PMDA Updates

September, 2020

News

1. PMDA-ATC Medical Devices Webinar 2020 for Thai FDA

From August 26 to 27, PMDA held a seminar entitled "PMDA-ATC Medical Devices Webinar 2020 for Thai FDA". This webinar was designed for medical devices and *in vitro* diagnostics (IVDs) reviewers from Thai Food and Drug Administration (Thai FDA) and 17 regulators participated.

The webinar opened with remarks by Mr. UZU Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs).

The program of the webinar included lectures by staff engaging in IVDs review from PMDA and Thai FDA on the topic of review experiences of COVID-19 diagnosis kits in each country, and a lecture by a staff engaging in medical devices review from PMDA on the topic of review experiences of high-risk devices applied in plastic surgery and cosmetic surgery. After each lecture, a round discussion based on questions from participants was held and enhanced understanding.

Please refer to the following web site for the details of PMDA-ATC Medical Devices Webinar 2020 for Thai FDA.

https://www.pmda.go.jp/english/symposia/0177.html

Opening ceremony
Left picture: Mr. UZU Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs from PMDA)
Center in the right picture: Mrs. Korrapat Trisarnsri (Director of Medical Devices Control Division from Thai FDA)

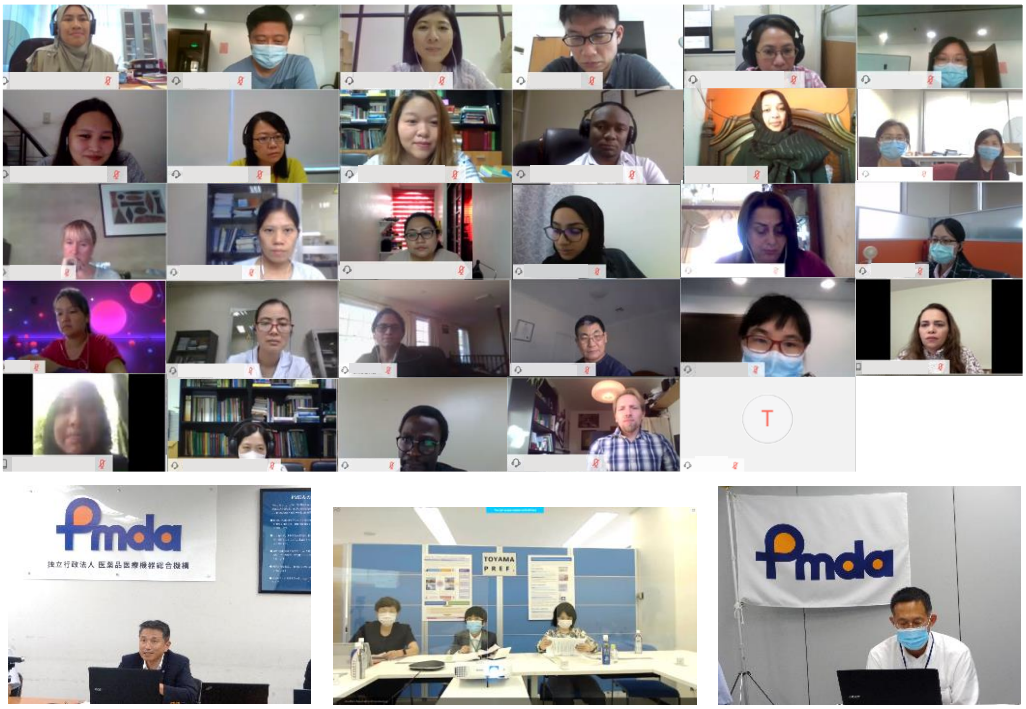
2. PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020

From September 9 to 11, PMDA held a webinar entitled "PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020". It is the first attempt for PMDA to provide a virtual seminar to multi regional regulators. This webinar was designed for officials of overseas regulatory agencies engaged in drug reviews, and participated by 30 regulators from Australia, Azerbaijan, Bahrain, Brazil, China, Germany, Malaysia, Maldives, Philippines, Singapore, Taiwan, Tanzania, Thailand, Uganda and Viet Nam.

In the webinar, recorded lectures by PMDA staff, representatives from Toyama prefectural government, Institute of Natural Medicine of Toyama University, National Institute of Health Sciences, and the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) were provided in advance as preliminary training materials, which then were followed by live Q&A sessions. The lectures covered the overview of regulations on Herbal Medicines in Japan, quality evaluation of crude drugs (herbal medicine), evaluation process and GMP inspection by prefectural authorities, regulation and review process of OTC Drugs, Japanese Pharmacopoeia (JP), Japanese standards for non-Pharmacopoeial crude drugs (non-JP crude drug standards), approval standards for Over-the-Counter Kampo medicines and crude drug preparations, and quality management and manufacturing management of crude drugs and herbal medicines.

On the last day, the program included a virtual site tour to the Center for Medicinal Plant Resources in Toyama Prefecture (Toyama Prefectural Institute for Pharmaceutical Research) on cultivation and processing of medicinal

plants, and a manufacturing facility of herbal medicine in Toyama on the process of Kampo manufacturing followed by Q&A sessions.



Picture on top: Webinar participants
Picture on the bottom left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs from PMDA)
Picture on the bottom center: PMDA Hokuriku Branch, Toyama Prefecture
Picture on the bottom right: Dr. FUJIWARA Yasuhiro (Chief Executive of PMDA)

3. International Coalition of Medicines Regulatory Authorities (ICMRA) Activities

International Coalition of Medicines Regulatory Authorities(ICMRA) was established in 2013 to serve as a place to discuss matters such as avoidance of redundant/duplicaited international activities and prioritization of important international activities by the heads of regulatory authorities from every region in the world. ICMRA membership consists of 28 regulatory authorities, such as MHLW/PMDA, EMA, Health Canada, MHRA, TGA, USFDA, and WHO as an observer. The chair and vice-chairs are elected from among the members. MHLW/PMDA has been one of core members of ICMRA; Dr. KONDO Tatsuya (Chief Executive Emeritus) acted as the vice-chair from 2013 to 2016, and since October, 2019, Dr. FUJIWARA Yasuhiro (Chief Executive) acts as the vice-chair.

ICMRA is organized by Executive Committee (ExC) and Working Groups (WGs). ExC is the place where the policy of ICMRA is determined. WGs are created on the topics in which members are interested, and practical discussions are proceeded there. Currently the main WGs are the Innovation Project, Pharmacovigilance, AMR (antimicrobial resistance), Supply Chain, Reliance, Drug Shortages. MHLW/PMDA serves as the co-chair of Innovation Project. In addition, PMDA is in charge of maintenance and management of ICMRA website to promptly announce latest activities to global regulators and healthcare professionals, etc.

Furthemore, under the COVID-19 pandemic, ICMRA has been taking initiatives in COVID-19-related activities including acceleration of development of medical products. Virtual meetings to discuss response against COVID-19 were held over 25 times, in which active discussions including developmental situations of vaccines and therapeutics, methods to evaluate clinical trials, utilizing RWE (Real World Evidence) for safety monitoring were held. PMDA has not only been gathering information through these meetings, but also contributed as the chair of some part of the workshops.

In the current circumstance of emerging innovative medical products, it is expected to enable more effective product development through discussions by regulatory authorities all over the world. In emergency situation like outbreak of COVID-19 as well as Ebola virus disease and Zika virus disease, ICMRA has rapidly published statements to take measures globally and appropriately. PMDA shall actively be involved in ICMRA activities and contribute to international collaboration on pharmaceutical regulatory area.

Please refer to the following websites for the details of ICMRA activities.
ICMRA website：http://www.icmra.info/
PMDA website ICMRA page：https://www.pmda.go.jp/int-activities/int-harmony/icmra/0001.html

4. Call for application to PMDA-ATC Pharmaceuticals Review Webinar 2020 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC Pharmaceuticals Review Webinar 2020" from December 15 to 17 through web conference system. This webinar is designed for pharmaceuticals reviewers from overseas regulatory authorities, and the participants will be required to join in the live sessions for Q&A and case studies after taking pre-recorded lectures as self-study. The objective of the webinar is to provide the participants with opportunities to further enhance the regulatory systems in their respective country/region by learning the review process for new drugs, generic drugs and biosimilars, and efficient review pathways for early access.

Please refer to the following web site for the details of PMDA-ATC Pharmaceuticals Review Webinar 2020.
https://www.pmda.go.jp/english/symposia/0183.html

English Translations of Review Reports

The followings are current information about English version of review reports on PMDA website.

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Non-proprietary Name	Posting date
Fasenra [Initial Approval]	benralizumab (genetical recombination)	August 18
Nubeqa [Initial Approval]	darolutamide	August 18
Hemlibra [Initial Approval]	emicizumab (genetical recombination)	August 25
Tepmetko [Initial Approval]	tepotinib hydrochloride hydrate	September 1
Romiplate [Partial Change Approval]	romiplostim (genetical recombination)	September 8

English Translations of Notifications and Administrative Notices

The following are English version of Notifications and Administrative Notices newly published on PMDA website.
https://www.pmda.go.jp/english/review-services/regulatory-info/0003.html

Issue Date	Document Type & No.	Title	Posting date
Mar. 30, 2020	PSEHB/PED Notification No. 0330-1	Guideline for preclinical safety assessment of oligonucleotide therapeutics	August 28, 2020

Safety Information

PMDA Medical Safety Information No.59 (August, 2020)

Outbreak of Fire from Medical Devices Due to a Short Circuit
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

PMDA Medical Safety Information No.60 (August, 2020)

Precaution when Handling Thoracic Catheters
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals and Medical Devices Safety Information No. 375 (August 21, 2020)

1. Revisions of Precautions in Package Inserts concerning the Dosing Intervals between Different Vaccines
2. Review of Contraindications including "patients with serious renal disorder" of Parenteral Nutrition Preparations and Amino Acid Preparations for Renal Failure
3. Important Safety Information
   (1) Iopamidol
4. Revision of Precautions (No. 315)
   (1) Iodixanol
   (2) Iohexol (preparations with indications of cerebral angiography) (and 5 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/0018.html

Pharmaceuticals Revisions of PRECAUTIONS (September 8, 2020)

- Ofloxacin (preparations for otic use)
- Chloramphenicol (preparations for otic use)
- Fosfomycin sodium (preparations for otic use)
- Gentamicin sulfate (injections)
- Cefmenoxime hydrochloride (preparations for otic and nasal use)
- Chloramphenicol (solution for topical use, oral dosage form)
- Tetracycline hydrochloride (powders, capsules)
- Polymixin B sulfate (powders)
- Clindamycin hydrochloride
- Clindamycin phosphate (injections)
- Benzylpenicillin potassium
- Benzylpenicillin benzathine hydrate
- Lincomycin hydrochloride hydrate
- Aztreonam
- Amoxicillin hydrate
- Ampicillin hydrate
- Ampicillin sodium
- Potassium clavulanate/amoxicillin hydrate
- Dibekacin sulfate (injections)

- Sultamicillin tosilate hydrate
- Cefaclor
- Cefazolin sodium
- Cefazolin sodium hydrate
- Cefalexin (oral dosage form with indications for otitis media)
- Cefalotin sodium
- Cefixime hydrate
- Cefepime dihydrochloride hydrate
- Cefozopran hydrochloride
- Cefotiam hydrochloride (intravenous injections)
- Cefcapene pivoxil hydrochloride hydrate
- Cefditoren pivoxil
- Cefdinir
- Ceftazidime hydrate
- Cefteram pivoxil
- Ceftriaxone sodium hydrate
- Cefpodoxime proxetil
- Cefroxadine hydrate
- Cefuroxime axetil
- Tebipenem pivoxil
- Doripenem hydrate
- Bacampicillin hydrochloride
- Panipenem/betamipron
- Faropenem sodium hydrate
- Flomoxef sodium
- Fosfomycin calcium hydrate
- Meropenem hydrate
- Chloramphenicol sodium succinate
- Demethylchlortetracycline hydrochloride
- Doxycycline hydrochloride hydrate
- Minocycline hydrochloride (oral dosage form)
- Kanamycin sulfate
- Lomefloxacin hydrochloride (preparations for otic use)
- Azithromycin hydrate (oral dosage form for pediatric use)
- Erythromycin
- Clarithromycin
- Spiramycin acetate
- Roxithromycin
- Tosufloxacin tosilate hydrate (oral dosage form without dosage and administration for pediatric use)
- Norfloxacin (oral dosage form with indications for otitis media)
- Erythromycin ethylsuccinate
- Erythromycin stearate
- Josamycin
- Josamycin propionate
- Tosufloxacin tosilate hydrate (oral dosage form for pediatric use)
- Relugolix
- Hydroxychloroquine sulfate

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0008.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
October 15-16	The 8th Joint Conference of Taiwan and Japan on Medical Products Regulation	Virtual
October 20	PMDA-ATC Japanese Pharmacopoeia Webinar 2020 for Thai FDA	Virtual
November 8-10	17th DIA Japan Annual Meeting	Virtual
November 16-20	PMDA-ATC Medical Devices Webinar 2020	Virtual

Reports from Overseas

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

Publication of the Big Data Steering Group workplan for 2020-2021

On 14th September 2020, the Big Data Steering Group workplan for 2020-2021 was published on EMA website [1]. The Steering Group was established in February 2020 to advise the EMA Management Board and HMA (Heads of Medicines Agencies) on implementing the ten priority recommendations [2] proposed by the joint Big Data Task Force of EMA and HMA in January 2020.

"Big Data" has been defined in the task force report as "extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general big data sets require advanced or specialised methods to provide an answer within reliable constraints" [3]. Data sources include real-world data (such as electronic health records, insurance claims data and data from patient registries), genomics, clinical trials, spontaneous adverse drug reaction reports, social media and wearable devices [4].

Elements of Big Data initiative have been incorporated into the recently published EMA's mid-/long-term strategies such as Regulatory Science Strategy 2025 [5] and draft European medicines agencies network strategy to 2025 [6], and this field will be intensively discussed for the next years. The use of big data including real-world data to assess the benefit-risk of medicinal products has been focused not only in EU but also in other regions including Japan. International communication at earlier stage will be critical for future alignment in this area, and the workplan indeed includes the aspect of international initiatives. Such strategic planning in important area is essential to be proactive both regionally and internationally. Although the workplan is subject to change due to the current situation, it's important to keep an eye on Big Data initiative.

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/news/ten-recommendations-unlock-potential-big-data-public-health-eu
3) https://www.ema.europa.eu/en/documents/minutes/hma/ema-joint-task-force-big-data-summary-report_en.pdf
4) https://www.ema.europa.eu/en/about-us/how-we-work/big-data
5) https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy
6) https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

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