PMDA Updates

February 2024

News

1. The 10th Thailand–Japan Symposium and Thailand–Japan Bilateral Meeting

The PMDA co-hosted the 10th Thailand–Japan Symposium on January 16, in collaboration with the Food and Drug Administration Thailand (Thai FDA), held in person in Bangkok, Thailand. A total of 200 participants joined the symposium, including representatives from Japan' s Ministry of Health, Labour and Welfare (MHLW), the PMDA, the Thai FDA, and industry stakeholders from both countries.

To commemorate the 10th anniversary of the symposium, a memorial session on "Regulation and Clinical Trials" was co-chaired by Mr. KOGA Daisuke (Director, Office of International Regulatory Affairs, MHLW) and Ms. Worasuda Yoongthong (Director of Medicines Regulation Division, Thai FDA). Presentations were delivered by Dr. Narong APHIKULVANICH (Secretary-General, Thai FDA) and Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), along with contributions from academia by Professor Thanyawee PUTHANAKIT (Director of CHULA CLINICAL RESEARCH CENTER: CHULA CRC, Faculty of Medicine, Chulalongkorn University, Thailand) and Dr. NAKAMURA Kenichi (Director, Department of International Clinical Development, National Cancer Center, Japan). A regulatory update session was followed by the pharmaceutical including advanced medical products session on “Regulatory efforts for efficient development of various pharmaceuticals” and the medical device session on “Regulatory efforts for efficient development of innovative medical devices” held by PMDA and Thai FDA experts, and latest information from each country was exchanged. A live Q&A session was conducted accordingly, and participants exchanged opinions on the latest situations in both countries.

The details of the symposium can be accessed through the following link:
https://www.pmda.go.jp/english/symposia/0286.html

On the following day, January 17, the Thai FDA, MHLW, and PMDA held a bilateral meeting to discuss future cooperation in the areas of pharmaceutical and medical device regulations. The PMDA and Thai FDA will continue their mutual cooperation and pursue closer communication, including the exchange of opinions at working-level meetings.

Group photo of the participants of the symposium

2. PMDA-ATC with National Cancer Center (NCC) MRCT Seminar 2024

The PMDA held the "PMDA-ATC with National Cancer Center (NCC) MRCT Seminar 2024" in collaboration with the NCC Hospital Japan from January 23 to 26. This seminar served as the Center of Excellence (CoE) workshop for the Multi-Regional Clinical Trial (MRCT) and Good Clinical Practice (GCP) inspection, designated by the Asia Pacific Economic Cooperation, Regulatory Harmonization Steering Committee (APEC-RHSC). This seminar was intended for officials of overseas regulatory agencies and clinical research investigators. It was attended by 27 participants, mostly regulators from Chinese Taipei, Egypt, Hong Kong, Indonesia, Malaysia, Pakistan, the Philippines, Saudi Arabia, Sri Lanka, Thailand, and Vietnam.

On the first day, lectures on scientific insights about ethnic factors and consideration for MRCT operation were provided. During the roundtable discussion, representatives presented on MRCT operations in each country/region, and active discussions followed. The second day included a lecture and a case study on "points to consider when planning and designing MRCT," while the third day covered "points to consider when evaluating MRCT results." The participants were divided into groups and had intensive discussions in each case study. On the final day, lectures on the development of the Asian Clinical Trial Network were provided. Throughout this seminar, in addition to PMDA and NCC staff members, lecturers and facilitators from the National Institute of Health Science (NIHS), Japan Pharmaceutical Manufacturers Association (JPMA), National Center for Global Health and Medicine (NCGM), and several industries also shared their expert knowledge and comments with participants, which contributed to this meaningful seminar.

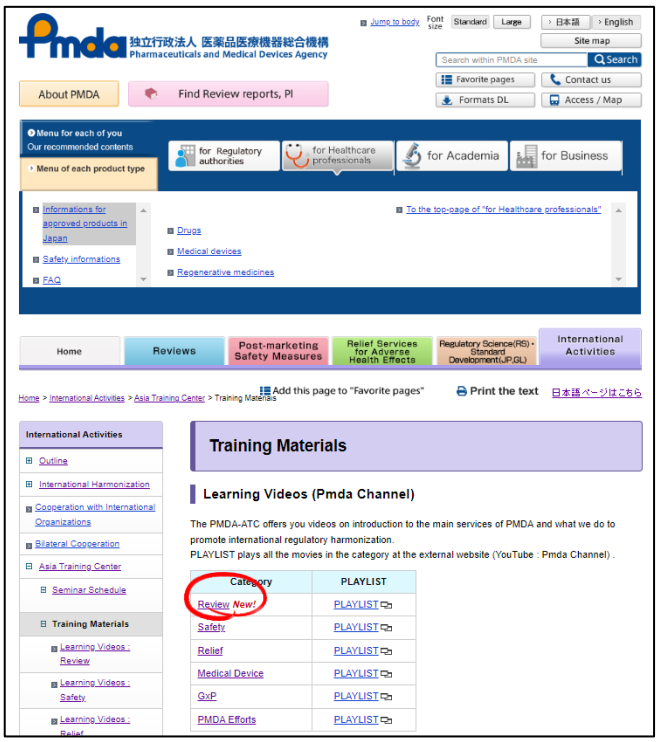
Group photo of the participants

Please refer to the following web site for the details of the PMDA-ATC with NCC MRCT Seminar 2024.
https://www.pmda.go.jp/english/symposia/0277.html

3. 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 "Quality Control for Cell and Gene Therapy Products" in the "Review" category of the PMDA-ATC Learning Videos.

Developing a quality control strategy that considers the nature of cellular/tissue-based and gene therapy products is essential. This video outlines the key points to consider for quality control to ensure the efficacy and safety of such products.



Please follow this link to access the learning video content:
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
(a) Comirnaty RTU Intramuscular Injection (b) Comirnaty RTU Intramuscular Injection for 1 person (c) Comirnaty Intramuscular Injection for 5 to 11 years old (d) Comirnaty Intramuscular Injection for 6 months to 4 years old [Special Approval for Emergency, Partial Change Approval]	Coronavirus (SARS-CoV-2) RNA Vaccine (Active ingredients: (a) Tozinameran and Famtozinameran (b) Tozinameran and Famtozinameran (c) Tozinameran and Famtozinameran (d) Tozinameran and Famtozinameran)	January 18, 2024
Imbruvica [Partial Change Approval]	Ibrutinib	January 23, 2024

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 407 (February 7, 2024)

1. Suspected Adverse Reactions to Influenza Vaccines in the 2022 Season
2. The Manuals for Management of Individual Serious Adverse Drug Reactions
3. Important Safety Information
    1. [1] Acetazolamide, [2] Acetazolamide sodium
    2. •Dexamethasone preparations ([1] Dexamethasone (oral dosage form) and 2 others)
       •Prednisolone preparations ([1] Prednisolone (oral dosage form) and 2 others)
       •Methylprednisolone preparations ([1] Methylprednisolone and 2 others)
       •Cortisone/Hydrocortisone preparations ([1] Cortisone acetate and 4 others)
    3. Atezolizumab (genetical recombination)
    4. [1] Encorafenib, [2] Binimetinib
    5. Pembrolizumab (genetical recombination)
4. Revision of PRECAUTIONS (No.347)
   Sertraline hydrochloride (and 11 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0021.html

Pharmaceuticals Revisions of PRECAUTIONS (February 8, 2024)

- Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio-*Haemophilus* type b conjugate combined vaccine (Gobik Aqueous Suspension Syringes)
- Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio-*Haemophilus* type b conjugate combined vaccine (Quintovac Aqueous Suspension Injection)

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
March 12–14	36th DIA Euro Meeting	Brussels
March 25–26	ICH Management Committee Interim Meeting	Lisbon
April 24	6th Asian Network Meeting	Tokyo

Reports from Overseas

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

Support for African Medicines Agency establishment

The treaty of African Medicines Agency (AMA) [1)] was adapted in 2019 by the heads of state and the African Union to improve regulatory harmonization in the field of medicines, including in the area of pharmaceutical manufacturing, in

an effort to improve access to quality assured medicines across the African continent. As of today, the treaty has been ratified by 27 countries such as Algeria, Benin, Botswana, Burkina Faso, Cameroon, Cape Verde, Chad, Democratic Republic of Congo, Egypt, Ethiopia, Gabon, Ghana, Guinea, Kenya, Lesotho, Mali, Mauritius, Namibia, Niger, Rwanda, Senegal, Seychelles, Sierra Leone, Tunisia, Uganda, Zambia and Zimbabwe.

EMA's contribution is part of the "Team Europe" initiative on manufacturing and access to vaccines, medicines and health technologies in Africa, launched by the commission in May 2021. EMA and the European Commission signed an agreement in December 2023 underpinning EMA's support for setting up the AMA through to November 2027. EMA has received a grant of ten million euros from the European Commission to support regulatory systems at national and regional level in Africa. EMA has committed to mobilizing experts to support AMA, its technical committees and African regulators in the set-up of AMA's governance and scientific and administrative processes. EMA will also offer training to reinforce scientific and regulatory expertise in the evaluation and supervision of medicines together with experts from EU Member States [2)].

Those cooperation and collaboration will avoid duplication of regulatory work and help to rationalize the limited available regulatory resources. It will also ultimately lead to faster delivery of medicines to patients. In addition to that it will accelerate the exchange of information on medicine safety.

It is hoped that these efforts will increasingly ensure that safe and reliable medicines reach patients more quickly.

1) African Union Development Agency https://amrh.nepad.org/african-medicines-agency-ama
2) African Medicines Agency (EMA website): https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-and-initiatives/african-medicines-agency-african-union

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