PMDA Updates

May 2021

News

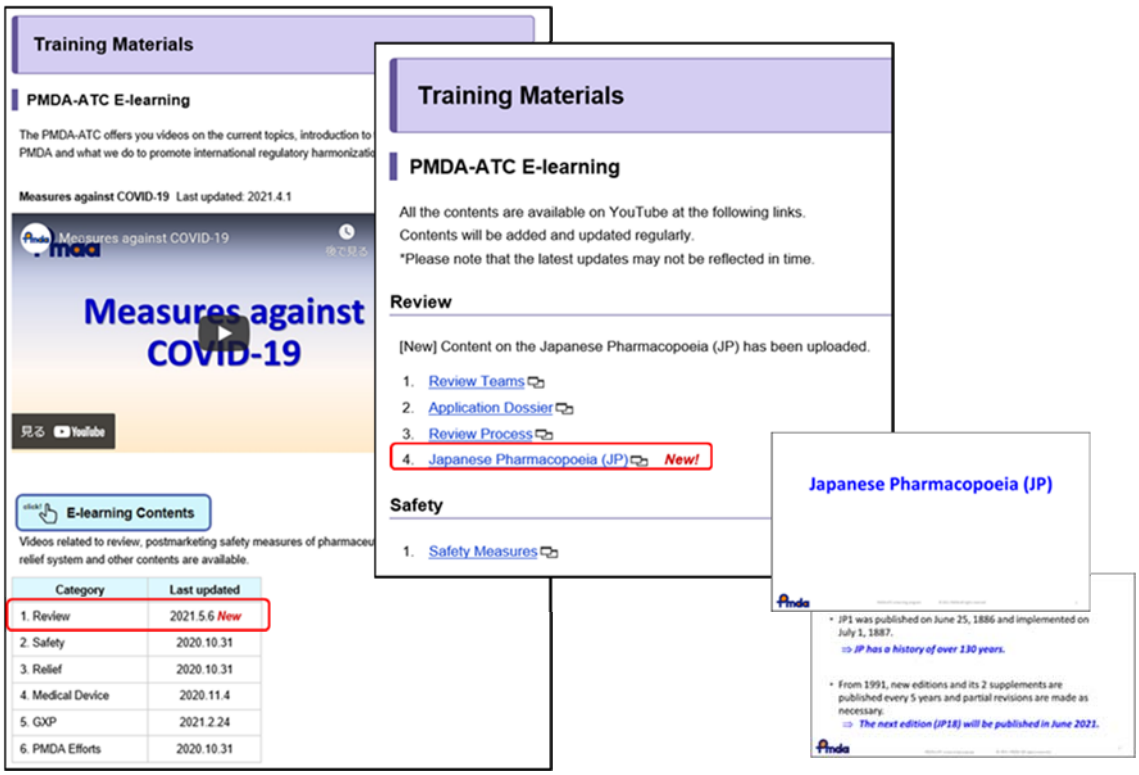
1. The 3rd Asian Network Meeting

The 3rd Asian Network Meeting was held virtually on April 14 this year due to the COVID-19 pandemic. The meeting was co-chaired by Japan, China, India, and Singapore, and was led by the Ministry of Health, Labour and Welfare (MHLW)/PMDA. Top-level executives of regulatory agencies from Asian countries including Indonesia, Korea, Malaysia, Philippines, and Vietnam joined the meeting. From a high-level perspective, the Members shared information on tackling the COVID-19 pandemic and accessing innovative medicines in Asian countries. They reiterated the importance of mutual understanding regarding various issues Asian countries currently face, sharing best practices, and promoting regulatory harmonization. They also committed to increase collaboration for further action.

In conjunction with the Asian Network Meeting, MHLW and PMDA held bi-lateral meetings on April 12 and 15 with each country. To enhance health in the Asian region, the latest information was exchanged and future collaboration plans were discussed. Continuous discussion on future regulatory cooperation with each country was affirmed.

2. PMDA-ATC E-learning Content Information Updated

The PMDA has been providing the PMDA-ATC E-learning system since January 2020. We are pleased to announce that new content on Japanese Pharmacopoeia (JP) for this system has been released. This content introduces the outline of the JP, how it is drafted and established, and a flowchart explaining how the JP reference standards are used in drug tests have been prepared. The e-learning website can be accessed through the following link:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



English Translations of Review Reports

The following provides current information on the English version of 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
Braftovi [Initial Approval]	encorafenib	April 20
Mektovi [Initial Approval]	binimetinib	April 20
Breztri Aerosphere [Initial Approval]	budesonide/glycopyrronium bromide/ formoterol fumarate hydrate	April 28
Bevespi Aerosphere [Initial Approval]	glycopyrronium bromide/formoterol fumarate hydrate	April 28

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 382 (April 27, 2021)

1. PI (Package insert)-navi: A Smartphone App Designed for Digitized Package Inserts.
2. Digitization of Reports from Medical Institutions on Adverse Drug Reactions and Post-vaccination Suspected Adverse Reactions.
3. Important Safety Information:
   (1) Ritodrine hydrochloride (injections)
   (2) Durvalumab (genetical recombination)
   (3) Onasemnogene abeparvovec
4. Revision of Precautions (No. 322):
   Magnesium sulfate hydrate/glucose (preparations indicated for prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy)
   (and 8 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/0019.html

Pharmaceuticals Revisions of PRECAUTIONS (May 13, 2021)

- Shosaikotokakikyosekko

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

Events

Conferences/Meetings that the PMDA Hosts or Participates in:

Date	Title	Location
June 7-8	IPRP Meeting	Virtual
June 18	Japan-China ICH Symposium	Virtual
June 22-24	PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021	Virtual
June 27-July 1	57th DIA 2021 Global Annual Meeting	Virtual

Reports from Overseas

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

A series of workshops around Big Data initiatives

As introduced in PMDA Updates September 2020, EMA, together with HMA (Heads of Medicines Agencies), has been intensively promoting Big Data initiative. According to the Big Data Steering Group workplan for 2020-2021 published in September 2020[1)], EMA has held a series of workshops for the last two months; workshop on metadata on 12th April 2021[2)], workshop on Artificial intelligence on 19-20 April 2021[3)] and workshop on Data Standardization on 18th May 2021[4)].

In my view, what is common in all workshops is that EMA attempts to gather inputs from a wide range of stakeholders in order to incorporate them in the deliverables, moreover explore synergies with related ongoing projects, if any. As some elements in Big Data initiatives should be considered internationally, it is important not only to monitor future developments closely but also engage proactively.

1) https://www.ema.europa.eu/en/documents/work-programme/workplan-hma/ema-joint-big-data-steering-group_en.pdf
2) https://www.ema.europa.eu/en/events/technical-workshop-real-world-metadata-regulatory-purposes
3) https://www.ema.europa.eu/en/events/joint-hmaema-workshop-artificial-intelligence-medicines-regulation
4) https://www.ema.europa.eu/en/events/data-standardisation-strategy-stakeholder-workshop

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