PMDA Updates

March 2023

News

1. Pharmacopoeial Discussion Group (PDG) Meeting

On February 28, 2023, the press release and meeting highlights on the Pharmacopoeial Discussion Group (PDG) Tokyo Meeting on October 18–21, 2022, which was co-hosted by the PMDA and Ministry of Health, Labor and Welfare (MHLW), were posted on the PMDA website. The PDG is an international council comprised of the representatives of the European Pharmacopoeia (Ph. Eur.), U.S. Pharmacopeia (USP), and Japanese Pharmacopoeia (JP). For the first time, the Indian Pharmacopoeia Commission (IPC) joined the meeting as a participant in the PDG pilot for global expansion. In this meeting, revisions of the general chapters, "Bulk density of powders," "Powder Flow," and "Peptide Mapping," and corrections to the excipient monographs, "Carmellose Calcium," "Hydroxypropylcellulose, Low Substituted," "Hypromellose," "Lactose, Anhydrous," "Lactose, Monohydrate," and "Methylcellulose," were signed-off. In addition, the initial harmonization work on the general chapter on "Dynamic Light Scattering" has been completed and is due to be signed-off separately in the near future. The PDG also discussed drafts of revised annexes of the ICH Q4B guideline, which describe interchangeability evaluation results of the pharmacopoeial tests in the ICH regions, as well as a way forward for stakeholder engagement and regulatory engagement to enhance the impact of the international harmonization of pharmacopoeial standards.

The next PDG meeting will be held in Hyderabad, India, hosted by USP from October 3 to 4, 2023.

Please see the following websites for details of the PDG Tokyo Meeting:

Press releases: https://www.pmda.go.jp/files/000249673.pdf
https://www.pmda.go.jp/files/000250952.pdf

Meeting highlights: https://www.pmda.go.jp/files/000250946.pdf

2. Schedule of PMDA-ATC Training Seminars

The Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) has been providing training courses for regulators with the aim of improving the regulatory standards and promoting regulatory convergence, particularly in Asia, as well as further strengthening the cooperation with each regulatory authority.

While all the seminars were held virtually from FY2020 to FY2022 due to the COVID-19 pandemic, face-to-face seminars will be resumed in phases in FY2023, considering the recent global situation.

The planned schedule for FY2023 is presented in the following. We look forward to receiving many applications from interested officers who wish to attend the seminar.

For details of the annual schedule, please refer to the following URL:

	Program	Date	Place/method
1	Pediatric Review*1	Jul. 10–13, 2023	Tokyo (PMDA)
2	Quality Control (Herbal Medicine)	Aug. 22–24, 2023	Toyama prefecture
3	Pharmaceuticals Review	Sept. 26–28, 2023	Online
4	Medical Devices (APEC CoE Workshop)*2	Nov. 14–16, 2023	Online
5	Medical Devices (PMDA Workshop)	Dec. 5–7, 2023	Tokyo (PMDA)
6	Multi-Regional Clinical Trials *2, *3	Jan. 23–26, 2024	Tokyo (PMDA)
7	Pharmacovigilance*2	Feb. 19–22, 2024	Online

https://www.pmda.go.jp/english/int-activities/training-center/0004.html

*1 Joint Seminar with U.S.FDA, *2 APEC-LSIF-RHSC CoE Workshop, *3 Collaboration with National Cancer Center Japan

3. The 6th India–Japan Symposium and Bilateral Meeting

The 6th Japan–India Medical Products Regulatory Symposium was held on February 1, 2023, with more than 380 participants, including the members of the Ministry of Health, Labor and Welfare (MHLW), PMDA, Ministry of Health and Family Welfare (MoHFW), Central Drugs Standard Control Organization (CDSCO), and industries in India and Japan. The symposium was held as part of efforts under the "Memorandum of Cooperation" signed between the MHLW and CDSCO in 2015 to promote dialogue and cooperation regarding the regulation of medicinal products. Regulators from each side presented lectures as follows: Keynote speech by Dr. FUJIWARA (PMDA) and Dr. Somani (CDSCO):"Lesson and learning from the Covid-19 pandemic: regulatory agility," including the emergency approval system and the sharing of safety information; Pharmaceutical session with the themes "Regulatory measures to promote Fast Patient Access" and "International Cooperation and Reliance"; Medical devices session, which focused on the activities that Japan was actively engaged in: "Updates on Medical Device and IVD Regulation"; and the Regenerative medicines session: "Updates of Regulation & Recent Trends in Regenerative Medical Products," followed by vitally productive Q&A sessions. On the next day of the symposium, discussions were held between the regulatory agencies of Japan and India on the future cooperation and harmonization of international regulations.

For more details on the symposium, please follow the link.
https://www.pmda.go.jp/int-activities/symposia/0132.html

(photos of symposium opening session)
(top row) middle: Mr. YAMAMOTO Akio (Vice Chairman, Japan Federation of Medical Devices Associations), Ms. YAMAMOTO Fumi (Councilor for Pharmaceutical Affairs, MHLW), Dr. SHIRAISHI Junichi (Director General, Japan Pharmaceutical Manufacturers Association)
right: Dr. SATO Junko (Director of International Program, PMDA)
(middle row) left: Mr. Rajiv Wadhawan (MoHFW),
middle: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA),
right: Dr. V.G. Somani (Drugs Controller General, CDSCO),
(bottom row) left: Mr. Himanshu Baid (Representative of Indian Medical Device industry),
right: Mr. Ravi U Bhaskar (Director General, Pharmexcil)

4. PMDA-ATC Pharmacovigilance Webinar 2023

From February 6 to 9, 2023, the PMDA held a webinar entitled "PMDA-ATC Pharmacovigilance Webinar 2023," as the Center of Excellence (CoE) Workshop in the field of pharmacovigilance recognized by the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC). This webinar was designed for regulatory officials in charge of pharmacovigilance (PV) from overseas regulatory authorities. A total of 31 regulators from 16 economies (Azerbaijan, Bhutan, China, Chinese Taipei, Ethiopia, India, Indonesia, Malaysia, Myanmar, the Philippines, Saudi Arabia, South Korea, Singapore, Thailand, Tunisia, and Uganda) participated in the webinar.

Before attending the live webinar, the participants took the PMDA-ATC E-learning course, "Pharmacovigilance." The live webinar comprised lectures and Q&A sessions on evaluation of benefit/risk balance, labeling process including e-labeling, PV of COVID-19 vaccines, recent PV activities in the United States, pharmacoepidemiology, and utilization of real-world data. The participants engaged in the case study group discussion on safety specifications, causality assessment, and risk minimization activities under the theme of risk management plan on the 2nd and 3rd days , and on the PV methods on the final day. A total of 19 lecturers and facilitators from the Japan Pharmaceutical Manufacturers Association (JPMA), Kitasato University, Keio University, U.S. FDA, and PMDA delivered lectures and facilitated group discussions.

From the top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), Mr. HORIUCHI Naoya (Senior Coordinator for International Training, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
In the middle: lecturers and facilitators
At the bottom: webinar participants

Please refer to the following website for details of PMDA-ATC Pharmacovigilance Webinar 2023.
https://www.pmda.go.jp/english/symposia/0264.html

5. Japan Officially Joins the Global Harmonization Working Party (GHWP) as Member

The GHWP annual meeting was held in Riyadh, the Kingdom of Saudi Arabia, from February 13 to 16,2023. Mr. TAKAHATA Masahiro, Director, Pharmaceutical Safety and Environmental Health Bureau, the Ministry of Health, Labor and Welfare (MHLW); Dr. KUSAKABE Tetsuya, International Coordination Officer, PMDA; and a staff member from the PMDA participated in the meeting.

The GHWP is one of the frameworks of the international harmonization of medical device regulations and communicates with the International Medical Device Regulators Forum (IMDRF).

At the meeting, the MHLW and PMDA, as Japanese regulatory authorities, and the Japan Federation of Medical Devices Associations (JFMDA), as representatives of the Japanese industry, were endorsed as members of the GHWP. Japan became the 33rd GHWP participating member. Mr. TAKAHATA expressed his appreciation for the

accession to the GHWP and the willingness to engage in the activities of the GHWP in the future. In addition, Dr. KUSAKABE took part in a panel discussion of fit-for-purpose change plans and explained operational states of the IDATEN (Improvement Design within Approval for Timely Evaluation and Notice) system, and a PMDA member made a presentation on Japan's regulatory updates including regulations related to marketing approval in emergencies and Software as a Medical Device.

We will further promote the harmonization of medical device regulations through these activities.

6. GCP symposium and PMDA-ATC GCP case study seminar 2023 in Bangkok, Thailand

The PMDA co-hosted the "GCP Symposium" and "PMDA-ATC GCP case study seminar 2023" at Bangkok, Thailand, on February 22, 2023, with the National Cancer Center, Food and Drug Administration Thailand (Thai FDA) and Faculty of Medicine, Siriraj Hospital, Mahidol University.

From the PMDA, Dr. SATO Junko (Director of Office of International Programs) and other staff members from the Office of Non-clinical and Clinical Compliance and Office of International Programs participated. A total of around 100 people from regulatory authorities, academia, and industries from Thailand and Japan participated. The themes of the symposium were GCP inspection and clinical trial. The latest information and opinions on the theme in both countries were exchanged.

The target of the "PMDA-ATC GCP case study seminar 2023" was Thai FDA and the academia in Thailand, and 32 individuals participated in it. The program of the seminar included lectures by the PMDA and NCC staffs on the topics of the GCP on-site inspection followed by practical case studies.

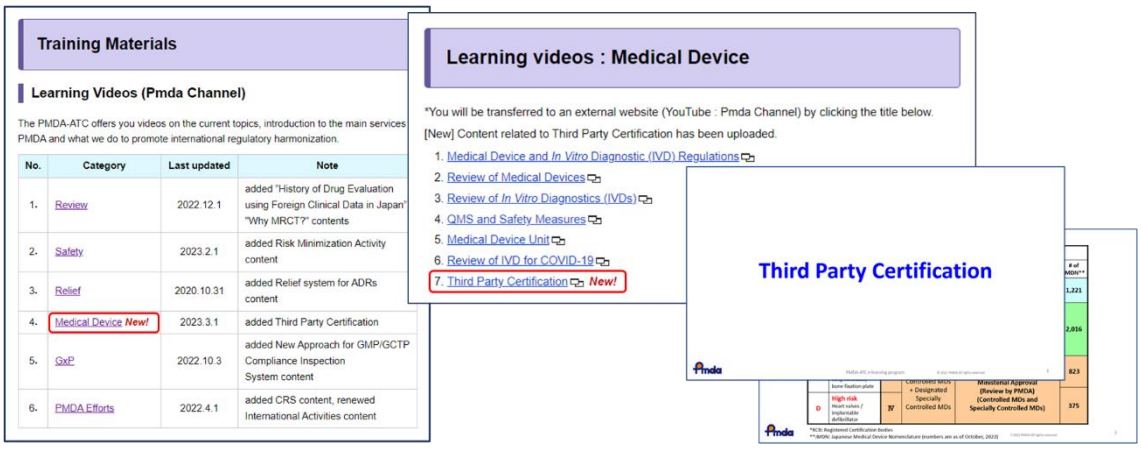
The PMDA continuously makes efforts to strengthen collaboration with the Thai FDA and support the building of the environment, thereby leading to the creation of clinical evidence in Thailand and the Asian region through training offered by the PMDA-ATC.

7. PMDA-ATC E-learning: Updated learning video 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 a new content video, entitled "Third Party Certification" in the "Medical Device" category of the Learning Videos.

For certain areas of medical devices and in vitro diagnostics (IVDs), the Minister of Health Labour and Welfare specifies the certification standards for ensuring the safety and effectiveness of the product, and if the conformity to such standards is certified by the third-party certification body (registered certification body: RCB), such products can be marketed without the review by the PMDA. This content explains the range of medical devices and IVDs subject to the third-party certification, certification criteria, and process and the requirements for RCBs.

Please follow this link to access the learning video contents:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



8. Call for applications: PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC), together with the Food and Drug Administration of the United States (U.S. FDA) will hold the "PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023," at the PMDA Office in Tokyo from July 10 to 13, 2023. This seminar is designed for pediatric drug application reviewers from overseas regulatory authorities. The objective of the seminar is to provide the participants with the opportunities to learn about global standard guidelines on the review of drug products being developed for the pediatric population and acquire knowledge and perspectives on a wide range of topics including pediatric clinical trials through lectures and case studies, and thus encourage the development of pediatric drugs in the participants' own countries or regions.

Please refer to the following website for details of the seminar and application method for PMDA-ATC & U.S. FDA Pediatric Review Seminar 2023.

https://www.pmda.go.jp/english/symposia/0263.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
Rinvoq [Partial Change Approval]	upadacitinib hydrate	February 8, 2023
Tavneos [Initial Approval]	avacopan	February 8, 2023
Hiyasta [Initial Approval]	tucidinostat	February 13, 2023
Moizerto [Initial Approval]	difamilast	February 16, 2023
Ostabalo [Initial Approval]	abaloparatide acetate	March 3, 2023
Cibinqo [Initial Approval]	abrocitinib	March 3, 2023

Medical Devices

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

Brand Name	Term Name	Posting date

ENROUTE Transcarotid Neuroprotection System[Initial Approval]	Catheter for embolic capture in the central circulatory system	February 17, 2023
Edwards SAPIEN 3 [Partial Change Approval]	Transcatheter bovine cardiac valve	March 3, 2023

Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
Abecma [Initial Approval]	idecabtagene vicleucel	February 17, 2023

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 399 (March 14, 2023)

1. Safety Control Measures for Generic Lenalidomide Preparations
2. Important Safety Information
   (1) Preparations containing GLP-1 receptor agonists and tirzepatide
   [1] Liraglutide (genetical recombination), [2] Exenatide, [3] Lixisenatide, [4] Dulaglutide (genetical recombination), [5] Semaglutide (genetical recombination), [6] Insulin degludec (genetical recombination)/liraglutide (genetical recombination), [7] Insulin glargine (genetical recombination)/lixisenatide, [8] Tirzepatide
   (2) Tazobactam/piperacillin hydrate
3. Revision of Precautions (No. 339)
   Exenatide, semaglutide (genetical recombination), dulaglutide (genetical recombination), lixisenatide, liraglutide (genetical recombination), insulin glargine (genetical recombination)/lixisenatide, insulin degludec (genetical recombination)/liraglutide (genetical recombination) (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/0020.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
April 18	The 12th Asia Partnership Conference of Pharmaceutical Associations	Tokyo
April 19	5th Asian Network Meeting	Tokyo
May 24–26	ASEAN-Japan Risk Management Plan Symposium 2023 ASEAN-Japan Risk Management Plan Seminar 2023	Jakarta

Reports from Overseas

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

Scientific Advice pilots for certain high-risk medical devices

EMA has launched a pilot to provide scientific advice to manufacturers of certain high-risk medical devices (all class III devices and class IIb active devices intended to administer and/or remove medicinal product(s)). As per Article 61(2) of Regulation (EU) 2017/745 [1)] on medical devices, the expert panels may give scientific advice to

manufacturers of some high-risk medical devices. The scope of the scientific advice is the clinical development strategy and proposals for clinical investigation of high-risk medical devices. This pilot is scheduled to continue for 1 year.

The pilot will prioritise certain types of medical devices such as; orphan devices (devices for the treatment of rare condition) and devices for pediatric use, devices addressing life threatening or cause permanent impairment of a body function, and novel devices with a possible major clinical or health impact [2]. From the end of February, the agency is accepting letters of interest [3] from companies that would like to be considered for the pilot. The expert panels will select ten applicants and provide free advice. The first five applications will be selected in April. Question and Answer on the submission of applications is currently being published at EMA website [4].

Once the pilot has been completed, EMA will assess the process and the applicant's and experts' experience, and will hold a meeting with stakeholders to discuss potential improvements. Moreover, this pilot will help to establish an efficient scientific advice procedure. Scientific advice is a key tool to foster innovation and promotes faster patient access to safer and more effective devices.

Thus, for medical devices, the EMA's role is likely to increase in the future to expedite access to safe and effective medical devices for patients.

1) Article 61(2) of Regulation (EU) 2017/745 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG
2) Information on EMA website https://www.ema.europa.eu/en/events/information-session-pilot-expert-panels-scientific-advice-manufacturers-high-risk-medical-devices
3) Letter of interest template for online application https://www.ema.europa.eu/en/documents/template-form/letter-interest-template-online-application-information-session-pilot-expert-panels-scientific_en.pdf
4) Question and Answer on the submission of applications for the expert panels' advice to manufacturers https://www.ema.europa.eu/en/documents/other/question-answer-information-session-pilot-expert-panels-scientific-advice-manufacturers-high-risk_en.pdf

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