PMDA Updates

November 2023

News

1. The 24th IMDRF Management Committee Meeting

The 24th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) meetings were held from September 25 to 29. Dr. KUSAKABE Tetsuya, International Coordination Officer, five staff members from the PMDA, and one staff member from the Ministry of Health, Labour and Welfare (MHLW) attended them in person. The meetings, chaired by the EU, took place in Berlin, Germany.

On September 25, a joint workshop was held between the IMDRF and industry groups, namely, the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA) and the Global Medical Technology Alliance (GMTA). In this workshop, under the topic of "Specialized Regulatory Pathways," regulators and industry representatives shared their experiences and challenges in the regulation of orphan, pediatric, personalized, and custom medical devices and innovative medical devices. During the session on orphan medical devices, Dr. KUSAKABE delivered a presentation on the designation criteria for orphan medical devices and incentives for research and development promotion in Japan.

The IMDRF Stakeholder Forum, attended by regulators, industry stakeholders, and international organizations, was held on September 26. Presentations were given on not only the latest regulatory information on each IMDRF country and region but also the interests and concerns of industry groups. The staff member from the MHLW reported on the latest regulatory efforts and accomplishments in Japan regarding Software as a Medical Device (SaMD), including the two-step approval scheme in the Package Strategy for Accelerating the Commercialization of SaMD 2 (DASH for SaMD 2). With an emphasis on discussion with the participants, a new approach called "flash panel" was taken in one of the sessions. The topics of the discussions were the Unique Device Identifier (UDI) and Digital Therapeutics, and the discussions were conducted using keywords proposed by the audience, including those who participated online.

The joint workshop and IMDRF Stakeholder Forum were streamed online. More than 350 people and over 200 virtually participated and actively exchanged their views.

On September 25, the Regulatory Authority Council (RAC) meeting of the Medical Device Single Audit Program (MDSAP) was held in the afternoon and attended by the five member countries. Japan, as the chair, led the discussions on the management of the MDSAP. At this meeting, it was agreed to accept the Affiliate Member Application from the Taiwan Food and Drug Administration, Chinese Taipei.

On September 27, an open meeting was held in the morning, attended by regulatory agencies, members of the Regional Harmonization Initiative (RHI), and industry groups. Invited Observers and RHIs presented their activities, and their views on how industry groups were involved in various IMDRF activities were exchanged.

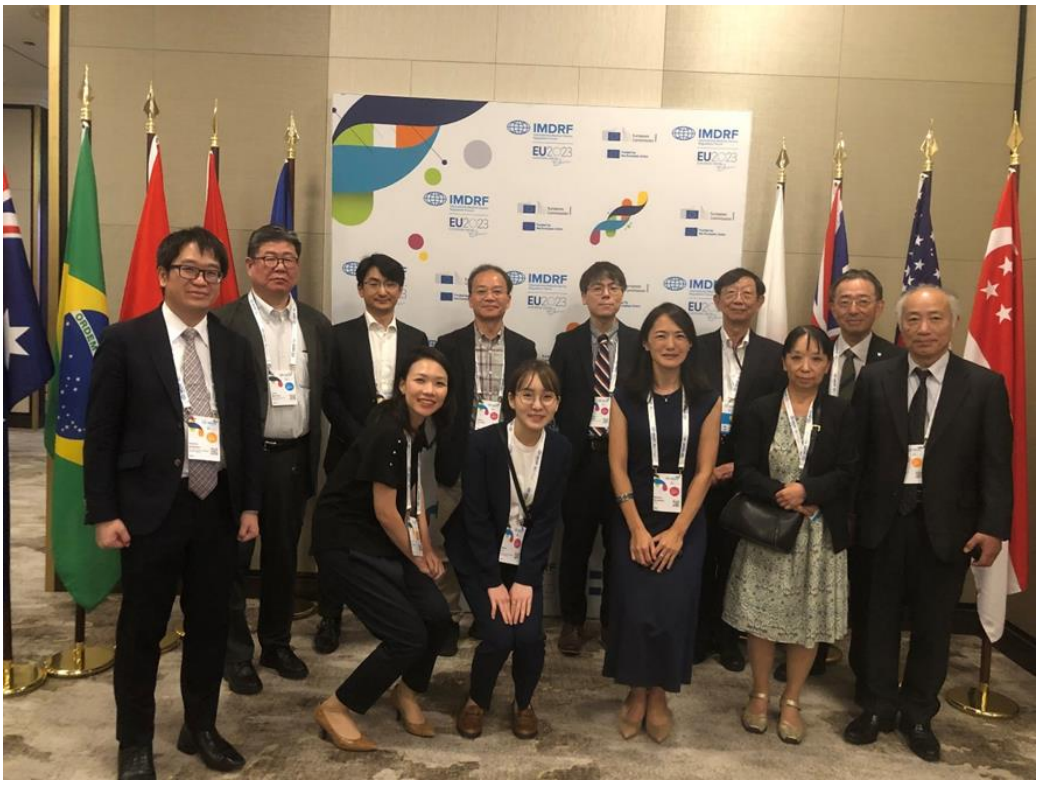
On September 28 and 29, a closed meeting was held with MC members. At this meeting, it was agreed to accept the RHI application of the African Medical Device Forum (AMDF) and Affiliate Member applications of the regulatory authorities of Montenegro, Cuba, Israel, Chile, and Egypt. The MC also agreed to the updates to the Standard Operating

Procedure document, including the criteria for IMDRF Membership. It was agreed to close the Medical Device Cybersecurity WG owing to the completion of all work items. In addition, the MC noted the release and publication of the first IMDRF training pilot video on adverse event terminology on the IMDRF website.

The next IMDRF MC Meeting, chaired by the U.S. FDA, will be held in March 2024.

The detailed outcomes of the 24th IMDRF MC Meeting are available on the following website:

https://www.imdrf.org/meetings/berlin-germany-hosted-european-commission-behalf-eu



Group photo of the participants

2. PMDA-ATC Pharmaceuticals Review Webinar 2023

From September 26 to 28, the PMDA held a webinar titled “PMDA-ATC Pharmaceuticals Review Webinar 2023. “ The webinar was provided online to officials of overseas regulatory agencies involved in pharmaceutical reviews. Twenty-nine regulators from Botswana, China, Chinese Taipei, Egypt, India, Indonesia, Kazakhstan, Malaysia, the Philippines, Saudi Arabia, Singapore, South Africa, and Thailand participated in the webinar.

On the first day of the webinar, lectures on new drug approval reviews, global clinical trials, and digital transformation for approval reviews were provided. On the second day, participants engaged in discussions in the case study group work on new drug reviews and attended a lecture on the review of biosimilars. On the third day, there was a lecture on the review of chemistry, manufacturing, and control (CMC) and a case study lecture on the review of generic drugs. Each lecture was followed by a lively Q&A session. All lecturers and facilitators of the webinar were PMDA staff members.

Please refer to the following website for details on the PMDA-ATC Pharmaceuticals Review Webinar 2023.

https://www.pmda.go.jp/english/symposia/0270.html

From the top left : Dr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. YAGINUMA Hiroshi (Senior Coordinator for International Training, PMDA)
In the middle : webinar lecturers
At the bottom : participants of the webinar

3. Pharmacopoeial Discussion Group (PDG) Hyderabad Meeting and the PDG Stakeholder Event

From October 3 to 4, the Pharmacopoeial Discussion Group (PDG) Meeting, hosted by the U.S. Pharmacopeial Convention (USP), was held in Hyderabad, India, where staff members of the Division of Pharmacopoeia and Standards for Drugs, Office of Review Management, PMDA participated as a part of representatives of Japanese Pharmacopoeia (JP). The PDG is an international council comprised of the representatives of the JP, European Pharmacopoeia (Ph. Eur.), U.S. Pharmacopoeia (USP), World Health Organization (WHO), an observer to the PDG, and Indian Pharmacopoeia Commission (IPC), who is newly added as a member after the participation of a one-year pilot. Accordingly, the Japanese name of the PDG was changed.

In this meeting, the operational impact of membership expansion was reviewed, and the future structure and organization of the PDG were discussed. The PDG also discussed the draft of the revised ICH Q4B guideline, which describes the interchangeability evaluation results of the pharmacopoeial tests in the ICH regions, as well as the draft of the revised SOP on annex maintenance.

The next PDG meeting will be held in Strasbourg, France, hosted by Ph. Eur. from October 1 to 2, 2024.

On October 5, the PDG Stakeholder Event, which was designed mainly for Indian stakeholders, was also held in a hybrid style. At the event, the over 30-year history of PDG's harmonization works on general chapters and excipient monographs, as well as PDG's future perspectives, were presented. Representatives from the JP, Ph. Eur., IPC, USP, and the WHO delivered presentations on each perspective and exchanged their opinions in panel discussions.

Please see the following websites for details on the PDG Hyderabad Meeting and the Stakeholder Event:

https://www.pmda.go.jp/files/000264840.pdf

https://www.pmda.go.jp/files/000265196.pdf

Group photo of the participants

4. The 11th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 5, the 11th Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Taipei, Taiwan, hosted by the Japan-Taiwan Exchange Association and the Taiwan-Japan Relations Association. It was the first meeting in four years that included face-to-face participation. Representatives from the PMDA, Japan's Ministry of Health, Labour and Welfare (MHLW), Taiwan Food and Drug Administration (TFDA), Center for Drug Evaluation (CDE), and other industries attended with more than 650 participants, including approximately 200 on-site and 450 online participants. At the conference, keynote speeches by Dr. TANAKA Daisuke (Director of the Office of International Programs, PMDA) and Dr. Shou-Mei Wu (Director-General, TFDA) presented the latest information on medical product regulations in Japan and Taiwan. Following the speeches, the topics for the pharmaceutical session included real world data (RWD)/ real world evidence (RWE) for acceleration of clinical development, new drug review cooperation between Japan and Taiwan and regenerative medicinal products regulation, the health insurance system, and the sharing of latest medical device issues. The Q&A sessions that followed each lecture were designed to promote understanding by allowing speakers to answer questions from both sides. The next conference is scheduled to be held in Japan in 2024.

Materials, including the program of the 11th Joint Conference of Taiwan and Japan on Medical Products Regulation, are available on the following website:

https://www.pmda.go.jp/int-activities/symposia/0139.html

Group photo of lecturers and moderators in symposium

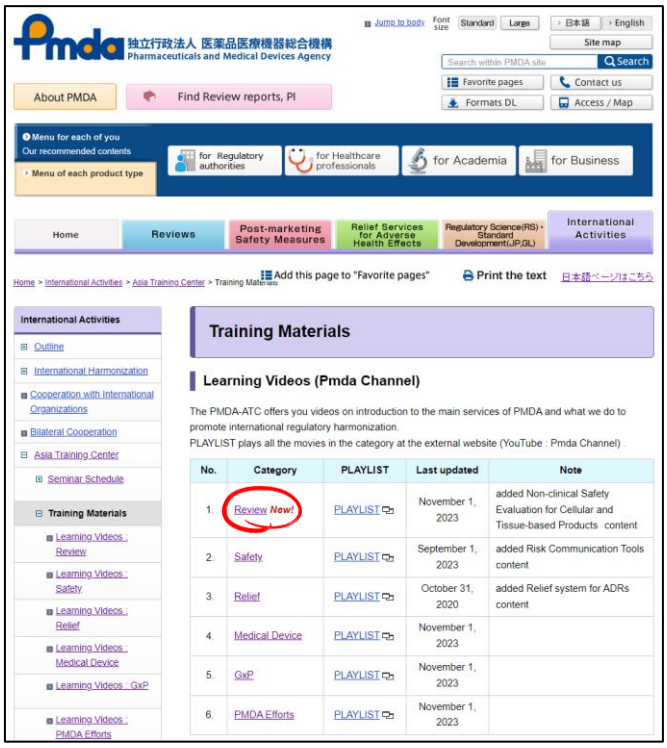
5. PMDA-ATC: Release of New Learning Video Content

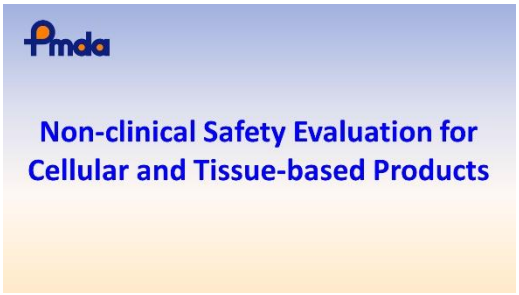
The PMDA-ATC provides online learning videos that offer an overview of pharmaceutical and medical device regulations in Japan and PMDA's services. This month, we are pleased to announce the release of a new content video entitled "Non-clinical Safety Evaluation for Cellular and Tissue-based Products" in the "Review" category of the PMDA-ATC Learning Videos.

This video shows non-clinical safety evaluation points such as risk (general toxicity and tumor formation) assessment for cellular and tissue-based 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
Wegovy [Initial Approval]	Semaglutide (genetical recombination)	October 30, 2023

Medical Devices

https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Brand Name	Term Name	Posting date

Synfolium [Initial Approval]	Synthetic myocardial patch	October 20, 2023
SUSMED Med CBT-i App for Insomnia [Initial Approval]	Software for insomnia	November 1, 2023

Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
Breyanzi [Partial Change Approval]	Lisocabtagene maraleucel	November 7, 2023

Safety Information

PMDA Medical Safety Information No.66 (October 2023)

Precautions in Handling of Tracheostomy Tubes (No. 2)

https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals and Medical Devices Safety Information No. 405 (November 9, 2023)

1. Summary of the Relief System for Adverse Drug Reactions and Request for Cooperation With the System
2. Revisions of PRECAUTIONS for Preparations Containing Acetaminophen (Prescription Drugs)
3. Important Safety Information
    1. Apalutamide
    2. Technetium (^{99m}Tc) tetrofosmin
4. Revision of Precautions (No. 345)
   Filgrastim (genetical recombination) (and 14 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

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
December 5	The 4th Vietnam-Japan Symposium	Hanoi
December 5–7	PMDA-ATC Medical Devices Seminar 2023	Tokyo (PMDA)
December 13	ICH Fund Training	Tokyo
January 16-17	10th Thailand - Japan Symposium	Bangkok
January 23-26	PMDA-ATC with National Cancer Center MRCT Seminar 2024	Tokyo (PMDA)

Reports from Overseas

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

Measures for Critical shortages of medicines

EMA published "MSSG solidarity mechanism"*1 on 24 October 2023. This was developed by Medicines Shortage Steering Group (MSSG). MSSG was established for reinforces the role of Agency in crisis preparedness and management for medicines and medical devices in order to monitor shortages and ensure a robust response to major events or public health emergencies and to coordinate urgent actions on the supply of medicines within the EU.

The solidarity mechanism, which is based on an informal set up during COVID-19, will enable any Member State facing a critical shortage that has been escalated to the MMSG for coordination at European level to request assistance from other Member States in obtaining medicine stock under very limited conditions.

EMA also published "MSSG Toolkit on recommendations on tackling shortages of medicinal products"*2. This includes recommendations for monitoring supply and demand, and approach that was used to tackle the widespread guidance on interaction with marketing authorization holders and manufactures to increase and redistribute existing stocks and the implementation of regulatory flexibilities, such as the exceptional supply of certain medicines that may not be authorized in a particular EU Member State, or full or partial exemptions to certain labelling and packaging requirements for medicines.

I believe, in emergency situation, such measures against shortages are very important, and such measures would provide transparency and reassurance to the public.

1) MSSG solidarity mechanism https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf
2) MSSG Toolkit https://www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf

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