# PMDA Updates

March 2022

# *News*

## 1. PMDA-ATC Pharmacovigilance Webinar 2022

On January 31 and from February 2 to 4, 2022, the PMDA held a four-day online seminar, entitled "PMDA-ATC Pharmacovigilance Webinar 2022." It was held as the Center of Excellence (CoE) Workshop of the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC). The webinar was designed for regulatory officials who are in charge of pharmacovigilance (PV) in overseas regulatory authorities. A total of 24 regulators from 10 economies, namely: Azerbaijan, India, Indonesia, Malaysia, Myanmar, Pakistan, Philippines, Sri Lanka, Thailand, and Vietnam, participated in the webinar.

Before attending the live online webinar, the participants attended the PMDA-ATC E-learning course on Pharmacovigilance, which covered topics including the pharmacovigilance system and pharmacovigilance international cooperation.

The live webinar was composed of lectures and Q&A sessions covering the evaluation of benefit/risk balance throughout the product lifecycle, labeling process (including E-labeling), recent pharmacovigilance activities in the US, pharmacoepidemiology and case studies on the safety specifications and the risk minimization activities under the risk management plan, as well as the PV methods.

Top row: Speakers in the opening and the closing ceremonies, from left in order of appearance, Mr. UZU Shinobu (Senior Executive Director and 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 and Director of the Office of Pharmacovigilance I, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. SATO Junko (Director of the Office of International Programs, PMDA)
Lower rows: Some of the participants of the webinar

Please refer to the website below for more details on the PMDA-ATC Pharmacovigilance Webinar 2022.
https://www.pmda.go.jp/english/symposia/0232.html

## 2. PMDA-ATC COVID-19 related IVDs Webinar for MDA

On February 8, the PMDA held the "PMDA-ATC COVID-19 related In Vitro diagnostics (IVDs) Webinar for the Medical Device Authority (MDA), the Ministry of Health Malaysia."

The webinar reviewed COVID-19 related IVDs. The PMDA shared information on the Japanese regulatory system and PMDA's experiences with 66 MDA staff members engaged in medical devices regulation including their pre-market control.

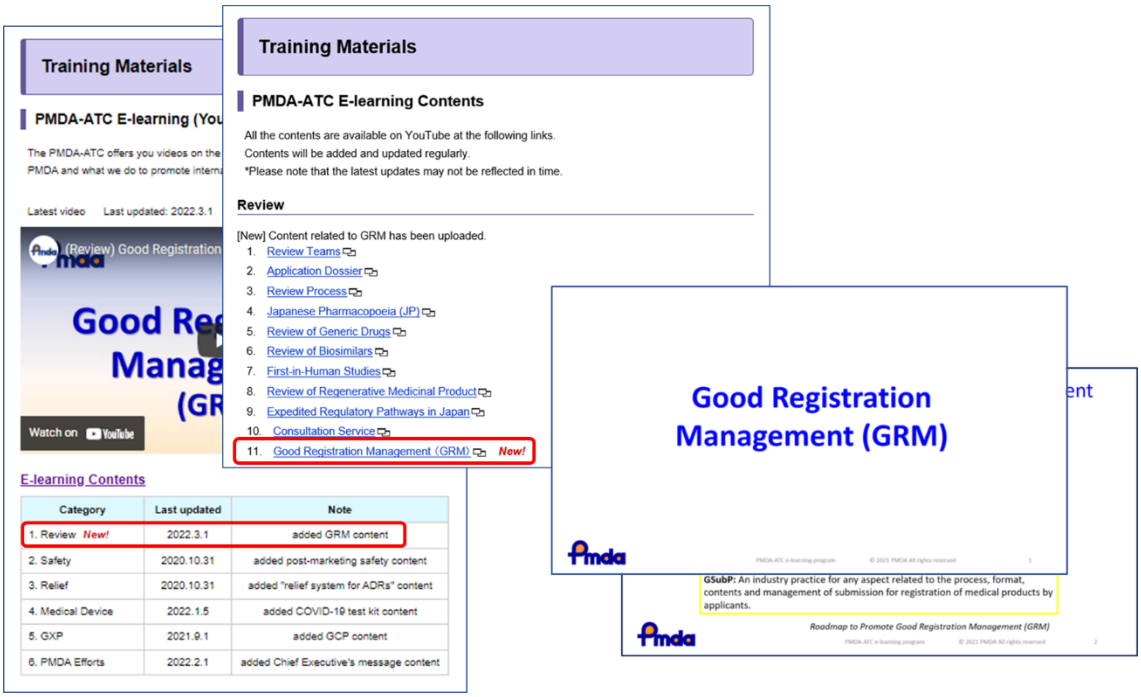
The PMDA continues to promote collaboration with MDA through training seminars and other activities.

## 3. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning system has been operational since January 2020. This month, we are pleased to announce the release of the "Good Registration Management (GRM)" content video.

GRM promotes an efficient review process of medical products through a collaborative promotion of Good Submission Practice (GSubP) and Good Review Practice (GRevP). It introduces PMDA's efforts in relation to GRevP, such as the configuration of the standard review timeline and pre-submission pre-consultation meeting, in order to realize an effective review process.

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 |
|---|---|---|
| Ronapreve [Special Approval for Emergency, Partial Change Approval] | casirivimab (genetical recombination) and imdevimab (genetical recombination) | February 7, 2022 |
| Lagevrio [Special Approval for Emergency] | molnupiravir | February 17, 2022 |
| Comirnaty [Special Approval for Emergency, Partial Change Approval] | Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (active ingredient: tozinameran) | February 22, 2022 |

| | | |
|---|---|---|
| Spikevax (previously COVID-19 Vaccine Moderna) [Special Approval for Emergency, Partial Change Approval] | Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) | March 9, 2022 |

### Medical Devices

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

| Brand Name | Term Name | Posting date |
|---|---|---|
| MitraClip NT System | Percutaneous repair system for mitral valve coaptation failure | February 17, 2022 |

# *Safety Information*

### Pharmaceuticals and Medical Devices Safety Information No. 390 (March 8, 2022)

1. Revision of Precautions for Aminolevulinic Acid Hydrochloride
2. Revision of Precautions (No. 330)
   Aminolevulinic acid hydrochloride (and 1 other)
3. 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

### PMDA Alert for Proper Use of Medical Devices (March 2022)

Bleeding Caused by the Use of IMPELLA Circulatory Assistance Pump Catheter
https://www.pmda.go.jp/english/safety/info-services/devices/0005.html

### Pharmaceuticals Revisions of PRECAUTIONS (March 15, 2022)

- Ticagrelor
- Nintedanib ethanesulfonate
- Efavirenz

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

# *Events*

### Conferences/Meetings that the PMDA will host or participate in

| Date | Title | Location |
|---|---|---|
| April 6 | 4th Asian Network Meeting | Virtual |
| April 24 | ATLAS International Symposium | Bangkok & Virtual |
| May 19-22 | 14th DIA China Annual Meeting | Suzhou |
| May 21-25 | ICH meeting | Athens |
| May 25-26 | IPRP meeting | Athens |

# *Reports from Overseas*

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

## Final report

This is my final report because my term of office of liaison officer to EMA expires at the end of this month.

Just after I was dispatched to the EMA in February 2020, COVID-19 pandemic started. I think the current pandemic has revealed the nature of nation, organization and individuals, and magnified their existing challenges. In terms of international activity in the field of medicine regulation, some regulatory agencies have enhanced their collaboration to cope with various problems facing regulators. In addition, in spite of a challenging situation, they have made steady progress in some essential collaboration work toward their goal. Future international collaboration will be built on these experiences.

It has been a valuable experience for me to work at EMA in this unprecedented time. With this experience I would like to contribute to future PMDA activities and collaboration with international partners including EMA.

Last but not least, I would like to express my deepest gratitude to all those who provided their support to my stay at EMA.

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