PMDA Updates

October 2024

News

1. The 13th ASEAN Medical Device Committee Meeting

On September 12, “The 13th ASEAN Medical Device Committee Meeting,” organized by the ASEAN Medical Device Committee (AMDC), was held in Yogyakarta, Indonesia. The PMDA was invited by the AMDC, to attend it as an observer.

At this meeting, the PMDA presented the results of “PMDA-ATC/AMDC Medical Devices Webinar 2023” and explained the next PMDA-ATC training webinar for AMDC to AMDC members for their input, which was then embraced.

The PMDA also showed the updated contents of the English-language version of the "Criteria for Medical Devices" webpage (Medical Devices and IVD Information page) on the PMDA website and the status of participating in the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) International Conference to share the latest information with the AMDC.

The PMDA will continue to cooperate with the AMDC through participation in meetings and the provision of technical training on pharmaceuticals and medical devices regulations.

2. The 26th IMDRF Management Committee Meeting

The 26th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) meetings were held between September 16 and 20. Mr. YASUDA Naoyuki (Associate Executive Director for International Programs), Dr. FUKUDA Eriko (International Coordination Officer), seven staff members from the PMDA, and one official from the Ministry of Health, Labour and Welfare (MHLW) attended them in person. The meetings, chaired by the U.S. FDA took place in Seattle, U.S.A.

On September 15, the Regulatory Authority Council (RAC) meeting of the Medical Device Single Audit Program (MDSAP) was held and attended by the five-member countries as well as official observers. At this meeting, several topics related to the operation of the MDSAP were discussed.

On September 16, a joint workshop on the development of the medical device regulatory system was held between the IMDRF and industry groups, where the PMDA shared views on the post-market control of medical devices and participated in the panel discussion.

On September 17, the IMDRF Stakeholder Forum, attended by regulators, industry stakeholders, and international organizations, was held. During this forum, there were updates from each IMDRF member country and region, along with the working groups (WGs) and industry groups. The latest information was presented from Japan, and this included the establishment of international hub offices of the PMDA.

On September 18, an open meeting was held. Regulatory agencies, members of the Regional Harmonization Initiative (RHI) and several invited organizations, including the industry, exchanged views on regulatory reliance and e-labeling. In addition, the MC, official observers (OO), and affiliate members gathered in the afternoon to discuss the future of the IMDRF Affiliate Membership.

On September 19 and 20, the MC and OO held closed meetings. At these meetings, two documents created by the Adverse Event Terminology (AET) WG were approved, namely the final document for the Common Data Set (CDS) guidance and the document for the consideration for the selection of IMDRF AET codes and terms for public consultation. For the New Work Item Proposals (NWIPs), work items related to the Predetermined Change Control Plan (PCCP) from the Software as a Medical Device (SaMD) WG, and AI lifecycle management from the Artificial Intelligence (AI)/Machine Learning (ML) WG were approved. Moreover, the regulatory authorities of Botswana, Costa Rica, the Dominican Republic, India, Oman, Paraguay, Peru, and Zambia were approved as IMDRF Affiliate Members, and the regulatory authority of Saudi Arabia was approved as an IMDRF OO.

The next IMDRF MC meeting will be held in Tokyo, Japan, in March 2025.

The detailed outcomes of the 26th IMDRF MC meeting are available on the following website:

https://www.imdrf.org/meetings/seattle-washington-usa-hosted-usa

Photos from the Meeting

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
Ebglyss [Initial Approval]	Lebrikizumab (genetical Recombination)	September 6, 2024
Daichirona [Partial Change Approval]	Coronavirus (SARS-CoV-2) RNA Vaccine (active ingredient: MAFB-7256a)	September 17, 2024
Talzenna [Initial Approval]	Talazoparib tosilate	September 25, 2024
Valixa [Partial Change Approval]	Valganciclovir hydrochloride	September 25, 2024
Fasenra [Partial Change Approval]	Benralizumab (Genetical recombination)	September 25, 2024

English Translations of Notifications and Administrative Notices

The following link provides the latest information on the English versions of the latest notifications and administrative notices 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
September 6, 2024	Administrative Notice	Submitting documents to be attached in the application for approval of new ethical drugs	September 13, 2024

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 413 (October 3, 2024)

1. Revision of PRECAUTIONS for Sodium Valproate
2. Revision of Precautions for Mirogabalin Besilate
3. Important Safety Information
   3-1 Mirogabalin besilate
   3-2 Pemafibrate
   3-3 Purified pineapple stem juice
   3-4 [1]Preparations containing sulfamethoxazole sodium, [2]Preparations containing sulfamethoxazole
4. Revisions of PRECAUTIONS (No.353)
   4-1 Sodium valproate (and 9 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/0022.html

Pharmaceuticals Revisions of PRECAUTIONS (October 8, 2024)

- Aspirin (preparations indicated for antipyresis/analgesia/anti-inflammation)
- Acemetacin
- Indometacin (suppositories)
- Indometacin farnesil
- Oxaprozin
- Tiaramide hydrochloride
- Proglumetacin maleate
- Meloxicam
- Ampiroxicam
- Ibuprofen
- Etodolac
- Naproxen
- Piroxicam (oral dosage form)

- Flurbiprofen (oral dosage form)
- Flurbiprofen axetil
- Loxoprofen sodium hydrate (oral dosage form)
- Lornoxicam
- Isopropylantipyrine/acetaminophen/allylisopropylacetylurea/anhydrous caffeine
- Salicylamide/acetaminophen/anhydrous caffeine/chlorpheniramine maleate
- Salicylamide/acetaminophen/anhydrous caffeine/promethazine methylenedisalicylate
- Ethenzamide
- Sulpyrine hydrate
- Ketoprofen (injections)
- Ketoprofen (suppositories)
- Zaltoprofen
- Dibucaine hydrocholoride/sodium salicylate/calcium bromide
- Celecoxib
- Nabumetone
- Bucolome
- Mefenamic acid
- Flufenamate aluminum
- Ibuprofen piconol
- Indometacin (patches)
- Diclofenac sodium (dermatologic preparation)
- Piroxicam (dermatologic preparation)
- Flurbiprofen (dermatologic preparation)
- Loxoprofen sodium hydrate (dermatologic preparation)
- Indometacin (topical preparations excluding patches)
- Esflurbiprofen/mentha oil
- Ketoprofen (dermatologic preparation)
- Glycol salicylate/l-menthol
- Methyl salicylate
- Methyl salicylate/dl-camphor/capsicum extract
- Methyl salicylate/dl-camphor/l-menthol
- Methyl salicylate/l-menthol/dl-camphor/glycyrrhetinic acid
- Felbinac
- Heparinoid/adrenal extract/salicylic acid
- Salicylic acid
- Diclofenac etalhyaluronate sodium
- Preparations containing ibuprofen (OTC drugs)
- Preparations containing naproxen (guidance-mandatory drugs)
- Preparations containing loxoprofen sodium hydrate (oral dosage form) (guidance-mandatory drugs, OTC drugs)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0012.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
November 2–6	ICH meeting	Montréal
November 6–7	IPRP meeting	Montréal
November 11–14	ICMRA Summit	Brasilia
November 12–15	PMDA-ATC Herbal Medicine Review Seminar 2024	Toyama
December 9–12	GHWP annual meeting	Kuala Lumpur
December 10–12	PMDA-ATC Pharmaceuticals Review	Virtual

Reports from Overseas

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

Greetings from OECD

This is the first time to post a report from a secondee to the OECD in this column, so I would like to start with a brief introduction of the OECD itself. The OECD (Organisation for Economic Co-operation and Development) is an intergovernmental organisation that works to build better policies for better lives, working with policy makers, stakeholders and citizens to establish evidence-based international standards and to find solutions to social, economic and environmental challenge. Its predecessor was the Organisation for European Economic Cooperation (OEEC), which was established in 1948 as a coordinating body for aid under the European Recovery Programme (Marshall Plan) promoted by the United States after the World War II, and was reorganised into the current OECD in 1961. Japan joined the OECD in 1964 as the first additional member country outside of the original member countries, and this year 2024 is the 60th anniversary of its accession. Since then, the number of member countries has increased to the current 38.

As part of the Mutual Acceptance of Data (MAD) system, the OECD established principles for Good Laboratory Practice (GLP) and the secretariat within the Environment Directorate of the OECD has contributed to the international operationalisation and coordination of GLP and MAD through important activities including holding Working Party Meetings, issuing guidance documents and others. PMDA has been actively contributing to the GLP secretariat, including by sending GLP inspectors to the GLP secretariat successively since 2006. I was appointed to the OECD in August 2023, and it has been about one year and two months since then. The OECD headquarters is located in the La Muette area of Paris' 16th arrondissement, and the offices of the Environment Directorate are in another building in the Boulogne-Billancourt district adjacent to the west of Paris.

The OECD Training Course for GLP Inspectors, a training program for GLP inspectors from each country, is also one of the important activities of the OECD GLP Programme. This training course is usually held every two years, and the next one is scheduled to be held next month (November 2024) in Mexico City. We are currently in the final stages of preparation of the workshop. PMDA GLP inspectors from the Office of Non-clinical and Clinical Compliance II will participate in this training course as a trainer and a trainee, and I am looking forward to seeing them again in Mexico City.

Dr. MIZUTA Hiroyuki
Policy Analyst, Environment Directorate, OECD