PMDA Updates

December 2021

News

1. ICH Vancouver Virtual Meeting

Due to the COVID-19 pandemic, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) held virtual meetings on November 9, 15–18, 2021 in lieu of the in-person meetings scheduled in Vancouver, Canada. Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), and Mr. YASUDA Naoyuki (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 outcomes of the meeting included the further expansion of the ICH membership and Management Committee and Assembly elections. The ICH Assembly empaneled the Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), Mexico, as a new member, in addition to three new observers: the Egyptian Drug Authority (EDA), Egypt; the Indonesian Food and Drug Authority (Indonesian FDA), Indonesia; and The State Expert Center of the Ministry of Ukraine (SECMOH), Ukraine. Dr. Theresa Mullin (FDA, United States) and Dr. NAKASHIMA (MHLW/PMDA, Japan) were re-elected as Management Committee Chair and Vice Chair, respectively, to serve a two-year term. For the Assembly elections, Ms. Lenita Lindström-Gommers (EC, Europe) was re-elected as Chair, and Dr. Gabriela Zenhaeusern (Swissmedic, Switzerland) was elected as Vice-Chair, to serve a two-year term each.

At this meeting, E8 (R1), M8, Q9 (R1), M7 (R2), and Q13. E8 (R1) reached Step 4 (Adoption of an ICH Harmonized Guideline) for the revision of general considerations for clinical studies. M8 also reached Step 4 for eCTD v4.0 Question and Answer (Q&A) Document v.1.6, and eCTD v3.2.2 Question and Answer (Q&A) Document v.1.32. Q9 (R1) reached Step 2(Adoption of the draft guideline) on quality risk management. M7 (R2) also reached Step 2 for Addendum to the guideline on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk. Q13 also reached Step 2 for the new ICH Q13 guideline on the continuous manufacturing of drug substances and drug products.

The ICH Assembly supported and endorsed the revised New Topic proposal and associated concept paper outline general considerations for model-informed drug development (MIDD). It was coded as M15 and allowed to establish an informal Working Group. In addition, the Assembly approved a report from the quality discussion group. Moreover, the assembly noted that the ICH 30th Anniversary Publication was issued on the ICH website in October 2021.

The proposed dates of the next ICH meeting are May 21–25, 2022, in Athens, Greece. The aim is to hold in-person meetings but it may be held in hybrid style.

2. PMDA-ATC Medical Devices Webinar 2021

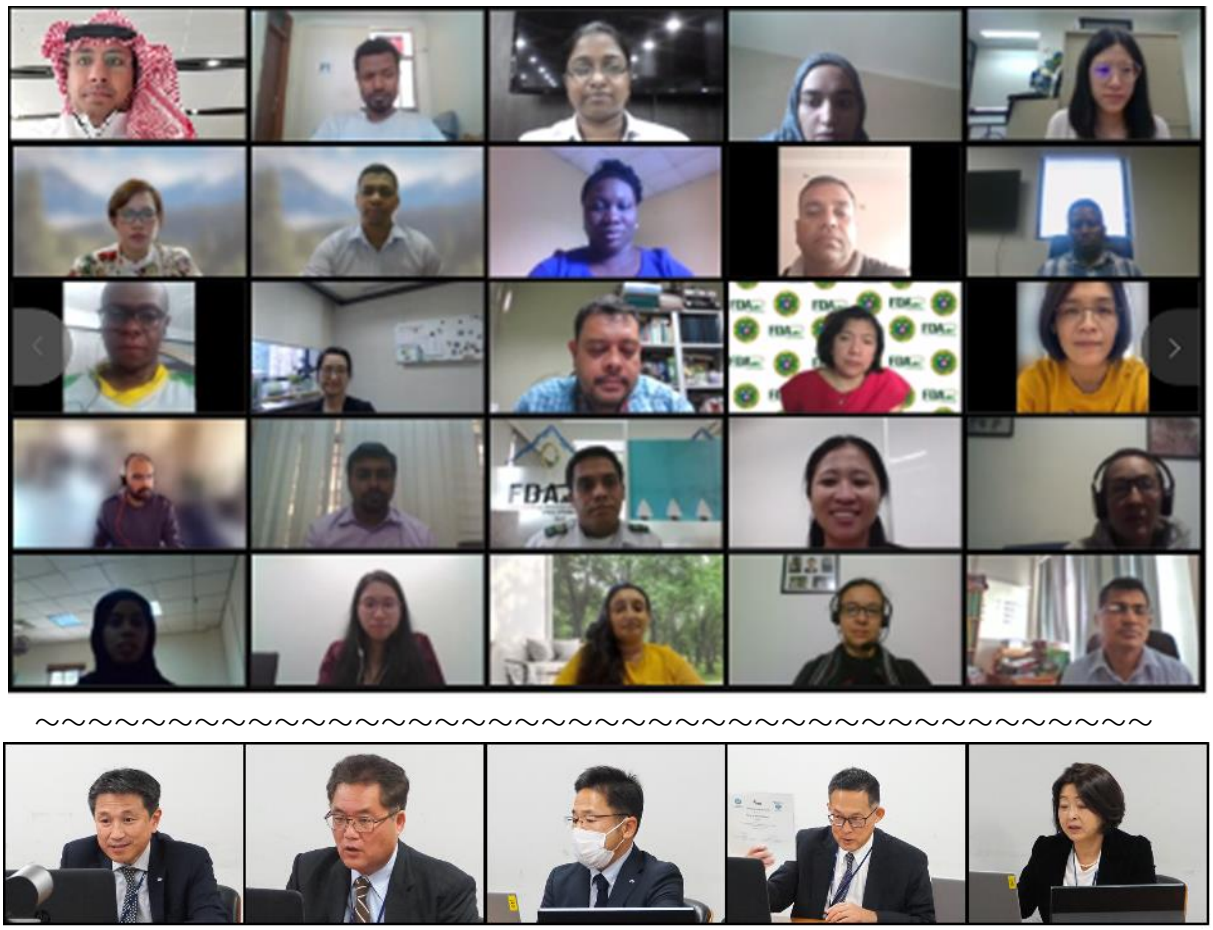
From November 15 to 17, 2021, the PMDA held a webinar entitled "PMDA-ATC Medical Devices Webinar 2021" as the Center of Excellence (CoE) Workshop in the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC).

This webinar was aimed at officials of overseas regulatory agencies involved in the regulation of medical devices or in vitro diagnostics (IVDs). A total of 32 regulators from Australia, Bahrain, Bangladesh, Botswana, Colombia, Ethiopia, Hong Kong, India, Malaysia, Nigeria, Oman, Philippines, Saudi Arabia, Sri Lanka, Taiwan, Tanzania, and Thailand attended the webinar.

Before attending the live webinar, participants took the PMDA - ATC E - learning course, "Medical Devices Review" covering the following: medical device and in vitro diagnostic (IVD) regulations, review of medical devices, review of in vitro diagnostics (ivds), medical device unit, review of medical devices and international harmonization, QMS inspection for medical devices, international standardization of medical devices, clinical evaluation of medical devices, and post-market safety measures for medical devices.

The live webinar comprised lectures and Q&A sessions on international harmonization of medical device regulations, international standardization of medical devices, and the Medical Device Single Audit Program (MDSAP), in addition to case studies on clinical evaluation of medical devices and post-market safety measures for medical devices.

At the end of the webinar, Dr. FUJIWARA Yasuhiro, Chief Executive of the PMDA, handed the course completion certificate virtually.



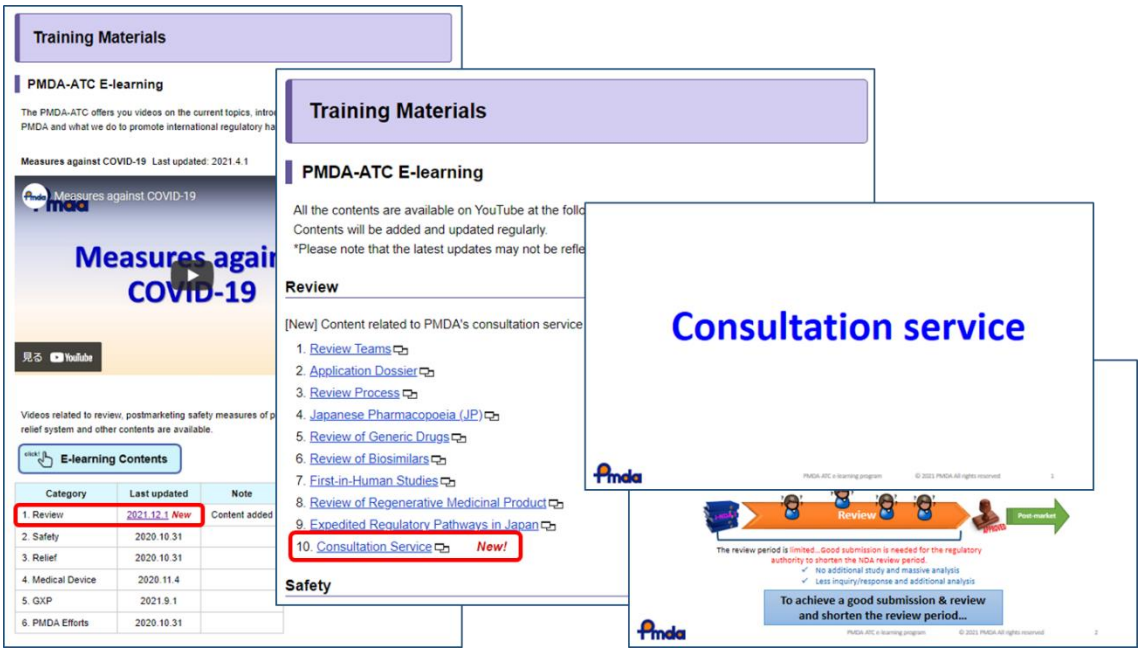
Picture on top: Webinar participants
Picture above, from left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. NAKASHIMA Nobumasa (Assosiate Executive Director forInternational Programs, PMDA), Dr. Ishii Kensuke (Office Director, Office of Medical Devices 1, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), and Dr. SATO Junko (Office Director, Office of International Programs, PMDA)

Please click on the following link for details of the PMDA-ATC Medical Devices Webinar 2021:
https://www.pmda.go.jp/english/symposia/0213.html

3. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning system has been in operation since January 2020. This month, we are pleased to announce the release of our "Consultation service" content video, which provides an overview of the several types of consultation services offered by PMDA at various stages of drug development.

Please follow the 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
Ongentys [Initial Approval]	Opicapone	November 11, 2021
Olumiant [Partial Change Approval]	Baricitinib	November 11, 2021
Xevudy [Special Approval for Emergency]	Sotrovimab (genetical recombination)	November 11, 2021
YESCARTA [Initial Approval]	Axicabtagene ciloleucel	November 15, 2021
Imfinzi [Partial Change Approval]	Durvalumab (genetical recombination)	November 24, 2021
Ofev [Partial Change Approval]	Nintedanib ethanesulfonate	December 6, 2021
Enaroy [Initial Approval]	Enarodustat	December 6, 2021

English Translations of Notifications and Administrative Notices

The following link provides the latest information on the English versions of the notifications and administrative notices newly published on the PMDA website:
https://www.pmda.go.jp/english/review-services/regulatory-info/0003.html

Issue Date	Document Type & No.	Title	Posting Date
February 21, 2018	PSEHB/PED Notification No. 0221-1	Points to Consider for Ensuring the Reliability of Post-marketing Database Study for Drugs	December 6, 2021
June 19, 2019	PSEHB/PED Administrative Notice	Questions and Answers (Q&A) on Points to Consider for Ensuring the Reliability of Post-marketing Database Study for Drugs	December 6, 2021
December 19, 2018	PSEHB/MDED Notification No. 1219-4	Points to Consider for Ensuring the Reliability of Post-marketing Database Study for Medical Devices	December 6, 2021
March 23, 2020	PSEHB/MDED Notification No. 0323-4	Points to Consider for Ensuring the Reliability of Post-marketing Database Study for Regenerative Medical Products	December 6, 2021

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (December 3, 2021)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)(Comirnaty intramuscular injection)
- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)(COVID-19 Vaccine Moderna Intramuscular Injection)

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

Pharmaceuticals Revisions of PRECAUTIONS (December 8, 2021)

- Tacrolimus hydrate (ointment)

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

Pharmaceuticals and Medical Devices Safety Information No. 388 (December 14, 2021)

1. Suspected Adverse Reactions to Influenza Vaccines in the 2020 Season
2. Important Safety Information
   (1) Atezolizumab (genetical recombination)
3. Revision of Precautions (No. 328)
   Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection) (and 2 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

Events

Conferences/Meetings that the PMDA will host or participate in

Date	Title	Location
January 18-21, 2022	PMDA-ATC with National Cancer Center MRCT Webinar 2022	Virtual
January 31, February 2-4, 2022	PMDA-ATC Pharmacovigilance Webinar 2022	Virtual

Reports from Overseas

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

Steady progress in EU Big Data initiative

As introduced in previous reports in PMDA Updates, EMA, together with HMA (Heads of Medicines Agencies), has been intensively discussing the utilization of real-world data/real-world evidence for regulatory purpose under the umbrella of Big data initiative 1). This report introduces two relevant events held at the end of November and early December.

On 30th November, EMA held the webinar to share the current experience, and discuss important challenges and future prospects in terms of using real-world data for regulatory purpose 2). EMA also organized the second stakeholder forum on big data on 7th December 3). The forum was held to inform stakeholders of the latest activities, listen to stakeholder views and feedback, and discuss areas for collaboration. PMDA staff member joined the forum as a discussant.

The latest workplan of Big data steering committee, extended to March 2023, has been published in August 2021 4). According to the workplan, the "European Medicines Regulatory Network Data Standardisation Strategy" 5) has been published on 17th December based on the workshop in May 2021. As international collaboration in this field will be more extensively discussed from next year onwards, it is of importance for PMDA to actively participate in these activities.

1) https://www.ema.europa.eu/en/about-us/how-we-work/big-data
2) https://www.ema.europa.eu/en/events/learnings-initiative-webinar-optimal-use-big-data-regulatory-purpose
3) https://www.ema.europa.eu/en/events/eu-big-data-stakeholder-forum
4) https://www.ema.europa.eu/en/documents/work-programme/workplan-2021-2023-hma/ema-joint-big-data-steering-group_en.pdf
5) https://www.ema.europa.eu/en/documents/other/european-medicines-regulatory-network-data-standardisation-strategy_en.pdf

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PMDA's International Liaison Officer stationed at EMA in the Netherlands

