PMDA Updates

January 2023

News

1. New Year's Greetings from the Chief Executive, Dr. FUJIWARA

I wish you all a happy new year.

This marks the fourth year we have been living with the COVID-19 pandemic. We have always had the awareness that we are performing essential duties to support the health of the citizens of our nation and have worked as one to ensure that each task of review, safety, and relief is carried out without fail at all times.

Chief Executive, Dr. Fujiwara

Last year, the PMDA established the Business Process Re-engineering/Digital Transformation (BPR/DX) Promotion Office and is working on various efforts to promote operational efficiency and digitalization. As a result, we were able to establish a remote working environment, ensure business continuity during the COVID-19 pandemic, and initiate online applications for pharmaceutical products and medical devices.

As we approach the final year of the fourth Mid-Term Plan, this will be an important year as we work to develop the fifth Mid-Term Plan. Under the PMDA's philosophy and the "4 Fs (Patient First, Access First, Safety First, Asia First)" that I have upheld since my appointment as the Chief Executive, I would like to continue working to further develop the PMDA this year as well.

In the area of reviews, we aim to become an organization that can give the world's first approval to 30 to 40% of products that will be given the world's first approval (international birth date) in the future. Our vision of the future is that not only regulatory authorities in Asia but also regulatory authorities in the world will conduct reviews for marketing authorization and approval by referring to the content of the review performed by the PMDA.

In the area of safety, in addition to existing safety measures, we will consider new information sources and further utilize pharmacoepidemiological methods, with the aim of building an efficient system that matches the digitalized future and continue our efforts toward improvement. In addition, we aim to contribute to the health of citizens around the world by having safety measures in Japan that can be used as a reference for other countries around the world.

The relief services for adverse health effects are important measures that support the lives of patients who suffer from adverse reactions. We will work to improve operational efficiency, including digitalization, to further disseminate and facilitate the use of the system.

Furthermore, in order to make the PMDA a more stable and strong organization, we will work to identify outstanding human resources and develop and retain PMDA staff.

Finally, while continuously ensuring transparency, the PMDA will value communication with all our stakeholders within Japan and around the world, including patients and the public, and further strengthen relationships of trust. We will fulfill our responsibilities as a leading global regulatory authority by working together with our stakeholders.

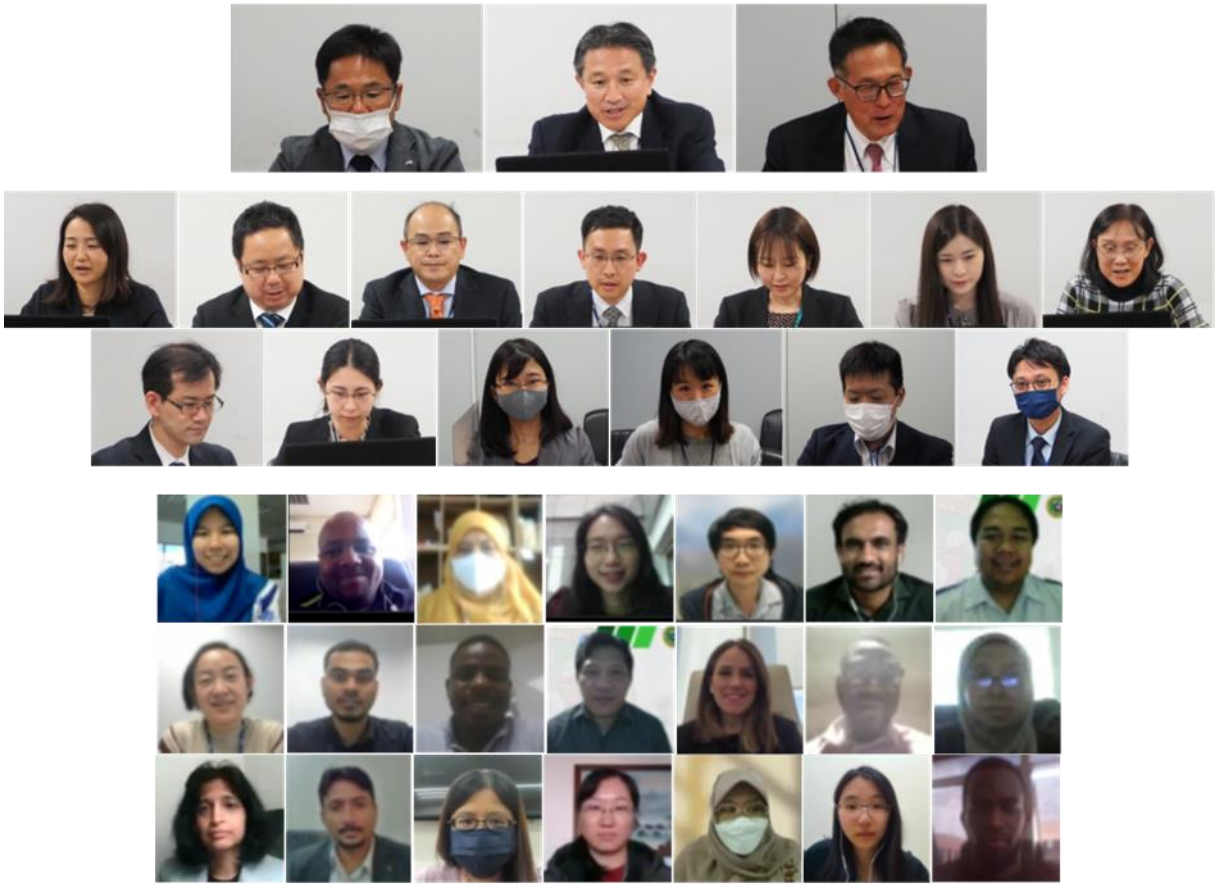
With this, I wish you all a very happy new year ahead!

2. APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022

The PMDA-ATC, as a Center of Excellence (CoE) for Regulatory Science in the field of medical devices by the

Asia Pacific Economic Cooperation, Life Science Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC), held a workshop entitled "APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022-Explanation of/Insight into the International Medical Device Regulators Forum (IMDRF) documents," From November 14 to 16, 2022. This workshop was intended for officials of overseas regulatory agencies involved in the review of medical devices and in vitro diagnostics (IVDs). Twenty-six regulators from Azerbaijan, Canada, China, Chinese Taipei, Ghana, Hong Kong, India, Indonesia, Malaysia, Pakistan, Peru, the Philippines, Tanzania, Turkey, the United States, Uganda, and Zimbabwe participated in the webinar.

The participants were required to take the PMDA-ATC E-learning course "Medical Devices Review" as preparation prior to the webinar. On the first day of the webinar, lectures on the international harmonization of medical device regulations, review of medical devices, QMS inspection for medical devices, and post-marketing safety measures for medical devices were given with subsequent Q&A sessions. Examples of clinical evaluation of medical devices and post-market safety measures for medical devices were given as case study materials on the second and the third day and the participants discussed intensively in four groups to form opinions. In addition to PMDA staff, a lecturer from Tohoku University Hospital was invited to provide academic insights.



From the top left: Dr. ISHII Kensuke (Senior Coordinator for International Training, PMDA), UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
In the middle: webinar lecturers
At the bottom: webinar participants

Please refer to the following website for details of the APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022 -Explanation of/Insight into the IMDRF documents.
https://www.pmda.go.jp/english/symposia/0239.html

3. PMDA-ATC PV Webinar 2022 for FDA Philippines, PMDA-ATC GCP inspection in MRCT Webinar 2022 for FDA Philippines

The PMDA held the PV (pharmacovigilance) webinar for the Food and Drug Administration, Republic of the Philippines (FDA Philippines), on November 21, 2022. It was designed for reviewers working in pharmacovigilance

in the FDA Philippines and included 52 participants. In the webinar, PMDA staff from the Office of Pharmacovigilance I, Office of Pharmacovigilance II, and Office of International Programs gave a lecture on GCP Inspections. A Q&A session was also held to enhance understanding of the topic.

The PMDA also held the GCP webinar for the FDA Philippines on December 6, 2022. It was designed as a regulator of pharmaceutical products in the FDA Philippines and included 32 participants. In the webinar, a PMDA staff member from the Office of Non-clinical and Clinical Compliance gave a lecture and case study on GCP inspection. A Q&A session was also held to enhance understanding of the topic.

The PMDA continuously makes efforts to strengthen collaboration with the FDA Philippines through training offered by the PMDA-ATC for Pharmaceuticals and Medical Devices Regulatory Affairs.

4. PMDA-ATC Medical Devices Webinar 2022

From November 28 to 30, 2022, the PMDA held a webinar entitled "PMDA-ATC Medical Devices Webinar 2022 -Implementation and Adaptation of IMDRF documents in Japanese Medical Device Regulations." This webinar was intended for officials of overseas regulatory agencies involved in reviewing medical devices and in vitro diagnostics (IVDs). Twenty-one regulators from Bhutan, Cambodia, Chinese Taipei, Ethiopia, India, Malaysia, Myanmar, Pakistan, the Philippines, South Africa, Tanzania, Thailand, and the United States participated in the webinar.

The participants were required to take the PMDA-ATC E-learning course "Medical Devices Review" as preparation prior to the webinar. On the first day of the webinar, lectures on regulations of IVDs and IVD medical devices, expedited review pathways, regulation for AI-based medical devices, and development and practical application were given with subsequent Q&A sessions. On the second and third days, examples of high-risk medical device reviews and software as medical device (SaMD) reviews were given as case study materials, and the participants discussed intensively in four groups to form opinions. In addition to PMDA staff, lecturers from the Ministry of Health, Labour, and Welfare, the National Cancer Center Japan, and Tohoku University Hospital were invited to provide academic insights.

From the top left: Dr. ISHII Kensuke (Senior Coordinator for International Training, PMDA), UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
In the middle: webinar lecturers
At the bottom: webinar participants

Please refer to the following website for details of the PMDA-ATC Medical Devices Webinar 2022 - Implementation and Adaptation of IMDRF documents in Japanese Medical Device Regulations.
https://www.pmda.go.jp/english/symposia/0240.html

5. The 3rd Vietnam-Japan Symposium

The 3rd Vietnam-Japan Symposium was held on November 29, 2022, and co-hosted by the Drug Administration of Vietnam (DAV) and PMDA. The event could not be held because of COVID-19 in 2021; it was held virtually in 2022, as it was in 2020. It was attended by more than 137 people in Vietnam and Japan. The participants from Japan included Dr. SATO Junko (Director of the Office of International Programs from PMDA) as well as staff from the Office of International Programs. From DAV, Ms. Vu Thi Hiep (Vice Head of Legal and Inspection Division from DAV), Ms. Nguyen Thi Minh Hoai (Vice Head of Pharmaceutical Business Management Division from DAV), Mr. Le Xuan Hoanh (Vice Head of Drug Registration Division from DAV), and other staff members participated in the symposium.

In this symposium, three sessions on Actions for COVID-19 by regulatory authorities, digitalization in the drug review system, and international collaboration to provide products satisfied with patients' needs in Asia were held. In each session, speakers answered questions from the audience to promote the understanding of pharmaceutical regulations on both sides.

Active discussions on future cooperation between the two countries were held and the development of bilateral relationships is expected.

The program of the symposium can be accessed by clicking on the following link.
https://www.pmda.go.jp/english/symposia/0249.html

Group photo of participants the symposium participants

6. PMDA-ATC Pharmaceuticals Review Webinar 2022

From December 6 to 8, 2022, the PMDA held a webinar titled "PMDA-ATC Pharmaceuticals Review Webinar 2022." It was intended for officials of overseas regulatory agencies involved in pharmaceutical reviews. Thirty-five regulators from Azerbaijan, Chile, China, Chinese Taipei, Egypt, Ethiopia, Hong Kong, India, Indonesia, Malaysia, Pakistan, the Philippines, Saudi Arabia, Sri Lanka, Tanzania, and Uganda participated in the webinar.

The participants were required to take the PMDA-ATC E-learning course "Pharmaceuticals Review" as preparation prior to the webinar. On the first day of the webinar, lectures on new drug approval review, review using foreign clinical data, and regulatory challenges against COVID-19 were offered with subsequent Q&A sessions. On the second day, participants engaged in discussion in the case study group work after attending a lecture on the review of orphan drugs. On the third day, there was a lecture on review of chemistry, manufacturing, and control (CMC) and a group discussion on the review of generic drugs. PMDA staff worked as lecturers and facilitators through the webinar.

From the top left: Dr. SATO Reiko (Senior Coordinator for International Training, PMDA), UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
In the middle: webinar lecturers
At the bottom: webinar participants

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

7. The 4th ICH Forum: ICH Efficacy Guideline Update

"The 4th ICH Forum: ICH Efficacy Guideline Update" was held at AP Hamamatsucho (Minato-ku, Tokyo) on December 8, 2022, in a hybrid style. More than 1200 people, mostly from the pharmaceutical industry, attended the forum.

The forum was held to facilitate the understanding of the Efficacy Guidelines with financial support from ICH. The program and presentation materials can be accessed by clicking on the following link.

https://www.pmda.go.jp/english/symposia/0247.html

Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA) presented the latest updates of the PMDA in the first half of the program. Subsequently, a panel discussion on the future work of ICH was held with panelists from the United States and Japan, who are representatives of the regulatory authorities and industries. In addition, the ICH Awarding ceremony wherein awardees were decided at the ICH meeting in November 2022, was held, and five awardees from Japan were presented tokens.

In the latter half, five presentations were conducted by experts who worked for the Guidelines as Expert Working Group members. A panel discussion on the efficiency and optimization of future pharmaceutical development from the perspective of Efficacy Guidelines was held at the end of the forum. The panelists included regulators, industries, and academia.

The PMDA plans to hold similar forums to exchange information and opinions on topics of high interest with stakeholders.

8. 14th Drug Information Association (DIA) China Annual Meeting (Virtual)

The Drug Information Association (DIA) China Annual Meeting 2022 was held virtually from December 8-11, 2022. Dr. NAKASHIMA Nobumasa (Associate Executive Director), Dr. SATO Junko (Director of the Office of International Programs), a staff member from the PMDA, and a staff member from the Ministry of Health, Labour, and Welfare (MHLW) participated in the four sessions mentioned below:

In a session titled "Global Regulatory Modernization Townhall," Dr. NAKASHIMA provided details of the PMDA's actions against the COVID-19 pandemic and its international activities.

In the "ICH DAY" session, Dr. SATO introduced activities to promote patient engagement in Japan.

In a session titled "Opportunities, Challenges and Suggestions for MAH Implementation in China," a staff member of the MHLW delivered a presentation on the regulatory experience of marketing authorization holder (MAH) implementation in Japan.

Dr. NAKASHIMA and Ms. NAKAGAWA Sachiko (managing director) from the Japan Pharmaceutical Manufacturers Association (JPMA) chaired the PMDA & JPMA Joint Session, "How Japanese Regulatory Authority and Industry Responded to Manage Clinical Trials under COVID-19 Pandemic." Staff members of the PMDA and MHLW shared their experiences and various actions taken in response to the COVID-19 pandemic, and the JPMA delivered a presentation on the industry's efforts to conduct clinical trials during the pandemic.

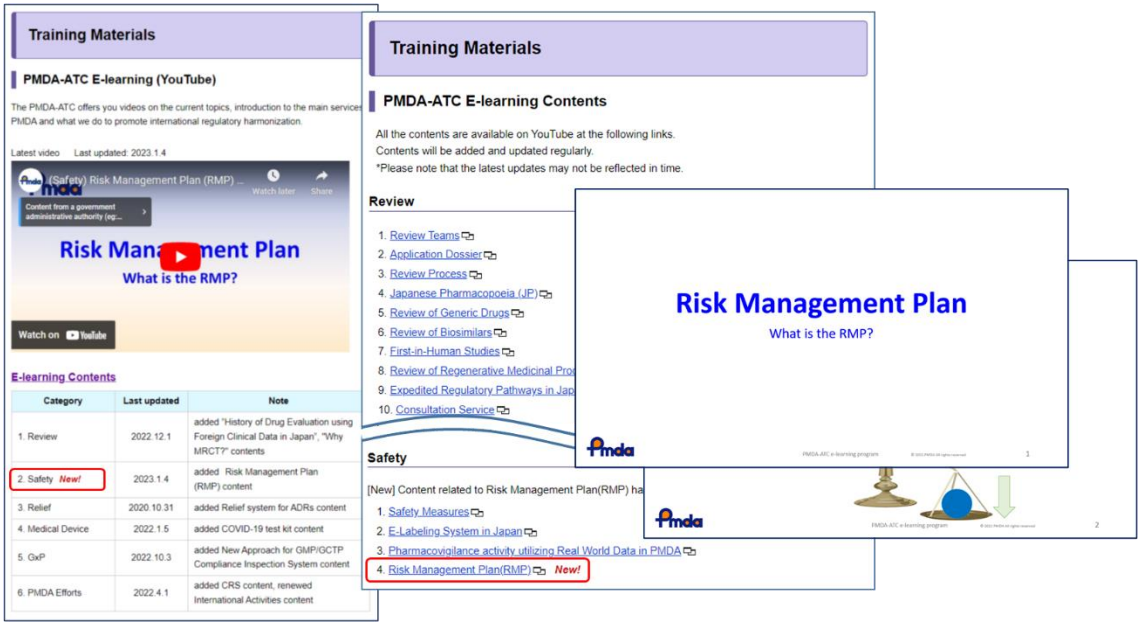
This session was followed by a panel discussion in which an active exchange of opinions among the speakers took place, which led to a greater understanding of Japan's latest actions to address the COVID-19 pandemic in Japan.

9. 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 "Risk Management Plan" in the "Safety" category.

The video introduces an overview of the risk management plan of pharmaceuticals, consisting of safety specifications, pharmacovigilance activities, and risk minimization activities, based on the concept of pharmaceutical risk management, as well as the key differences in the risk management systems among the US, EU, and Japan.

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
Comirnaty Intramuscular Injection for 6 months to 4 years old [Special Approval for Emergency]	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (active ingredient: tozinameran)	January 12, 2023

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 397 (December 14, 2022)

1. Suspected Adverse Reactions to Influenza Vaccines in the 2021 Season
2. Important Safety Information
   (1) Roxadustat
   (2) Preparations containing hydrochlorothiazide
   (3) Imatinib mesilate
3. Revision of Precautions (No. 337)
   Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty RTU intramuscular injection (Bivalent: Original/Omicron BA.1), Comirnaty RTU intramuscular injection (Bivalent: Original/Omicron BA.4-5), Spikevax Intramuscular Injection (Bivalent: Original/Omicron BA.1)) (and 12 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

Pharmaceuticals Revisions of PRECAUTIONS (January 12, 2023)

- Hydroxyethylated starch 70000
- Hydroxyethylated starch 70000/sodium chloride/potassium chloride/calcium chloride hydrate/sodium lactate
- Hydroxyethylated starch 130000

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

Pharmaceuticals Revisions of PRECAUTIONS (January 17, 2023)

- Acetaminophen (oral dosage form, suppositories)
- Tramadol hydrochloride/acetaminophen
- Salicylamide/acetaminophen/anhydrous caffeine/chlorpheniramine maleate
- Salicylamide/acetaminophen/anhydrous caffeine/promethazine methylenedisalicylate
- Diprophylline/dihydrocodeine phosphate/dl–methylephedrine hydrochloride/diphenhydramine salicylate/acetaminophen/bromovalerylurea
- Acetaminophen (injections)
- Isopropylantipyrine/acetaminophen/allylisopropylacetylurea/anhydrous caffeine
- Clopidogrel sulfate
- Clopidogrel sulfate/aspirin
- Alendronate sodium hydrate
- Ibandronate sodium hydrate
- Etidronate disodium
- Zoledronic acid hydrate (preparations indicated for osteoporosis)
- Minodronic acid hydrate
- Sodium risedronate hydrate
- Hydroxychloroquine sulfate
- Imatinib mesilate
- Oral live attenuated human rotavirus vaccine
- Preparations containing acetaminophen (oral dosage form, suppositories) (OTC drugs)

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
February 6-9	PMDA-ATC Pharmacovigilance Webinar 2023	Virtual
February 22	GCP symposium PMDA-ATC GCP case study seminar 2023 in Bangkok, Thailand	Thailand
March 22-24	35th DIA Euro Meeting	Basel
March 27-28	ICH Management Committee Interim Meeting	Lausanne

Reports from Overseas

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

EMA-Vaccines Europe meeting

On 28 November 2022, EMA and Vaccines Europe [1)] held the first bilateral meeting [2)]. The purpose of the meeting is to exchange views and promote dialogue on topics of common interest.

Vaccines Europe, is a specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA), the professional association of the innovative pharmaceutical industry in Europe which created in 1991.

At the meeting, Vaccines Europe presented COVID-19 pandemic learning and highlighted propriety interests such as Electronic Patient Information Leaflet (ePIL), the labelling flexibilities, the Genetically Modified Organisms (GMOs) legislation requirements, the importance of any review of the Vaccine definition in the legislation. They had discussion on experiences of Rolling review/expedite review during the pandemic crisis period, the Emergency use authorization and the Variation regulation revision that Vaccines Europe supports in terms of simplification for vaccines life cycle changes maintenance.

EMA also presented the International cooperation efforts such as ICMRA (International Coalition of Medicines Regulatory Authorities) collaborative assessment/hybrid inspection pilot status, OPEN pilot initiative (Antimicrobial resistance, collaborative assessment of CMC, PRIME products, and COVID-19 learnings/future public health emergencies), and establishment of the Quality innovation Group (QIG) to support innovative manufacturing approaches.

Also this meeting covered the close cooperation between EMA, European Health Emergency Preparedness and Response Authority (HERA) and European Centre for Disease Prevention and Control (ECDC).

They also had a discussion to address vaccine hesitancy which include importance of relevant and appropriate interactions with industries, the use fact-based science and adequate/meaningful communication, transparency on clinical study data.

It was decided that ongoing communication is important and to hold this meeting annually.

1) Vaccines Europe https://www.vaccineseurope.eu/
2) First European Medicines Agency - Vaccines Europe meeting https://www.ema.europa.eu/en/events/first-european-medicines-agency-vaccines-europe-meeting

Ms. UEDA Mami
PMDA's International Liaison Officer stationed at EMA in the Netherlands

