PMDA Updates

July 2023

News

1. PMDA-ATC Pharmaceutical Review Seminar 2023 for DAV, Vietnam

On April 19, 2023, the PMDA hosted "The 5th Asian Network Meeting," a forum for closed discussion among top-level executives of regulatory agencies from Asian countries. It held the "PMDA-ATC Pharmaceutical Review Seminar 2023 for DAV, Vietnam" on April 21, 2023. This seminar was designed for seven staff members of the Drug Administration, Ministry of Health, Vietnam (DAV), who are engaged in the review of pharmaceuticals.

Through the PMDA's information sharing, the DAV staff learned about the PMDA's activities via an overview of new drug approval reviews and visited the Center for Drug Evaluation. The PMDA staff members from the Office of New Drug II and the Office of International Programs also had fruitful discussions with them regarding related issues during the Q&A sessions.

The PMDA continues to help improve the DAV's capacity building through training opportunities and other forms of support that both sides have agreed on.

2. PMDA-ATC GMP Inspection Seminar 2023 in New Delhi, India

On May 29, 2023, the PMDA held a seminar titled "PMDA-ATC GMP Inspection Seminar, 2023 in New Delhi, India" in New Delhi, India, for regulatory officials of the Central Drugs Standard Control Organization (CDSCO), a national drugs regulatory authority of India, and various state and union territories of India. Approximately 80 regulatory officials participated in the seminar.

The seminar opened with remarks from Dr. OGATA Akiko (Division Director, Division of Asia I, Office of International Programs, PMDA) and Dr. Rubina Bose (Deputy Drug Controller, CDSCO-Head Quarter (HQ)). The seminar sessions provided opportunities for the active exchange of opinions on the themes of GMP regulations and experiences in Japan and India, Japan's preparation for accession to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), and various Quality Risk Management (QRM) tools. The seminar concluded with closing remarks by Dr. V.G. Somani (Joint Drug Controller, CDSCO-HQ).

The feedback was collected through seminar evaluation forms, and digital certificates (open badges) were given to the participants.

Top: CDSCO seminar participants
Bottom: PMDA inspectors

Top: Dr. V.G. Somani (CDSCO)
Middle: Dr. Rubina Bose (CDSCO)
Bottom: Dr. OGATA Akiko (PMDA)

3. ICH Meeting in Vancouver

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met from June 10 to 13 in Vancouver, Canada. Dr. OKUDAIRA Shinichi (Division Director, Division of Regulatory Cooperation Office of International Programs, Office of International Programs, PMDA), Working Group Experts, and Mr. YASUDA Naoyuki (Office Director, Office of International Regulatory Affairs from the Ministry of Health, Labour and Welfare (MHLW)) attended these meetings with other officers from the MHLW and PMDA.

The main outcome of the meeting was the further expansion of the ICH membership. The ICH Assembly welcomed the Egyptian Drug Authority (EDA), Egypt, as a new member, and the National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria, as a new observer, bringing the ICH membership to 21 members and 36 observers. The Assembly also adopted three new topics, including "Nonclinical Safety Studies for Oligonucleotide-based Therapeutics" proposed by the MHLW/PMDA and European Commission (EC), for harmonisation at the meeting, with the starting timeframe set to be in 2024 or later. In addition, the Assembly approved a new ICH Reflection Paper (a document that presents opportunities for a strategic approach to future ICH Guideline development) titled "International Harmonisation of Real-World Evidence (RWE) Terminology and Convergence of General Principles Regarding Planning and Reporting of Studies Using Real-World Data (RWD), with a Focus on Effectiveness of Medicines" and it will be released for public consultation. Moreover, the Assembly supported the formation of a new expert discussion group in the future based on the Reflection Paper on Strategic Approach to International Harmonisation of Cell and Gene Therapy Products, which had been approved prior to the meeting.

Since the last ICH meeting, Q9(R1) reached Step 4 (Adoption of an ICH Harmonised Guideline) of the guidelines on "Quality Risk Management"; S12 reached Step 4 of the guidelines on "Nonclinical Biodistribution Considerations for Gene Therapy Products"; and M7(R2) reached Step 4 of the guidelines on "Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk" and accompanying Addendum titled "Application of the Principles of the ICH M7 Guideline to the Calculation of Compound-Specific Acceptable Intakes."

In addition, Mr. YASUDA was elected as the new ICH Management Committee Vice-Chair, following the mid-term departure of the previous Vice-Chair in March. Mr. YASUDA is expected to serve until the autumn of 2023, which is the remainder of the previous Vice-Chair's term.

The next ICH meeting is scheduled from October 28 to November 1, in Prague, Czech Republic.

4. The 15th Drug Information Association (DIA) China Annual Meeting

The Drug Information Association (DIA) China Annual Meeting 2023 was held from June 16 to 19, 2023, in Suzhou, China. Dr. SATO Junko (Director of the Office of International Programs), four staff members from the PMDA, and a staff member from the Ministry of Health, Labour and Welfare (MHLW) virtually participated in the five sessions mentioned below.

Dr. SATO chaired the "Japan Town Hall," with a speaker from the Japan Pharmaceutical Manufacturers Association, while staff members of the PMDA and MHLW shared information about the system and efforts being made to implement digital transformation, including online applications and e-labeling, from the perspectives of both the government and industry. Through the panel discussion and questions from the floor, an active exchange of opinions took place, and a further understanding of Japan's efforts for medical digitalization was promoted.

Capacity building for regulators and industry to implement ICH guidelines was introduced in the "ICH Day Plenary" session, while the ICH E17 implementation and challenges in Japan was introduced in the "ICH Day E17" session. In a session titled "Rare disease drug development," a regulatory approach to promote orphan drug development in Japan was shared. In addition, PMDA's approach to good review practice was introduced by its staff members in the "Global Regulatory Modernization Townhall."

The PMDA regards this meeting as a tool to strengthen the relations with China and would like to continue participation.

5. PMDA-ATC Introduced "Open Badges" as Digital Certificates

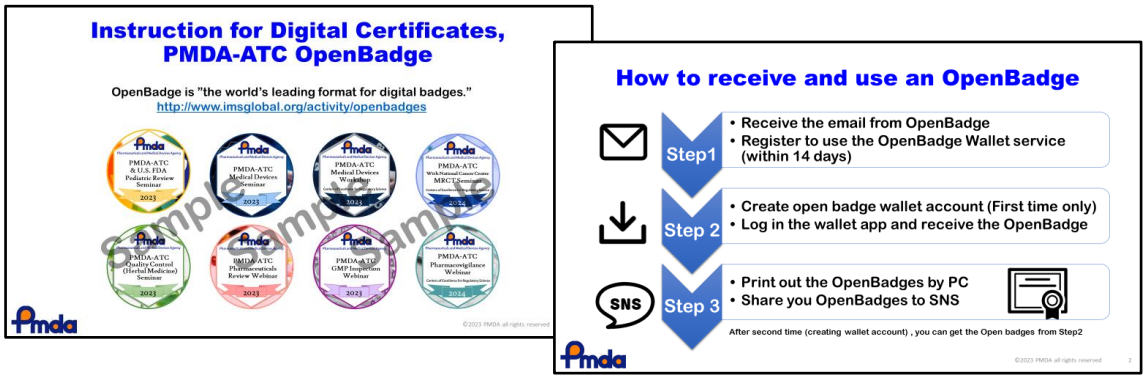
The PMDA issues certificates to those who have completed PMDA-ATC seminars and webinars. In response to the recent digitization, the PMDA has started to issue these certificates as "Open Badges," which are digital certificates and certifications issued in compliance with the IMS Global Learning Consortium, a global technical

standard. Open Badges have metadata (e.g., an explanation of the badge, earning criteria, learning, and skills) embedded in the images and can be published online, on social networking sites, and in email signatures.

The participants of applicable seminars and webinars will receive an Open Badge according to the email sent by Open Badge.

For more information of "Open Badges," please refer to the link below.

http://www.imsglobal.org/activity/openbadges



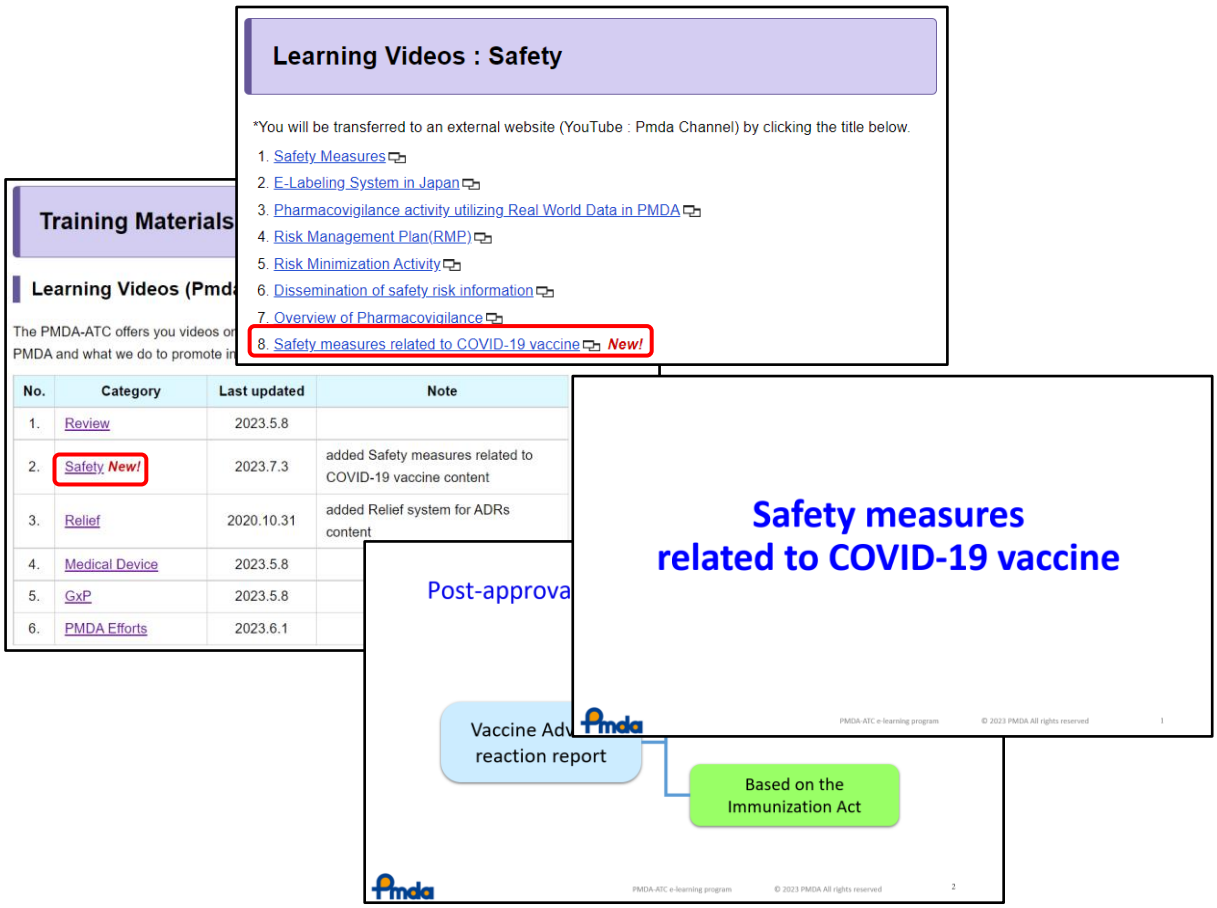
6. PMDA-ATC E-learning: Updated Learning Video Content Information

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 "Safety measures related to COVID-19 vaccine" in the "Safety" category of the Learning Videos.

The video introduces the vaccine adverse reaction reporting system in Japan. This explains how COVID-19 vaccine safety measures were implemented during the pandemic.

Please follow this link to access the learning video contents:

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
Mitchga [Initial Approval]	nemolizumab (genetical recombination)	June 16, 2023
Comirnaty Intramuscular Injection for 5 to 11 years old [Special Approval for Emergency, Partial Change Approval]	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (Active ingredients: (a) Tozinameran, (b) Tozinameran and Famtozinameran)	June 21, 2023

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
Sep. 27, 2018	PSEHB/PED Notification No. 0927-3	Points to Consider for Quality Assurance and Evaluation of Oligonucleotide Therapeutics	June 30, 2023
Jun. 9, 2022	PSEHB/PED Administrative Notice	Questions and Answers (Q&A) on "Points to Consider for Quality Assurance and Evaluation of Oligonucleotide Therapeutics"	June 30, 2023

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 402 (July 11, 2023)

1. The Manuals for Management of Individual Serious Adverse Drug Reactions
2. Reports from Healthcare Professionals on Adverse Drug Reactions/Infections/Malfunctions and Post-vaccination Suspected Adverse Reactions Are to Be Sent to the PMDA Online [Report Reception Site]
3. Important Safety Information
    1. [1] Nivolumab (genetical recombination)
       [2] Ipilimumab (genetical recombination)
4. Revision of Precautions (No. 342)
   Haemophilus influenzae type b conjugate vaccine (tetanus toxoid conjugate) (and 2 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
August 22–24	PMDA-ATC Quality Control (Herbal Medicine) Seminar 2023	Toyama
September 25–29	IMDRF Management Committee Meeting	Berlin
September 26–28	PMDA-ATC Pharmaceuticals Review Webinar 2023	Virtual

Reports from Overseas

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

OPEN initiative

During the COVID-19 pandemic, EMA initiated the OPEN (Opening Procedures at EMA to Non-EU authorities) pilot. This pilot was targeted only for Covid-19 related therapeutics and vaccines. The pilot enhanced communication channels and facilitated discussions and exchanges. Moreover, Open allowed regulators to accelerate and align on decisions [1)].

The OPEN pilot on COVID-19 vaccines and therapeutics is terminated. EMA has extended the scope of OPEN in June 2023 [2)] based on a review of the pilot's first year, to cover medicines intended to help combat Antimicrobial resistance, designated under the PRIME (priority medicines scheme), products that address a high unmet medical need, and products intended to address Public health threats and public health emergencies. Regulators from Australia, Brazil, Canada, Switzerland, the World Health Organization and Japan participate under the terms of existing confidentiality arrangements with EMA. All the participants may attend and contribute to meetings of EMAs Committee for Medicinal Products for Human Use (CHMP) and Emergency Task Force (ETF).

OPEN aims at facilitating sharing of scientific expertise to tackle common challenges, facilitating alignment of regulatory approaches between regulatory authorities, speeding up patient access to innovative medicines and enhancing transparency on regulatory decision. EMA publishes a revised Q&A on the OPEN framework on 3rd July 2023 [3)] and it contains a more detailed description.

It is hoped that such activities will be further stimulated to speed up access to medicines for patients and standardize the review process.

1) OPEN Pilot: One-year review and recommendations https://www.ema.europa.eu/en/documents/report/open-pilot-one-year-review-recommendations_en.pdf
2) OPEN initiative https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/opening-procedures-ema-non-eu-authorities-open-initiative#scope-and-development-of-open-section
3) Questions and Answers on the 'OPEN' Framework https://www.ema.europa.eu/en/documents/other/questions-answers-open-framework_.pdf

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