PMDA Updates

December 2023

News

1. Announcement by the NPRA to Include PMDA as a Reference Authority for Abbreviated Review Pathway

The National Pharmaceutical Regulatory Agency (NPRA), Malaysia, announced that the PMDA would become a new reference authority according to the G*uideline for Facilitated Registration Pathway (FRP), Revision 1, 2023*, issued on November 16, 2023. This will take effect from the beginning of 2024. Accordingly, the review period for a drug (new drug products, generic medicines and biologics including cell and gene therapy products) registration with the NPRA within three years from the date of approval in Japan will be shortened from the 245 working days set for standard review procedures of new drugs to 90 working days if the product meets the eligibility criteria and documentary requirements, including a review report from the PMDA. This abbreviated review pathway will allow for an earlier launch of pharmaceuticals in Malaysia. Moreover, it would enhance access to medicines approved in Japan and is expected to contribute toward improving the quality of healthcare in Malaysia.

The Ministry of Health, Labour and Welfare (MHLW) and the PMDA continue to promote closer collaboration with regulatory agencies in Asia in international regulatory convergence activities, such as bilateral meetings and training seminars by the PMDA-Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs.

The MHLW's press release is available at the following link:

https://www.mhlw.go.jp/stf/newpage_36799.html (in Japanese)

2. ICH Meeting in Prague

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met from October 28 to November 1 in Prague, Czech Republic. Mr. YASUDA Naoyuki (Associate Executive Director for International Programs, PMDA), Working Group experts, and Mr. KOGA Daisuke (Office Director, Office of International Regulatory Affairs from the Ministry of Health, Labour and Welfare (MHLW)) attended these meetings with other officers from the MHLW and PMDA.

The main outcome of the meeting was the further expansion of ICH membership. The ICH Assembly welcomed the Pharmacy and Poisons Board of Hong Kong (PPBHK), China, as a new observer, bringing the ICH membership to 21 members and 37 observers.

At this meeting, Q2(R2) reached Step 4 (Adoption of an ICH Harmonised Guideline) of the guidelines on "Validation of Analytical Procedures," Q5A(R2) reached Step 4 of the guidelines on "Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin," and Q14 reached Step 4 of the guidelines on "Analytical Procedure Development."

In addition, Mr. YASUDA was reelected as the Management Committee (MC) Vice-Chair, following the end of the terms of the Chair and Vice-Chair of the Assembly and the MC in November this year. Mr. YASUDA is expected to serve a two-

year term commencing after this meeting.

Moreover, the ICH Assembly approved the ICH Association's budget for 2024 and a 10% decrease in the 2024 Medical Dictionary for Regulatory Activities (MedDRA) subscription fees.

Additionally, the ICH Award was awarded to six Working Group experts. The awardees from Japan are Dr. HIROSE Akihiko (formerly of the National Institute of Health Science, now the Chemicals Evaluation and Research Institute, Japan) and Mr. HISADA Shigeru (Japan Pharmaceutical Manufacturers Association). This award is for Working Group experts who have made outstanding contributions to ICH Harmonisation for Better Health and ICH leadership roles in ICH Working Groups.

The next ICH meeting is scheduled for June 1 to 5, 2024, in Fukuoka, Japan.

3. ICMRA Summit Meeting in Melbourne

The International Coalition of Medicines Regulatory Authorities (ICMRA) Summit meeting was held in Melbourne, Australia, from November 14 to 15, 2023. From the PMDA, Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. YASUDA Naoyuki (Associate Executive Director for International Programs), and two other staff members participated in the meeting. In addition, from the Ministry of Health, Labour and Welfare (MHLW), Mr. KOGA Daisuke (Office Director, Office of International Regulatory Affairs), and a staff member participated in the meeting.

On the first day, three topics, namely, “Artificial Intelligence and Machine Learning,” “Evolution of Clinical Trials,” and “Advanced Medical Products,” were discussed by agency-level heads. Dr. FUJIWARA co-chaired the session on “Advanced Medical Products,” delivered a presentation on Japan's experience with review and regulation, and participated in a panel discussion.

On the second day, international regulators discussed regular ICMRA work streams, such as the Innovation Project and Pharmaceutical Quality Knowledge Management System (PQKMS), and communicated about future ICMRA work. Japan presented recent updates on the Innovation Project as co-lead and explained the analysis of ICMRA website which is maintained and hosted by the PMDA.

Moreover, the ICMRA celebrated its 10th anniversary this year. At this meeting, past achievements of the ICMRA were outlined, and expectations for the future were expressed by participants.

The next ICMRA Summit meeting will be held in the autumn of 2024.

Photo from “Summit Session”
On the far right: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)

From left: Dr. FUJIWARA Yasuhiro (ICMRA co-vice chair), Ms. Emer Cooke, Executive Director of the European Medicines Agency (ICMRA Chair)

4. PMDA-ATC: Release of New Learning Video Content

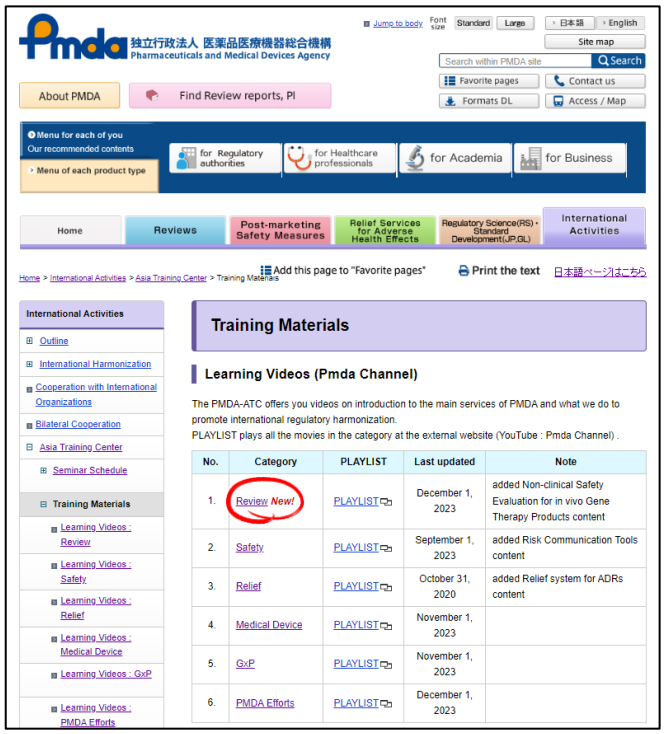
The PMDA-ATC provides online learning videos that offer an overview of pharmaceutical and medical device regulations

in Japan and PMDA's services. This month, we are pleased to announce the release of a new content video entitled "Non-clinical Safety Evaluation for in vivo Gene Therapy Products" in the "Review" category of the PMDA-ATC Learning Videos.

As a form of innovative medicine, the development of gene therapy products is actively pursued worldwide. To protect subject (patient) safety, non-clinical safety should be carefully evaluated before starting clinical trials. This video shows points of non-clinical safety evaluation for gene therapy products.

Please follow this link to access the learning video content:

https://www.pmda.go.jp/english/int-activities/training-center/0003.html



Announcements

【Warning】Please Be Aware of Phishing E-mails Pretending to be from the PMDA

The PMDA warns that we have confirmed cases of e-mails pretending to be from the PMDA staff that try to gather information from recipients.

https://www.pmda.go.jp/english/about-pmda/0017.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
Cablivi [Initial Approval]	Caplacizumab (genetical recombination)	November 22, 2023

Rituxan [Partial Change Approval]	Rituximab (genetical recombination)	December 1, 2023

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (November 21, 2023)

- Metyrapone
- Apixaban
- Edoxaban tosilate hydrate
- Dabigatran etexilate methanesulfonate
- Rivaroxaban
- Warfarin potassium
- Technetium (^{99m}Tc) galactosyl human serum albumin diethylenetriamine pentaacetic acid

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0011.html

Pharmaceuticals Revisions of PRECAUTIONS (November 24, 2023)

- Nivolumab (genetical recombination)

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
January 16–17	10th Thailand - Japan Symposium	Bangkok
January 23–26	PMDA-ATC with National Cancer Center MRCT Seminar 2024	Tokyo (PMDA)
February 6–7	PMDA-ATC GMP Inspection Webinar 2024	Virtual
February 26–29	PMDA-ATC Pharmacovigilance Webinar 2024	Virtual

Reports from Overseas

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

OPEN framework

As I wrote in the July issue, I would like to write about the OPEN (Opening Procedures at EMA to Non-EU authorities) framework again. OPEN framework was established by EMA in December 2020 as a framework to increase international collaboration and share scientific expertise on the evaluation. OPEN started as a pilot during the COVID-19 pandemic and was targeted only for Covid-19 related therapeutics and vaccines. The OPEN pilot report was published on July 2022[1)].

After the pilot, EMA has extended the scope of OPEN in July[2)3)] 2023 based on a review of the pilot's first year, to cover medicines intended to help combat Antimicrobial resistance (AMR), respiratory syncytial virus (RSV) infections or newly diagnosed myelodysplastic syndromes (and other hereditary diseases), designated under the PRIME (priority

medicines scheme; exclude Advanced Therapy Medicinal Products), products that address a high unmet medical need, and products intended to address Public health threats and public health emergencies. Regulators from Australia, Brazil, Canada, Switzerland, the World Health Organization and Japan can participate under the terms of existing confidentiality arrangements with EMA. OPEN allows to conduct near-concurrent reviews of certain new medicines and exchange their views and reports on the product assessments. This can help accelerate and align regulator decisions in several regions in the world leading to fewer questions for industry and more alignment on product labeling, while maintaining regulators' independence in their decision making.

Under this OPEN framework, the cooperation of the applicant (industry) is essential because drug applications must be submitted almost simultaneously. Further cooperation between regulators and industry is needed to ensure the rapid delivery of new drugs to patients.

1) OPEN Pilot: One-year review and recommendations https://www.ema.europa.eu/en/documents/report/open-pilot-one-year-review-recommendations_en.pdf
2) OPEN initiative https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/opening-procedures-ema-non-eu-authorities-open-initiative#scope-and-development-of-open-section
3) OPEN framework extended to a wider range of medicines https://www.ema.europa.eu/en/news/open-framework-extended-wider-range-medicines

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