PMDA Updates

April 2022

News

1. ICH Management Committee Interim Virtual Meeting

Due to the COVID-19 pandemic, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) held interim virtual meetings on March 15, 16, and 18, 2022 in lieu of the in-person meetings scheduled in Brussels, Belgium. Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA) and Mr. YASUDA Naoyuki (Office Director, Office of International Regulatory Affairs, MHLW) attended this meeting with other officers from the MHLW and PMDA.

The purpose of this meeting is to efficiently implement the process of adopting new topic proposals by the ICH Assembly which will be held in Athens, Greece in May this year. We also discussed some issues regarding the format of Athens meetings, efficiency of ICH operations, and training projects. Active discussion was held for each issue and contributed significantly to the efficiency of discussion in the ICH Assembly/Management Committee in May 2022, and it was a very meaningful meeting.

The next ICH meeting is planned to be held on May 21–25, 2022, in Athens, in a hybrid style combining in-person and virtual.

2. 34th DIA Europe Meeting

The 34th DIA Europe Meeting was held in Brussels, Belgium from March 29 to 31, 2022 in a hybrid style. From the PMDA, Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. TAMIYA Kenichi (Associate Executive Director for New Drug Evaluation), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), the Ministry of Health, Labour and Welfare (MHLW), and Mr. YASUDA Naoyuki (Director of the Office of International Regulatory Affairs) presented in this virtual meeting.

In this meeting, Dr. NAKASHIMA chaired a session entitled "PMDA Updates." Mr. YASUDA provided regulatory updates, including regulatory measures against COVID-19, Dr. FUJIWARA delivered a presentation on PMDA's recent efforts, including the actions taken to tackle COVID-19, and Mr. TAMIYA spoke on further advancement for early patient access. Intense discussions on PMDA and MHLW's activities among speakers during panel discussions done after presentations facilitated an understanding of Japan's pharmaceutical regulations.

The 35th DIA Europe Meeting will be held in Basel, Switzerland from March 22 to 24, 2023.

"PMDA Updates" Session
Top row, from left: Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
Bottom row, from left: Mr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs, MHLW), Mr. TAMIYA Kenichi (Associate Executive Director for New Drug Evaluation, PMDA)

3. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning has been in operation since January, 2020. This month, we are pleased to announce the release of a new content video entitled "Center for Regulatory Science (Center for RS),"along with the renewed "International Activities" content video under the "PMDA Efforts" category.

The Center for RS content introduces the efforts of the Center for RS, established at the PMDA to promote RS, which forms the basis of regulatory decisions including the Science Board, Comprehensive Partnership Agreements, collection and analysis of electronic data, and assessment of real-world data.

The International Activities content explains the efforts of the PMDA in international regulatory harmonization activities such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Asia-Pacific Economic Cooperation – Life Science Innovation Forum – Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC), and the International Medical Device Regulators Forum (IMDRF).

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 link provides 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
Zejula [Initial Approval]	niraparib tosilate hydrate	April 4, 2022
Keytruda [Partial Change Approval]	pembrolizumab (genetical recombination)	April 8, 2022
Comirnaty for 5 to 11 years old [Special Approval for Emergency]	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (active ingredient: tozinameran)	April 8, 2022

Safety Information

PMDA Medical Safety Information No.61 (March)

Failure to Break Separation of Two-chamber Bag Preparations (Bag-type Kit Preparations)
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals Revisions of PRECAUTIONS (March 23, 2022)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection)

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

PMDA Medical Safety Information No.62 (March)

PCPS/ECMO Cannula Accidental Removal
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

PMDA Medical Safety Information No.63 (March)

Precautions for the Pre-operational Check Prior to the Use of Ventilators
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

PMDA Medical Safety Information Extra 3 (March)

Reminder Series No. 3 (Precautions for Magnetic Resonance Imaging (MRI) Scans)
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals Revisions of PRECAUTIONS (April 4, 2022)

- Interferon beta-1a (genetical recombination)
- Interferon beta-1b (genetical recombination)

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

Pharmaceuticals Revisions of PRECAUTIONS (April 4, 2022)

- Somatropin (genetical recombination)

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

Pharmaceuticals and Medical Devices Safety Information No. 391 (April 12, 2022)

1. Revision of Precautions of Levonorgestrel (indicated for emergency contraception)
2. Digitization of Reports from Medical Professionals on Adverse Reactions/Infections/Malfunctions and Suspected Adverse Reactions [Information on the Report Reception Site]
3. Important Safety Information
   (1) Nintedanib ethanesulfonate
4. Revision of Precautions (No. 331)
5. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0020.html

Events

Conferences/Meetings that the PMDA will host or participate in

Date	Title	Location
May 19-22	14th DIA China Annual Meeting	Suzhou
May 21-25	ICH meeting	Athens
May 25-26	IPRP meeting	Athens

June 19-23	58th DIA 2022 Global Annual Meeting	Chicago

Reports from Overseas

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

Greetings from Amsterdam

I am UEDA Mami and have been working as the 6th MHLW/PMDA liaison official for European Medicines Agency (EMA) since April 2022. I could have a transition period from predecessor, I was dispatched to the EMA in Amsterdam, the Netherlands on March 12, 2022.

MHLW/PMDA and EMA have been collaborating in a variety of fields through bilateral and multilateral communications, and I hope to contribute to the development and promotions of this collaboration, as well as to the expansion of its fields.

I will share and update my activities and relevant information monthly. I hope you will enjoy it.

Finally, I would like to take this opportunity to express my deepest gratitude to all those who assisted me in this dispatch.

Ms. UEDA Mami
PMDA's International Liaison Officer stationed at EMA in the Netherlands

