PMDA Updates

September 2022

News

1. PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022

The PMDA held the "PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022" from August 23 to 25. It was designed for officials of overseas regulatory agencies engaged in drug reviews and attended by 25 regulators from Azerbaijan, Bhutan, Botswana, China, Ethiopia, India, Laos, Malaysia, Mexico, Pakistan, the Philippines, Saudi Arabia, Sri Lanka, Sudan, Taiwan, Thailand, and Tunisia.

Before attending the webinar, participants took the PMDA-ATC E-learning course, "Quality Control (Herbal Medicine)" covering the following topics: Regulation and Review Process of Over-the-Counter (OTC) Drugs, Japanese Pharmacopoeia (JP), Non-JP Crude Drug Standards, Approval Standards for OTC Kampo Medicines and Crude Drug Preparations, GMP Inspection by Prefectural Authorities, Efforts of the Center for Medicinal Plant Resources. The webinar comprised lectures and Q&A sessions on: Overview of Regulations on Herbal Medicines in Japan, Quality Evaluation of Crude Drugs, Quality Management and Manufacturing Management of Crude Drugs, Overview of JP and Approval Standards for OTC Kampo Medicines and Crude Preparations, as well as case studies including group discussions on "GMP Inspection for Herbal Medicines" and "Approval of Herbal Medicines based on the Approval Standards."

From the top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Ms. ISHIDA Miki (Director, Pharmaceutical Policy Division, Health, and Welfare Department of Toyama Prefectural Government)
In the middle: webinar lecturers
At the bottom: webinar participants

Please refer to the following website for details on the PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022.
https://www.pmda.go.jp/english/symposia/0235.html

2. Regulatory Affairs Workshop in the Danish embassy

The Regulatory Affairs Workshop was convened at the Royal Danish embassy of Japan on August 31, 2022. Delegates from the Danish Medicines Agency (DKMA), personnel from the Royal Danish embassy, representatives from Danish pharmaceutical companies and academia attended the workshop, as did six representatives from PMDA, including Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), Dr. SATO Junko (Director of the Office of International Programs), and Mr. YASUDA Naoyuki (Director of the Office of International Regulatory Affairs) from the Ministry of Health, Labour and Welfare (MHLW). Presentations on the status and issues concerning pharmaceutical and medical device regulations were delivered at the workshop, and Mr. UZU introduced topics such as the SAKIGAKE designation system (expedited review pathway) and the use of real-world evidence. The presentations were followed by Q&A sessions where questions from Danish pharmaceutical companies were answered, and attendees actively exchanged information on the Japanese and Danish regulations.

In addition, a bilateral meeting between the DKMA and MHLW/PMDA was held ahead of the workshop, wherein areas for future collaboration were actively discussed.

Mr. UZU Shinobu (Senior Executive Director) giving a presentation at the Workshop

Participants of the bilateral meeting

3. Call for applications: PMDA-ATC Pharmaceuticals Review Webinar 2022

The PMDA-ATC will hold the "PMDA-ATC Pharmaceuticals Review Webinar 2022" on November 29 (preliminary session) and from December 6 to 8 through a web conference system. This webinar was designed by overseas regulatory authorities for pharmaceutical reviewers. The objective of the webinar is to provide the participants with opportunities to acquire knowledge and perspectives on the new drug review and orphan drug review, as well as the generic drug review through online lectures and case study-based group discussion, and consequently apply them to enhance the regulatory system in the participants' own organizations.

Please refer to the following website for details on the PMDA-ATC Pharmaceuticals Review Webinar 2022:
https://www.pmda.go.jp/english/symposia/0241.html

4. PMDA-ATC E-learning Updated 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 "E-Labeling system in Japan" in the "Safety" category.

In Japan, it is necessary to provide information such as composition, indication, dosage and administration, warning, contraindication, etc. to healthcare professionals, as the product labeling. Moreover, the provision of relevant information is necessary for the safe utilization of drugs. To provide such up-to-date information, the

PMDA transforms documentations such as labeling, drug guides for patients, interview forms, risk management plans, etc. in an electronic format and makes them available on its homepage, so that healthcare professionals and patients can access the information easily and in a timely manner. This content introduces the E-labeling system in Japan, which enables efficient provision of drug safety information in an electronic form.

Please follow this link to access the e-learning website:
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
Xarelto [Partial Change Approval]	rivaroxaban	August 12, 2022
Jyseleca [Initial Approval]	filgotinib maleate	August 19, 2022
Freeze-dried Smallpox Vaccine Prepared in Cell Culture LC16 "KMB" [Partial Change Approval]	freeze-dried smallpox vaccine prepared in cell culture	August 23, 2022

Regenerative Medical Products

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

Brand Name	Generic Name	Posting date
Sakracy [Initial Approval]	human (autologous) oral mucosa-derived epithelial cell sheet using human amniotic membrane substrate	August 25, 2022

English translations of Notifications and Administrative Notices

The following are the English versions of the Notifications and Administrative Notices, newly 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
May 25, 2022	PMDA/CPE Notification No. 0525001	Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products	August 31, 2022

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 394 (August 23, 2022)

1. Genome Research on Drug-induced Interstitial Lung Disease
2. Revision of Precautions for Zolpidem Tartrate, Zopiclone, Eszopiclone, Triazolam
3. Important Safety Information
    1. Durvalumab (genetical recombination)
    2. Avelumab (genetical recombination)
4. Revision of Precautions (No. 334)
   Recombinant COVID-19 (SARS-CoV-2) vaccine (Nuvaxovid Intramuscular Injection) (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/0020.html

Pharmaceuticals Revisions of PRECAUTIONS (August 30, 2022)

- Hydroxychloroquine sulfate
- Ramucirumab (genetical recombination)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Pharmaceuticals Revisions of PRECAUTIONS (September 13, 2022)

- Riociguat
- Atazanavir sulfate
- Ritonavir
- Lopinavir/ritonavir

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
October 20-21	The 10th Joint Conference of Taiwan and Japan on Medical Products Regulation	Tokyo
October 25-26	PMDA-ATC GMP Inspection Webinar 2022	Virtual
November 7-9	ICMRA Summit	Dublin
November 12-16	ICH meeting	Incheon

November 14-16	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022*	Virtual
November 16-17	IPRP meeting	Incheon
November 28-30	PMDA-ATC Medical Devices Webinar 2022	Virtual

* APEC-LSIF-RHSC CoE Workshop

Reports from Overseas

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

Accelerating Clinical Trials in the EU

The European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have published the 2022-2026 workplan [1)] of the Accelerate Clinical Trials in the EU (ACT EU) initiative. The ACT EU initiative aims to develop the EU further as a competitive center for innovative clinical research. The initiative builds on the Clinical Trials Regulation (CTR) [2)] and Clinical Trials Information System's(CTIS) [3)] launch on January 2022, just before the CTR became applicable, and seeks to promote the development of high-quality, safe and effective medicines by strengthening the European clinical-trials environment. The workplan is structured in line with the ten priority actions of ACT EU and highlights key focus areas, such as innovation in clinical trials, robust methodologies and collaboration across stakeholders.

1. Mapping & governance
2. Implementation of CTR
3. Multi-stakeholder platform
4. Good Clinical Practice modernization
5. Clinical trials data analytics
6. Targeted communication campaign
7. Scientific advice
8. Methodologies
9. Clinical trial safety
10. Training curriculum

The deliverables for 2023 include multinational clinical trials, CTIS and CTR training activities, setting up a multi-stakeholder platform, modernizing good clinical practice, publishing a methodology roadmap and providing guidance on decentralized clinical trials.

I will continue to monitor this activity carefully.

1) ACT EU multi-annual Workplan 2022-2026: https://www.ema.europa.eu/en/documents/other/act-eu-multi-annual-workplan-2022-2026_en.pdf
2) CTR: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation
3) CTIS: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme

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