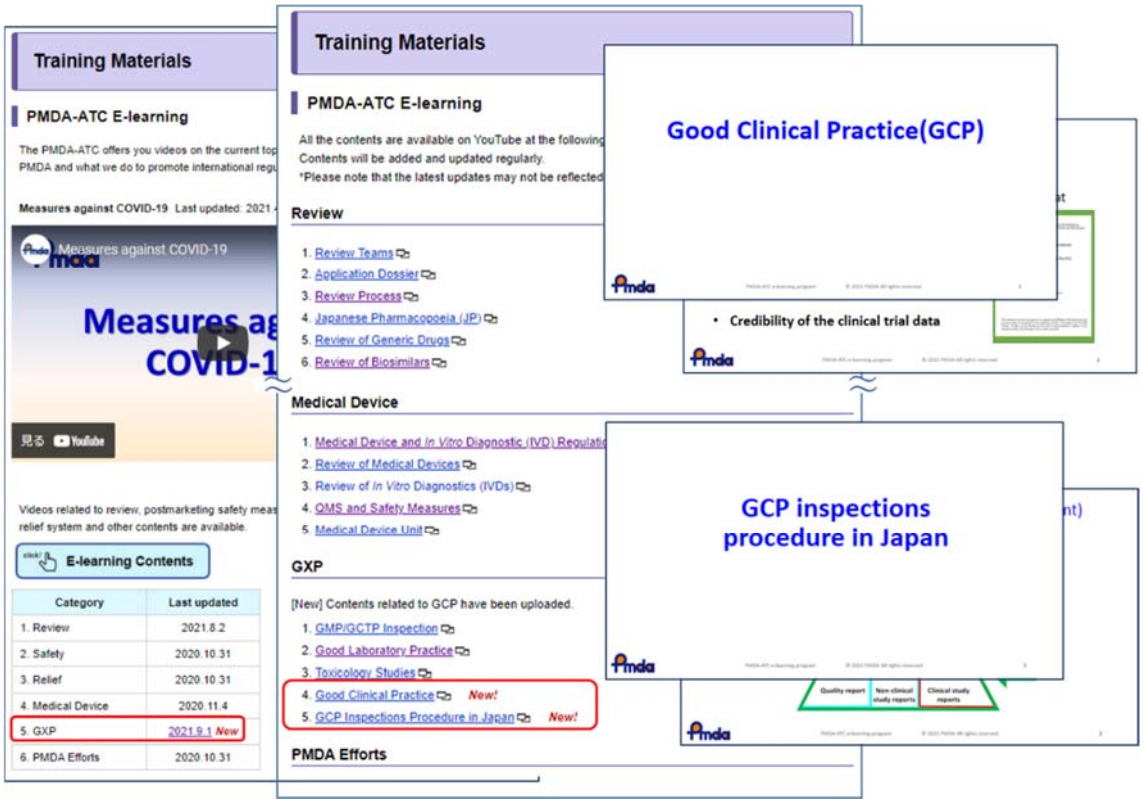
The theme of the webinar was R-SUD. The PMDA shared the Japanese regulatory system and PMDA's experience with 32 MDA regulators who engage in the review of medical devices, etc.

The PMDA continuously contributes to capacity building by training MDA staff in the PMDA-ATC for Pharmaceuticals and Medical Devices Regulatory Affairs.

4. PMDA-ATC E-learning Updated Content Information

The PMDA has been providing the PMDA-ATC E-learning system since January 2020. This month, we are pleased to announce the release of the two contents under the "GXP" category, entitled "Good Clinical Practice (GCP)" and "GCP inspections procedure in Japan". These contents introduce the concept of GCP based on ICH documents and the procedures of document-based and on-site inspection of GCP. 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 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
Izcargo [Initial Approval]	pabinafusp alfa (genetical recombination)	August 17
Vaxzevria [Special Approval for Emergency]	COVID-19 (SARS-CoV-2) Vaccine (recombinant chimpanzee adenovirus vector)	August 18
Delytact [Initial Approval]	Teserpaturev	September 7
Olumiant [Partial Change Approval]	Baricitinib	September 8

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 385 (August 20, 2021)

1. Revision of Proper Control Procedures for Revlimid/Pomalyst (RevMate)
2. Important Safety Information
   1. [1] Magnesium sulfate hydrate/glucose
      [2] Magnesium sulfate hydrate
3. Revision of Precautions (No. 325)
   Nivolumab (genetical recombination) (and 9 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/0019.html

Pharmaceuticals Revisions of PRECAUTIONS (September 7, 2021)

- Istradefylline
- Lomitapide mesilate

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

Events

Conferences/Meetings the PMDA will host or participate in:

Date	Title	Location
October 14-15	The 9th Joint Conference of Taiwan and Japan on Medical Products Regulation–	Virtual
November 9, 15-18	ICH meeting	Virtual
November 11	Japan-China Medical and Health Forum 2021	Virtual
November 15-19	PMDA-ATC Medical Devices Webinar 2021	Virtual
November 19, 22	IPRP meeting	Virtual
November 25-26	PMDA-ATC GMP Inspection Webinar 2021	Virtual

Reports from Overseas

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

Launch of European Health Emergency preparedness and Response Authority (HERA)

Based on the early lessons from the current pandemic, the discussions on measures to better prepare for future public health emergencies have been undertaken in various regions such as EU and Japan. This issue highlights the most important recent development in EU.

On 16th September, the European Commission (EC) launched the European Health Emergency preparedness and Response Authority (HERA) to prevent, detect and rapidly respond to health emergencies [1]. The EC has also proposed a council regulation to develop the framework for HERA activities [2].The COVID-19 pandemic revealed gaps in foresight, including demand/supply dimensions, preparedness and response tools, and therefore HERA is expected to be a central element for strengthening the European Health Union [3] with better EU preparedness and response to serious cross-border health threats [4]. Of several documents published on 16th September, the factsheet [5] and Q&A [6] are worth reading to get an overview of the new authority. HERA will be set up as an internal Commission structure and not a new 'agency' and will be fully operational in early 2022. Its functioning will be reviewed and adapted on an annual basis until 2025, when a full review will be carried out.

The EC set out the roadmap for establishing HERA January 2021, followed by public consultation as a normal process [4]. For those who are interested in the process of how the EC makes laws and policies, please also see the EC website [7].

As HERA will work closely with other EU agencies such as EMA and the European Centre for Disease Prevention and Control (ECDC) to complement each other, and also with international partners, a lot of people in Japan will be interested in the future activities of HERA.

1) https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4672
2) https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/hera_2021_propcouncreg_medical-countermeasures_en.pdf
3) https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en
4) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-_en
5) https://ec.europa.eu/commission/presscorner/detail/en/fs_21_4734
6) https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_4733
7) https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law_en#how-their-scope-is-defined

Dr. KISHIOKA Yasuhiro
PMDA's International Liaison Officer stationed at EMA in the Netherlands

