PMDA Updates

January 2022

News

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

I wish you all a happy new year 2022.

This marks the third year we have been living with coronavirus. Last year, in order to support the health of the Japanese people, the PMDA made every effort to provide advice at the development stage, swift reviews, post-marketing safety measures and other activities for various medical products, including COVID-19 related products, within our review, safety, and relief departments.

The outbreak of infection with the Omicron variant of SARS-CoV-2 is spreading; however, the PMDA's work is essential for maintaining public health and social life, and should not be allowed to stagnate. On January 1st, we established the Business Process Re-engineering/Digital Transformation (BPR/DX) Promotion Office to strengthen our efforts in improving business processes and to transform the PMDA into an organization that can continue to compete in the coming future generations.

Since my appointment, I have placed importance on communication with each and every one of the PMDA employees in order to make it easier for them to do their work. As of the end of December last year, I have already held individual interviews with over 900 employees. We will implement further reforms to maximize the capabilities of the PMDA by utilizing the ideas of our employees.

FUJIWARA Yasuhiro, MD, PhD
Chief Executive

First, the medium- to long-term goals of the PMDA are to recruit, develop, and retain the right personnel, and to improve awareness in promoting our DX initiative as mentioned above. By moving this DX initiative forward, we will improve the workplace environment to make it easier for employees to work, and I am confident that this initiative will contribute to the retention of our employees and lead to more stable operations within the PMDA.

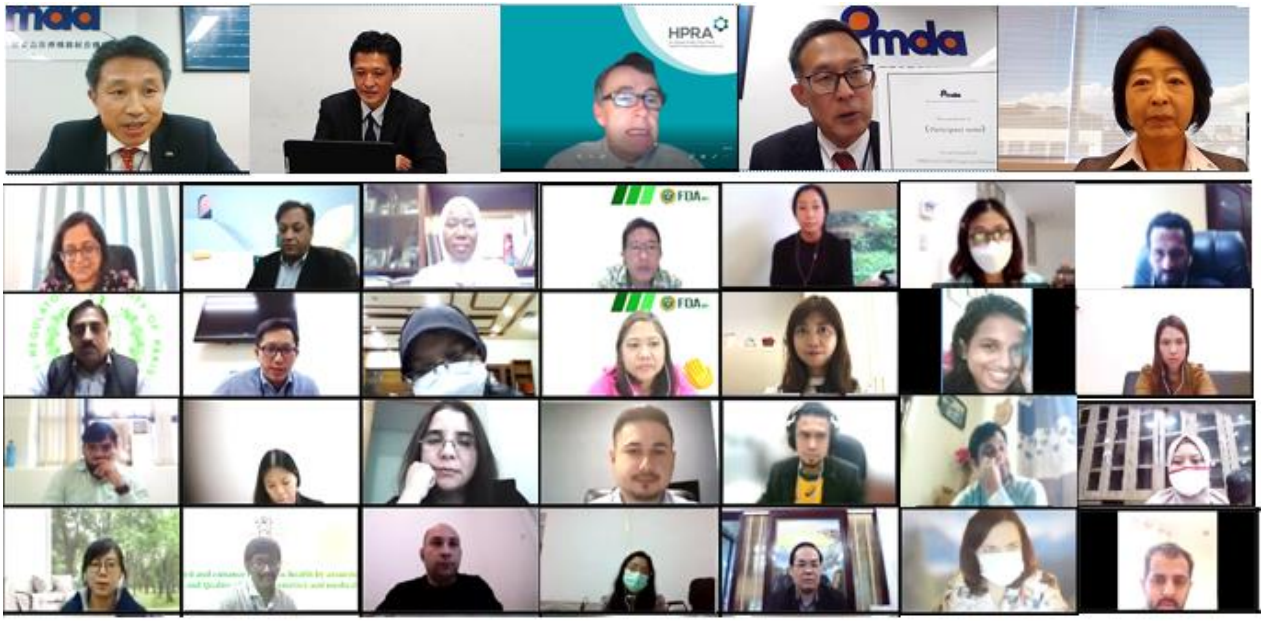
Finally, the PMDA will continue to enhance good communications and trust with all stakeholders within Japan and around the world, including patients. We will work together with stakeholders to promptly respond to changes in society and fulfill our responsibilities as a leading global regulatory authority.

I sincerely hope that this will be a joyful, healthy and safe new year ahead for everyone, and wish you all a happy new year.

2. PMDA-ATC GMP Inspection Webinar 2021

On November 25 and 26, 2021, the PMDA held a webinar entitled "PMDA-ATC GMP Inspection Webinar 2021." This webinar, supported by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), was aimed at officials of overseas regulatory agencies involved in the GMP inspection. A total of 29 regulators from Azerbaijan, Australia, Bangladesh, Ethiopia, Hong Kong, India, Indonesia, Libya, Malaysia, Moldova, Myanmar, Pakistan, Philippines, Saudi Arabia, Sri Lanka, Taiwan, Tunisia, Ukraine, and Vietnam attended the webinar.

The first day of the webinar comprised a lecture on GMP regulations in Japan, followed by a comprehensive discussion with participants introducing GMP systems in their own countries/regions. The second day included a lecture on the basic concepts of quality risk management (QRM), followed by solving QRM case studies in groups. Participants were able to engage in an in-depth and active Q&A session and have interactive opinion exchanges by sharing their own experiences and issues.



From top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Mr. ENO Hideo (Director, Office of Manufacturing Quality for Drugs, PMDA), Dr. Kevin O'Donnell (Chair person of the PIC/S Working Group on QRM), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. SATO Junko (Director of the Office of International Programs, PMDA)
At the bottom: participants of the webinar

Please refer to the following website for details on the PMDA-ATC GMP Inspection Webinar 2021:
https://www.pmda.go.jp/english/symposia/0229.html

3. MDSAP Forum 2021

The MDSAP Forum 2021 was held from November 29 to December 3, 2021. The Medical Device Single Audit Program (MDSAP) is an international joint program aimed at realizing a single audit of medical device QMS using third-party auditing organizations and has been active since November 2012. The MDSAP Forum is an annual meeting of stakeholders, such as Regulatory Authorities and Auditing Organizations related to the MDSAP. It was conducted as a web conference due to the COVID-19 pandemic.

The main agenda was the remote audit, which is a type of audit that utilizes ICT tools associated with the COVID-19 pandemic. The MDSAP Regulatory Authorities have issued a transmittal[1)] regarding remote audits under the COVID-19 pandemic situation. As a result, the Auditing Organization is permitted to conduct a remote QMS audit in situations where on-site audits are difficult as a temporary measure under the influence of COVID-19. During the meeting, the MDSAP Regulatory Authorities and Auditing Organizations discussed the continuation of remote audits as a temporary extraordinary measure. Considering the situation where the spread of COVID-19 has not converged due to the Omicron variant, it was decided to continue the remote audit as a temporary extraordinary measure. In addition, MDSAP Affiliate member[2)] countries participated in the forum and reported their usage of MDSAP audit reports/certificates. The PMDA provides the latest information on the acceptance status of the MDSAP audit reports. (MDSAP audit reports were used at a high rate in FY2020, as in FY2019 for QMS audits conducted by the PMDA. The results of acceptance from FY2017 to FY2020 are published on the PMDA's website[3)].) We also reported that the acceptance of MDSAP audit reports, which had been carried out as a trial since June 2016, will be officially adopted in the Japanese regulatory framework from April 2022, and the MDSAP audit reports will continue to be used effectively.

1) https://www.fda.gov/media/144883/download
2) MDSAP Affiliate members are Regulatory Authorities that utilize MDSAP audit reports/certificates and support MDSAP activities. Argentina, South Korea, and Singapore have been recognized as affiliate members.
3) https://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0004.html

4. ICMRA Summit Meeting (Virtual)

The International Coalition of Medicines Regulatory Authorities (ICMRA) Summit meeting was held virtually from December 1 to 2, 2021. About 100 members from 35 countries, regions, and international organizations participated. From the PMDA, Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), Dr. SATO Junko (Office Director, Office of International Programs), three staff members from the Office of International Programs and the Ministry of Health, Labour and Welfare (MHLW), Ms. YAMAMOTO Fumi (Councilor for Pharmaceutical Affairs, Minister's Secretariat), Mr. YASUDA Naoyuki (Office Director, Office of International Regulatory Affairs), and one staff member participated in this meeting.

On the first day, agency-level heads participated in panel discussions on four topics: COVID-19 therapeutics and vaccines, experiences in the COVID-19 pandemic, ensuring manufacturing capacity and rapid streamlined regulatory action, and medicines for use during pregnancy and lactation. Dr. FUJIWARA facilitated the session on "COVID-19 Therapeutics and Vaccines: Lessons Learned on Drug Product Lifecycle Management during COVID-19 pandemic" as a moderator. Mr. YASUDA joined the discussion as a panelist for the session of "Ensuring manufacturing capacity and rapid streamlined regulatory action."

On the second day, international regulators exchanged opinions about SARS-CoV-2 variants as well as had discussions regarding regular ICMRA workstreams. The MHLW/PMDA presented recent updates of the Innovation project co-led by Japan, and on the ICMRA website that is maintained and hosted by the PMDA.

The next ICMRA meeting will be held in the second half of 2022.

The details of the meeting are available on the following ICMRA website:
https://www.icmra.info/drupal/en/meetings/2021Brazil

5. ICH Quality Forum

The ICH Quality Forum was held at Tokyo Conference Center Shinagawa (Minato-ku, Tokyo) on December 14, 2021, in a hybrid style. More than 750 individuals, mostly from the pharmaceutical industry, attended the forum.

The forum was held to facilitate the understanding of the Quality guidelines with financial support from ICH (Program and presentation materials are available on the following link:
https://www.pmda.go.jp/english/symposia/0217.html).

In the first half of the program, Dr. FUJIWARA Yasuhiro (Chief Executive) presented the latest updates on the PMDA. Following this, a panel discussion on the ICH's current activities was held with panelists from the United States, Canada, and Japan, who are representatives of the regulatory authorities and industries. In the latter half, four presentations were shown by experts who worked on the guidelines. A panel discussion on the Q12 guideline was held at the end of this forum. The panelists consisted of regulators and industries.

The PMDA plans to hold similar forums to exchange information and opinions with stakeholders and to facilitate understanding of the ICH guidelines on topics of high interest with MHLW/JPMA.

6. PMDA-ATC Pharmaceuticals Review Webinar 2021

From December 18 to 21, 2021, the PMDA held a webinar entitled "PMDA-ATC Pharmaceuticals Review Webinar 2021." This webinar was aimed at officials of overseas regulatory agencies involved in the review of pharmaceuticals. A total of 34 regulators from Brazil, Ethiopia, Hong Kong, India, Indonesia, Myanmar, Philippines, Saudi Arabia, South Africa, Taiwan, Thailand, and Uganda attended the webinar.

Before attending the live webinar, participants took the PMDA-ATC E-learning course, "Pharmaceuticals Review" covering the following subjects: Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Review of New Drugs, Review of Generic Drugs, Review of Biosimilars, and Expedited regulatory pathways.

The LIVE webinar comprised lectures and Q&A sessions on New Drug Approval Review, Consultation Meetings, Regulatory Challenges against COVID-19, and Review of Chemistry, Manufacturing, and Control (CMC), in addition to case studies on the Review of New Drugs and the Review of Generic Drugs, where participants actively engaged in discussion and exchanged opinions.

At the end of the webinar, Dr. FUJIWARA Yasuhiro, Chief Executive of the PMDA distributed the course completion certificate virtually.

From top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. ASAKURA Wataru (Director, Office of New Drug I, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. SATO Junko (Director, Office of International Programs, PMDA)
At the bottom: participants of the webinar

Please refer to the following website for details of the PMDA-ATC Pharmaceuticals Review Webinar 2021:
https://www.pmda.go.jp/english/symposia/0216.html

7. 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 the "Review of IVD for COVID-19" content video, which introduces the priority review system for IVDs intended for COVID-19 and IVDs approved under this system, namely, nucleic acid test kits, antigen test kits, and antibody test kits.

Please follow the 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 link provides 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
Vafseo [Initial Approval]	Vadadustat	December 14, 2021
Enspryng [Initial Approval]	Satralizumab (genetic recombination)	December 22, 2021

Medical Devices

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

Brand Name	Non-proprietary Name	Posting Date
Gore Viabahn Stent Graft [Initial Approval]	Heparin-coated stent-graft for the central circulatory system Heparin-coated stent-graft for blood vessels	December 14, 2021
PD Laser [Partial Change Approval] EC-PDT Probe [Initial Approval]	PDT semiconductor laser Single-use probe for PDT semiconductor laser	December 28, 2021

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (December 17, 2021)

- Blonanserin (oral dosage form)
- Blonanserin (patches)
- Suvorexant
- Fingolimod hydrochloride
- Posaconazole
- Concentrated human blood platelet (non-irradiated preparations)
- Synthetic blood (non-irradiated preparations)
- Washed human red blood cell (non-irradiated preparations)
- Human red blood cells (non-irradiated preparations)
- Whole human blood (non-irradiated preparations)
- Frozen-thawed human red blood cells (non-irradiated preparations)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Medical Devices Revisions of PRECAUTIONS (December 24, 2021)

- Revision of PRECAUTIONS in the Package Insert of Power Morcellators

https://www.pmda.go.jp/english/safety/info-services/devices/0002.html

Pharmaceuticals Revisions of PRECAUTIONS (January 6, 2022)

- Aminolevulinic acid hydrochloride

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Pharmaceuticals and Medical Devices Safety Information No. 389 (January 18, 2022)

1. How to Start and Proceed with Improving Polypharmacy among the Elderly in Hospitals
2. Important Safety Information
   (1) Fingolimod hydrochloride
3. Revision of Precautions (No. 329)
   Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection) (and 11 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/0019.html

Events

Conferences/Meetings that the PMDA will host or participate in

Date	Title	Location
January 31, February 2-4	PMDA-ATC Pharmacovigilance Webinar 2022	Virtual
March 15-16	ICH Management Committee Interim Meeting	Brussels
March 29-31	34th DIA Euro Meeting	Brussels & Virtual

Reports from Overseas

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

Regulatory Science Research Needs initiative

Several regulatory agencies including PMDA and EMA have been advancing Regulatory Science in order to ultimately benefit patients. As of 15th December 2021, in addition to the mid-term plan; "Regulatory Science to 2025" [1)] published in March 2020, EMA has issued a list of regulatory science topics [2)] that need further research to close gaps and improve medicine development and evaluation to enable access to innovative medicines for patients. The list was developed based on the interviews with chairs of EMA's scientific committees and working parties, and also with external experts and opinion leaders from the principal stakeholder groups [3)]. It is the first time for EMA to publish such a list and it's aimed to stimulate researchers and funding organisations to consider addressing these topics in their research agendas and share their findings and results with regulators. On 18th January, EMA held the webinar to explain the initiatives and the video recording will be made available on EMA website [4)]. It may be interesting to see topics being interested in EU and compare with the ones in Japan.

1) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf
2) https://www.ema.europa.eu/en/documents/other/regulatory-science-research-needs_en.pdf
3) https://www.ema.europa.eu/en/news/ema-launches-regulatory-science-research-needs-initiative
4) https://www.ema.europa.eu/en/events/regulatory-science-research-needs-launch-event

Dr. KISHIOKA Yasuhiro
PMDA's International Liaison Officer stationed at EMA in the Netherlands

