PMDA Updates

February, 2020

News

1. Japan-China Medical and Health Forum 2020

On January 6, the Japan-China Medical and Health Forum 2020 was held in Beijing, China. It was attended by about 300 participants from regulatory agencies, industries, and other relatives in China and Japan. PMDA participants included Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. SATO Junko (Director for Office of International Programs), and one staff member.

In the forum, Dr. FUJIWARA gave opening remarks and presentations of Japanese and Chinese pharmaceutical regulation were provided. From PMDA, Dr. FUJIWARA provided a presentation titled "PMDA's challenges" that introduced PMDA's recent activity including the expedited review system and international cooperation. The other staffs gave lectures of "Pharmacovigilance activities in Japan", "Orphan and pediatric medicines: MHLW/PMDA's initiatives to promote development", "RWD utilization in Japan", and "Clinical trials in Japan". From China, the information on Chinese pharmaceutical regulation that was amended in December 2019 was mainly presented. High interest in the Japanese regulation and expectation for future collaboration were shown through the forum.

In addition to the forum, the opinion exchange between PMDA and executive staff of NMPA was took placed and we confirmed necessity of collaboration in the future on both sides.

Dr. FUJIWARA as speaker

Dr. SATO as speaker

2. PMDA-ATC MRCT Seminar 2020

From January 20 to 23, PMDA held a seminar entitled "PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2020". This seminar, focusing on multi-regional clinical trials, was designed for pharmaceutical reviewers from overseas regulatory authorities, and was held as a Center of Excellence Workshop for the MRCT/GCP Inspection Priority Work Area, which is led by Japan with Thailand as a champion economy, in the APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

The seminar was participated by 27 regulators from Bangladesh, Brazil, Chile, Hong Kong, India, Indonesia, Malaysia, Peru, Philippines, Russia, Saudi Arabia, Sri Lanka, Taiwan, and Thailand.

Group photo of participants and PMDA directors

Front row from left to right, Dr. FUKUDA Eriko (Office Director, Office of International Cooperation) (1st), Dr. HAYASHI Yoshikazu (Senior Executive Director) (2nd), Dr. FUJIWARA Yasuhiro (Chief Executive) (3rd), Dr. NAKASHIMA Nobumasa (Associate Executive Director) (4th), Dr. NAKAMURA Ryuta (Senior Coordinator for International Training)

The program of the seminar included lectures by staff members from PMDA, Japan Pharmaceutical Manufacturers Association (JPMA), and academic institutions on the topics such as points to consider at protocol designing and planning of MRCT, clinical operation, clinical data evaluation, regulatory review based on results of GCP inspections, post-market safety evaluation of approved drugs based on MRCT, together with international cooperation and regulatory convergence among regulatory authorities. Besides the lectures, group work with case studies, introduction of review systems and regulations by participants and clinical site tour were provided as well. Participants had active discussions throughout the seminar.

At the end of the seminar, the course completion certificates were handed to each participant by Dr. HAYASHI Yoshikazu (Senior Executive Director of PMDA).

Please refer to the following website for the details of PMDA-ATC MRCT Seminar 2020.
https://www.pmda.go.jp/english/symposia/0160.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
Yervoy [Partial Change Approval]	ipilimumab (genetical recombination)	January 20
Opdivo [Partial Change Approval]	nivolumab (genetical recombination)	January 20
Lonsurf [Partial Change Approval]	trifluridine and tipiracil hydrochloride	January 22
Lenvima [Partial Change Approval]	lenvatinib mesilate	January 22
Galafold [Initial Approval]	migalastat hydrochloride	February 3
Benlysta [Initial Approval]	belimumab (genetical recombination)	February 6
Tafinlar [Partial Change Approval]	dabrafenib mesilate	February 6
Mekinist [Partial Change Approval]	trametinib dimethyl sulfoxide	February 6
Shingrix [Initial Approval]	dried recombinant herpes zoster vaccine (derived from Chinese hamster ovary cells)	February 12

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (January 21, 2020)

- Levodopa (oral dosage form/ injectable dosage form)
- Levodopa/carbidopa hydrate
- Levodopa/benserazide hydrochloride
- Levodopa/carbidopa hydrate/entacapone
- Olmesartan medoxomil
- Olmesartan medoxomil/azelnidipine
- Ipragliflozin L-Proline

- Sitagliptin phosphate hydrate/ipragliflozin L-Proline
- Secukinumab (genetical recombination)
- Alemtuzumab (genetical recombination)

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0007.html

Pharmaceuticals and Medical Devices Safety Information No. 370 (February 18, 2020)

1. For the Promotion of Pediatric Clinical Development (development and safety measures) through Active Use of Medical Information Database (Part 1)
   Maintaining the Pediatric Medical Data Collecting System and Examples of a Survey on the Drug Use in Children through Active Use of the System
2. Post-Marketing Information Collection and Malfunctions Report from Medical Institutions for Medical Devices
3. Important Safety Information
   1. Ipragliflozin L-Proline
   2. Olmesartan medoxomil
   3. Secukinumab (genetical recombination)
4. Revision of Precautions (No. 310)
   1. Levodopa
   2. Levodopa/carbidopa hydrate
   3. Levodopa/benserazide hydrochloride (and 6 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0017.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
March 16	ICMRA Plenary Meeting	Brussels
March 17-19	32th DIA Euro Meeting	Brussels
March 19-20	ICH Management Committee Interim Meeting	Brussels
April 8	3rd Asian Network Meeting	Tokyo
April 22	7th Thailand – Japan Symposium	Bangkok

Reports from overseas

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

Greetings from Amsterdam

I am KISHIOKA Yasuhiro and have been working as the 5th MHLW/PMDA liaison official for European Medicines Agency (EMA) since March 2019. Although I had been working remotely from Japan in 2019, I was dispatched to the EMA in Amsterdam, the Netherlands on February 3, 2020 when EMA completed its relocation.

MHLW/PMDA and EMA have been collaborating in a variety of fields through bilateral and multilateral communications, and I would like to facilitate our continuing collaboration.

On my first day at EMA, I was fortunate to witness the ceremony to raise the EU flags in the lobby of the new building[1)]. The flag-raising ceremony was also an occasion for EMA to start celebrating its 25th anniversary. Please

have a look at the 25th anniversary news on EMA website which provides a summary of its milestones and achievements[2].

I will share my activities and relevant information monthly on PMDA Updates. I hope you will enjoy it.

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

1) http://www.ema.europa.eu/en/news/eu-flags-are-emas-new-building-amsterdam
2) http://www.ema.europa.eu/en/news/ema-celebrates-25-years-advancing-public-animal-health

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

