PMDA Updates

July 2024

News

1. ICH Meeting in Fukuoka

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met from June 1 to June 5 in Fukuoka, Japan. Mr. YASUDA Naoyuki (Associate Executive Director for International Programs, PMDA), Working Group experts, Mr. YOSHIDA Yasunori (Councillor for Pharmaceutical Affairs from the Ministry of Health, Labour and Welfare [MHLW]), and Mr. KOGA Daisuke (Office Director, Office of International Regulatory Affairs from the MHLW) attended these meetings with officers from the MHLW and PMDA. Mr. YOSHIDA delivered the opening remarks at the Assembly, and welcomed the participants.

Mr. YOSHIDA (Councillor for Pharmaceutical Affairs from the MHLW) delivered opening remarks at the Assembly.

The following regulatory members were elected to the Management Committee at the Assembly: the National Health Surveillance Agency (ANVISA), Brazil; the Ministry of Food and Drug Safety (MFDS), Republic of Korea; and the National Medical Products Association (NMPA), China. In addition, the Saudi Food and Drug Authority (SFDA), Saudi Arabia elected as a new member. The following industry members were also elected: the Biotechnology Innovation Organization (BIO) and International Generic and Biosimilar Medicines Association (IGBA). To further expand the ICH membership, the Assembly welcomed the National Administration of Drugs, Food, and Medical Devices (ANMAT), Argentina, and the Jordan Food and Drug Administration (JFDA), Jordan, as new members, increasing the membership to 23, with 35 observers.

As the main outcome of the meeting, the Assembly adopted a new topic, “an Addendum to the M7 guideline on “Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,” to address the safety assessment and establish appropriate controls for nitrosamine impurities, as well as to develop a “harmonised set of acceptable intakes” at the meeting. The Management Committee will discuss its initiation timeframe.

Since the last ICH meeting, M12 reached Step 4 (Adoption of an ICH Harmonised Guideline) of the guidelines on “Drug Interaction Studies.” E2D(R1) reached Step 2 (Adoption of the Draft Guideline) of the guidelines on “Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports” and M14 reached Step 2 of the guidelines on “General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies That Utilize Real-World Data for Safety Assessment of Medicines.”

The next ICH meeting is scheduled later this year, from November 2 to November 6, in Montréal, Canada.

2. BIO International Convention 2024

The BIO International Convention 2024 was held in San Diego, US from June 3 to June 6. Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. Maruyama Yoshiaki (Director, Office of Cellular and Tissue-based Products, PMDA), and four staff members attended the convention.

Dr. FUJIWARA spoke at the session, “Spurring Biotech Innovation And Access Across the Globe: A High- Level Discussion,” on the latest initiatives, including innovative technologies, such as cell/gene therapy, orphans and pediatric medicine, necessity of Phase 1 studies in Japanese prior to initiating multi-regional clinical trials, and the establishment of PMDA’s overseas offices. In the panel discussions, the participants discussed subjects, such as the impact of AI and genomics on clinical trials, and securing human resources in these fields. The audience was asked questions about support for venture companies and the development of iPS cell products in Japan. Dr. MARUYAMA also spoke at the session, “Patients Wait Less: Streamlining Regulatory Pathways for Cell/Gene Therapies in Asia-Pacific Region,” on the current status on cell/gene therapy development in Japan.

Dr. FUJIWARA exchanged opinions with the CEO and Board members of BIO and introduced the merits of innovative products, encouraging them to develop these in Japan. Participants demonstrated significant interest in the establishment of the PMDA Washington D.C., and enquired about accelerated approval pathways in Japan, such as the “SAKIGAKE” designation system.

Additionally, as part of the outreach activities, PMDA staff members contacted companies that delivered lectures at Company Presentations to know about the intended development in Japan with development items in the clinical stage. They conducted activities to encourage development plans in Japan, e.g., providing information on PMDA's RS consultation and Japan's pharmaceutical regulations.

The next BIO International Convention will be held in Boston, US, from June 16 to June 19, 2025.

Photographs from the sessions

From left: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. MARUYAMA Yoshiaki

(Director, Office of Cellular and Tissue-based Products, PMDA)

3. PMDA-ATC Pharmaceuticals Review Seminar 2024 for PPWG member states

The PMDA-ATC Pharmaceuticals Review Seminar 2024 for PPWG member states was conducted from June 11 to June 14. In April this year, the PMDA held the PMDA-ASEAN Reliance Meeting, inviting regulatory authorities of ASEAN member states and WHO. In the discussions at the meeting, it was demonstrated that the technical skills of the regulators of ASEAN, who are engaged in pharmaceutical review, should be enhanced to promote the utilization of Reliance. Considering this, this seminar provided ASEAN regulatory reviewers with a practical case study-based training program to improve their skills in evaluating data on new drugs. A total of 27 people participated from Brunei Darussalam,

Cambodia, Indonesia, Laos PDR, Malaysia, Myanmar, Philippines, Thailand, and Vietnam.

On the first day, lectures were delivered on an overview of new drug reviews in Japan and points to consider when evaluating new drugs. Subsequently, in the roundtable discussion, participants presented the status and issues of the joint assessment, followed by a discussion with all participants and the WHO (online). On the second day, lectures were delivered on the structure and content of the PMDA review report and risk management plan. A case study of data evaluation, using an application document, was conducted on quality data. On the third day, case studies were conducted to evaluate the toxicological, pharmacological, and pharmacokinetic data. On the fourth day, a case study was conducted to evaluate the clinical data. A total of 19 lecturers and facilitators were appointed from the PMDA.

Group photograph of the participants of the PMDA-ATC Pharmaceuticals Review Seminar 2024 for PPWG member states

Please refer to the following website for details of the PMDA-ATC Pharmaceuticals Review Seminar 2024 for PPWG member states.
https://www.pmda.go.jp/english/symposia/0293.html

4. The DIA 2024 Global Annual Meeting

The Drug Information Association (DIA) 2024 Global Annual Meeting was held in San Diego, US, from June 16 to June 20. Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. UYAMA Yoshiaki (Associate Executive Director for regulatory science research, PMDA), Dr. SATO Junko (Associate Executive Director for Non-clinical and Clinical Compliance, PMDA), Dr. TANAKA Daisuke (Director of the Office of International Programs, PMDA), 11 PMDA staff members, and Mr. KOGA Daisuke (Director of the Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare) attended the meeting in person.

The "International Regulatory Convergence: Regulatory Science to Address Challenges Brought by Pharmaceutical Innovation" forum attracted an audience of approximately 300 people. Regulatory executives shared their perspectives and discussed ways to solve the challenges in drug development. Dr. FUJIWARA spoke at this forum about the future role of the International

Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA) attending The DIA 2024 Global Annual Meeting

Coalition of Medicines Regulatory Authorities (ICMRA) and how it should be utilized.

In the "PMDA Town Hall" session, chaired by Dr. TANAKA, which was attended by more than 100 people, Mr. KOGA and industry speakers in Japan and abroad provided their presentations. Dr. UYAMA then joined the discussion as a panelist. In this session, in addition to global trends in drug development and the advantages of developing drugs in Japan, updates on Japanese pharmaceutical regulations were presented, including recent initiatives for orphan and pediatric drugs and handling of Japanese Phase I trial data prior to initiating multi-regional clinical trials. PMDA's latest initiatives, such as the establishment of overseas offices, were also introduced. A lively discussion ensued, which included questions from the audience.

Other forums, sessions, and poster presentations attended by executives and staff members of the PMDA are listed in the table below.

In addition to the booth exhibition, individual consultations were held between onsite participants and the PMDA in a meeting room set up at the venue, to clarify the practical application of promising seed-stage resources, discovered in basic research, to create innovative medicines in Japan by overseas companies. Discussions and consultations were held to answer various questions from people requiring advice.

The next DIA Global Annual Meeting will be held in Washington D.C., US, from June 15 to June 19, 2025.

A picture of the PMDA booth

Photograph from “PMDA Town Hall” session

From left: Dr. TANAKA Daisuke (Director of the Office of International Programs, PMDA), Dr. UYAMA Yoshiaki (Associate Executive Director for regulatory science research, PMDA) and Mr. KOGA Daisuke (Director of the Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare)

Dr. UYAMA Yoshiaki	Updated Status of Multiregional Clinical Trials Based on ICH E17 Guideline: 5 Years After the Implementation (as a chair)
Dr. SATO Junko	• GCP Renovation: How Will GCP Inspection Change in Europe, Japan, and the US? (as a chair) • How to Provide Necessary Medicinal Products to Children? (as a chair) • How to Ensure Compliance in a Changing Regulatory Environment: A Regulators Perspective

Staff members	• GCP Renovation: How Will GCP Inspection Change in Europe, Japan, and the US? • The State of Real-World Evidence for Regulatory Decision-Making: Views from FDA, EMA, and PMDA • Impact of Accelerated Pathways on Patients in Five Countries/Regions • Supporting Regulatory Convergence and Reliance Through a Pharmaceutical Quality Knowledge Management Capability • International Harmonization to Support Pharmaceutical Quality and Lifecycle Management • How to Provide Necessary Medicinal Products to Children? • Bringing Transformational Treatments to Patients: Regulatory Convergence and Reliance on Cell and Gene Therapy Products • ICMRA Post-Pandemic: Regulators Looking into the Future • Implementing Changes to Drug-Device Combination Products Globally • Updated Status of Multiregional Clinical Trials Based on ICH E17 Guideline: 5 Years After the Implementation • Comparing safety between generic and brand drugs of statins marketed in Japan: a cohort study using MID-NET® (in the poster session)

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
Alhemo [Initial Approval]	Concizumab (genetical recombination)	June 13, 2024
Spikevax [Special Approval for Emergency, Partial Change Approval]	Coronavirus (SARS-CoV-2) RNA Vaccine (Active ingredients: (a) Elasomeran; (b) Elasomeran and Imelasomeran; (c) Elasomeran and Davesomeran)	July 1, 2024

Medical Devices

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

Brand Name	Term Name	Posting date
Medtronic Percept PC [Partial Change Approval]	Tremor brain electrical stimulator	June 20, 2024

Regenerative Medical Products

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

Brand Name	Non-proprietary Name	Posting date

Abecma [Partial Change Approval]	Idecabtagene vicleucel	June 18, 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
March 29, 2024	PSB/PED Notification No. 0329-1	Partial revision of “Planning of the Pediatric Drug Development Program during Development of Drugs for Adults"	June 12, 2024
March 29, 2024	Administrative Notice	Q&A for “Planning of the Pediatric Drug Development Program during Development of Drugs for Adults”	June 12, 2024
January 16, 2024	PSB/PED Notification No. 0116-1･PSB/MDED Notification No. 0116-1	Partial Revision of “Designation of Orphan Drugs etc.”	June 12, 2024
January 16, 2024	Administrative Notice	Questions and Answers (Q&A) for Designation of Orphan Drugs etc.	June 12, 2024
January 16, 2024	PSB/PED Notification No. 0116-3	Partial Revision of “Handling of Re-Examination Period”	June 12, 2024
January 12, 2024	PSB/PED Notification No. 0112-3	Planning of the Pediatric Drug Development Program during Development of Drugs for Adults	June 12, 2024
November 26, 2020	Administrative Notice	Questions and Answers (Q&A) for Extension of Re-Examination Period in Association with Development of Pediatric Dosage and Administration	June 12, 2024
August 31, 2020	PSEHB/PED Notification No. 0831-5	Handling of Designation of Drugs for Specific Use	June 12, 2024
August 31, 2020	PSEHB Notification No. 0831-11	Re-Examination Period of Prescription Drugs	June 12, 2024

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (July 4, 2024)

・ Freeze-dried smallpox vaccine prepared in cell culture

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

Pharmaceuticals and Medical Devices Safety Information No. 411 (July 9, 2024)

1. Revisions of PRECAUTIONS for Preparations Containing Brimonidine Tartrate
2. Recent Efforts on MID-NET
3. Important Safety Information
   [1] Brimonidine tartrate
   [2] Brimonidine tartrate/timolol maleate
   [3] Brimonidine tartrate/brinzolamide
   [4] Ripasudil hydrochloride hydrate/brimonidine tartrate
4. Revisions of PRECAUTIONS (No.351)
   Pembrolizumab (genetical recombination) (and 6 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

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
August 29	International Symposium for Asia Regulatory Coordination	Bangkok
September 16–20	IMDRF Management Committee Meeting	Seattle