PMDA Updates

May 2022

News

1. PMDA-ATC COVID-19 related Medical Products Webinar 2022 for DAV

The PMDA held a COVID-19 related Medical Products Webinar for the Drug Administration of Vietnam (DAV) on March 30, 2022. This webinar was designed for DAV reviewers of pharmaceutical products and included 11 participants.

In the webinar, a PMDA staff member, engaged in international programs, gave a lecture on the COVID-19 related medical products review and risk assessment of the SARS-CoV-2 vaccine. A Q&A session was held to enhance the understanding of the topic, including risk assessment methods.

Another webinar is planned with the aim to strengthen the partnership with DAV.

2. The 4th Asian Network Meeting and Bilateral Meeting with Asian Countries

The Ministry of Health, Labour, and Welfare (MHLW) and PMDA held the annual Asian Network Meeting on April 6, 2022. The fourth meeting was held virtually this year and the participants included the MHLW, PMDA, and top-level representatives of regulatory agencies from host countries, including China, India, and Singapore, and other Asian member countries, such as Indonesia, Korea, Malaysia, the Philippines, and Thailand. The participants agreed to facilitate cooperation on actions against the COVID-19 pandemic, build a pharmaceutical ecosystem in the Asian region from a high-level perspective and decided to hold another meeting next year.

In conjunction with the Asian Network Meeting, the MHLW and PMDA held bilateral meetings on April 4 and 7, with most participating countries. Opportunities for future collaborations to improve medical care in Asian countries were discussed in these bilateral meetings.

3. Asian Clinical Trials Network for Cancers Project (ATLAS) International Symposium

The ATLAS International Symposium was held on April 24, 2022, co-hosted by the National Cancer Center Central Hospital, Thai Society of Clinical Oncology, Clinical Research Malaysia, and PMDA and supported by the Embassy of Japan in Thailand.

Dr. FUJIWARA Yasuhiro, Chief Executive of PMDA, made a presentation and facilitated the discussion with representatives from the Indonesian FDA, Thai FDA, NPRA, and Malaysia regarding regulations on clinical trials in their countries and expectations for Asian clinical trials.

Top left: FUJIWARA Yasuhiro (Chief Executive, PMDA), Right: Mrs. Siti Asfijah Abdoellah (Indonesian FDA)
Bottom left: Dr. Suchart Chongprasert (Thai FDA), Right: Dr. Zaril Harza Zakaria (NPRA, Malaysia)

4. Call for Applications: PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) is pleased to announce a web conference on the "Quality Control (Herbal Medicine) Webinar 2022" to be held from August 23 to 25, 2022. This webinar is designed exclusively for officials from overseas regulatory authorities with the objective to provide opportunities to share the knowledge and experiences of approval review, quality control, and manufacturing control of crude drugs and herbal medicine through online lectures, case studies, and group discussions on the review process of OTC herbal medicine products. All participants of the webinar should take the PMDA-ATC Quality Control (Herbal Medicine) E-learning course prior to attending the live sessions.

Please refer to the following weblinks for the entry details:

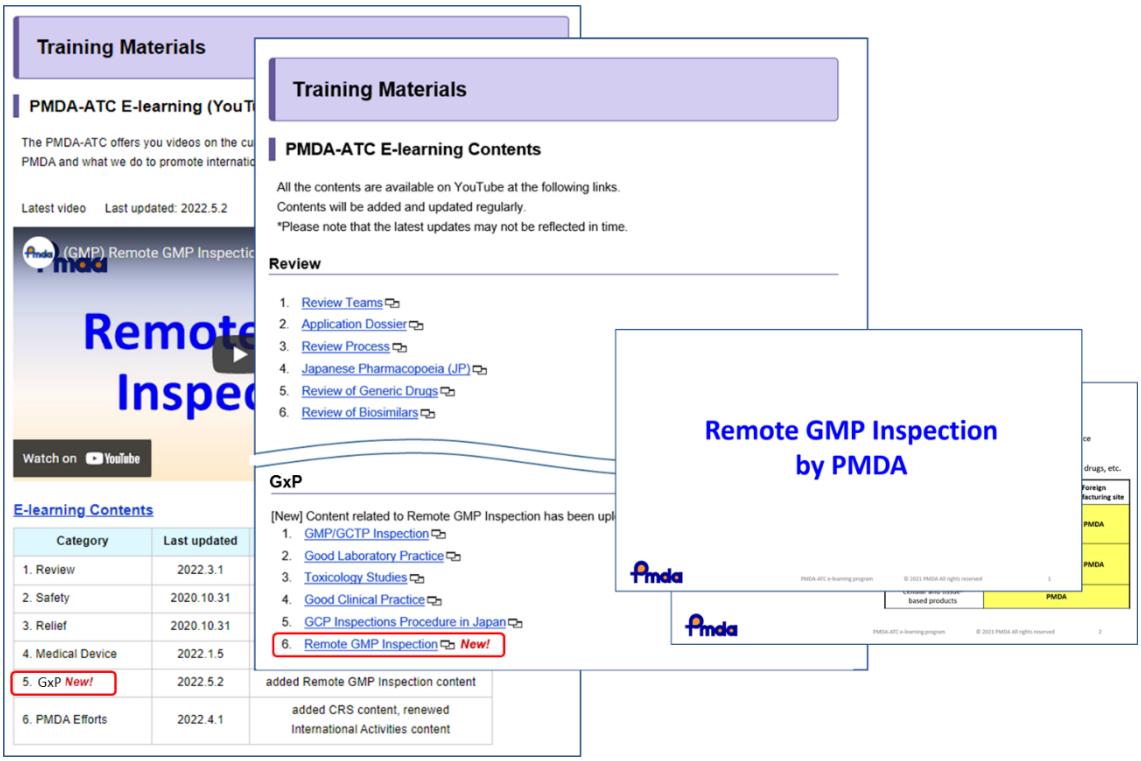
1. PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022: https://www.pmda.go.jp/english/symposia/0235.html
2. PMDA-ATC e-learning course: https://www.pmda.go.jp/english/int-activities/training-center/0006.html

5. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning system has been operational since January 2020. This month, we are pleased to announce the release of a new video entitled, "Remote GMP Inspection."

This video introduces the GMP (Good Manufacturing Practice) inspection system in Japan, including on-site inspection and desktop inspection, and the points to consider for the remote GMP inspection during the COVID-19 pandemic with implementation examples.

Please follow this link to access the e-learning website:
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
Lenvima [Partial Change Approval]	lenvatinib mesilate	April 19, 2022
Paxlovid PACK [Special Approval for Emergency]	nirmatrelvir and ritonavir	May 9, 2022

Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
Ocural [Initial Approval]	human (autologous) oral mucosa-derived epithelial cell sheet	May 9, 2022

English Translations of Notifications and Administrative Notices

The following link provides the latest information on the English versions of the latest notifications and administrative notices published on the PMDA website:

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

Issue Date	Document Type and Number	Title	Posting date
December 10, 2021	PSEHB/PED Administrative Notice	Amendment to the "Basic Principles on Global Clinical Trials (Reference Cases)"	April 20, 2022
October 27, 2014	PFSB/ELD Administrative Notice	Basic Principles for Conducting Phase I Trials in the Japanese Population Prior to Global Clinical Trials	April 25, 2022

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (April 26, 2022)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection)
- Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2)(Spikevax Intrammuscular Injection (former brand name: COVID-19 Vaccine Moderna Intramuscular Injection))

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Pharmaceuticals Revisions of PRECAUTIONS (May 13, 2022)

- Dexamethasone (oral dosage form) (preparations indicated for pituitary suppression tests)
- Dexamethasone (oral dosage form) (preparations not indicated for pituitary suppression tests)
- Dexamethasone palmitate
- Dexamethasone sodium phosphate (injections)
- Betamethasone (oral dosage form)
- Betamethasone (suppositories)
- Betamethasone acetate/betamethasone sodium phosphate
- Betamethasone sodium phosphate (enemas)
- Betamethasone/d-chlorpheniramine maleate
- Betamethasone sodium phosphate (injections)
- Teicoplanin

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Events

Conferences/Meetings that the PMDA will host or participate in

Date	Title	Location
June 19-23, 2022	58th DIA 2022 Global Annual Meeting	Chicago
July 13-15 and 19, 2022	PMDA-ATC Pharmaceuticals Review Webinar 2022 for Japan International Cooperation Agency trainees	Virtual

Reports from Overseas

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

Impact of Pandemic: Meeting and Digitalization

Approximately one month has passed since I came to EMA and I started attending several EMA meetings. In the Netherlands, the restrictions on COVID-19 have been lifted and it is no longer necessary to wear a mask or show proof of vaccination in shops and restaurants. In EMA, the wearing of masks in common areas is mandatory. Many people have resumed work in their offices; however, in order to avoid the concentration of people in the same office, the system has been placed to indicate the days that people are working from the office in order to avoid congestion.

EMA has begun to hold hybrid (in-person and web-based) meetings, whereas large meetings were previously held only virtually. First of all, the Pharmacovigilance Risk Assessment Committee (PRAC) held its meeting from May 2 to 5 in a hybrid format. The number of people who can participate face-to-face in the meeting is still limited by the size of the meeting room. We still have a long way to go before we can hold a full face-to-face meeting, but we have begun to explore the possibility of applying it to the with-COVID-19/post-COVID-19 era. The COVID-19 pandemic has revealed the importance of digital services in the health area. The European Commission launched the European Health Data Space (EHDS) [1)], one of the central building blocks of a European Health Union, on 3 May 2022. People will have immediate access to the own health data in electronic form, free of charge. Patient summaries, ePrescriptions, images and image reports, laboratory results, discharge reports summaries will be issued in a common European format, allowing them to be easily shared with other healthcare professionals in member states. Citizens will be in full control of their data. However, interoperability and security will be essential requirements. Besides, the EHDS are creating a strong legal framework for the use of health data for research, innovation, policy-making, and regulatory purposes. This is expected to improve and promote drug development, health care systems, etc. by allowing researchers, public institutions and industries that meet strict requirements to access these health data. These proposals will now be discussed in the European Council and the European Parliament.

1) Article website: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711

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