



Ginkgo biloba

PMDA Updates

November, 2019

News

1. The 7th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 1, the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Taiwan, hosted by the Japan-Taiwan Exchange Association and the Taiwan-Japan Relations Association. This conference was attended by more than 300 people from regulatory agencies industry and others from Taiwan and Japan. Japanese participants included Dr. Yoshikazu Hayashi (Senior Executive Director); Dr. Junko Sato (Office Director, Office of International Programs); and 7 staff members from PMDA as well as Mr. Naoyuki Yasuda (Office Director); and 4 officers from the Ministry of Health, Labour and Welfare (MHLW). Taiwanese participants included Dr. Shou-Mei Wu (Director-General) with about 35 staff members from the Taiwan Food and Drug Administration (TFDA) as well as Dr. Churn-Shiuh Gau (Executive Director) with about 15 staff members from the Center for Drug Evaluation (CDE).



Group photo of participants

In this conference, briefings on the latest of regulations in Japan and Taiwan were provided by PMDA's Dr. Hayashi and TFDA's Dr. Wu, and the past cooperative activities between Japan and Taiwan were introduced. This conference covered a range of topics for presentations including multi-regional clinical trials (ICH E17), utilization of E-labeling, the newest regulations on OTC drugs, and health insurance and drug pricing system, in the pharmaceutical sessions; and, regulations for in vitro diagnostics, and priority review system for medical devices, in the medical devices sessions: the listeners actively discussed the topics with the speakers during the questions and answers section of those sessions. The next conference is scheduled to be held in Japan in 2020.

Materials including the program of the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation are available at the website shown below.

<https://www.pmda.go.jp/int-activities/symposia/oo84.html>

2. Pharmacopoeial Discussion Group (PDG) Tokyo Meeting and the PDG 30th Anniversary Symposium

From October 1 to 2, Pharmacopoeial Discussion Group (PDG) Meeting was held at the PMDA in Tokyo.

PDG is an international council comprised of the representatives of the European Pharmacopoeia (Ph. Eur.), U.S. Pharmacopoeia (USP), and Japanese Pharmacopoeia (JP).

In this meeting, revisions to monographs on Gelatin and Sodium Lauryl Sulfate were signed off. Thus, to date, 28 of the 31 General Chapters and 46 of the 60 excipient monographs on the current work program have been agreed for harmonization. The PDG also discussed a way forward for the future maintenance of ICH Q4B annexes, which describe interchangeability evaluation results of the harmonized tests in the ICH regions, as well as a mechanism for sharing the harmonized texts of pharmacopoeial activities with other pharmacopoeias outside of the PDG through the International Meeting of World Pharmacopoeias (IMWP).

The next face-to-face PDG meeting will be held in Rockville, the USA, hosted by USP from September 22 to 23, 2020.

On October 3, the PDG 30th Anniversary Symposium was also held at Seiryō-Kaikan Hall (Chiyoda-ku, Tokyo) and was attended by about 200 participants. At the symposium, representatives from the Ph. Eur., JP, and USP

gave presentations on the 30-year history and future perspectives of the PDG. Representatives from the World Health Organization (WHO), observer to the PDG, and pharmaceutical industry groups also shared their expectations with the PDG.

Please see the following websites for details of PDG Tokyo Meeting and PDG 30th Anniversary Symposium.

Press Release for PDG Tokyo Meeting: <https://www.pmda.go.jp/files/000231993.pdf>

PDG 30th Anniversary Symposium: <https://www.pmda.go.jp/english/symposia/o162.html>

3. The 1st Vietnam-Japan Symposium

The 1st Vietnam-Japan Symposium was held in Hanoi, Vietnam on Oct 8, co-hosted by Drug Administration of Vietnam (DAV) and PMDA, and attended by 199 people in total.

The participants from Japan included Dr. Yasuhiro Fujiwara (Chief Executive, PMDA), Dr. Nobumasa Nakashima (Senior Director for International Programs, PMDA), as well as staff from Office of Pharmacovigilance I and Office of International Cooperation of PMDA and staff of MHLW. From DAV, Mr. Do Van Dong (Deputy Director-General, DAV), Dr. Nguyen Ngoc Anh (Deputy Director, Drug Registration Division, DAV), and many other staff participated in the symposium.

Mr. Dong and Dr. Fujiwara were made opening remarks in this symposium and then at the sessions on Regulatory system, Pharmaceutical Review and Pharmacovigilance, presentations and discussions were held by the participants from both countries to share regulatory system of pharmaceuticals.

The details of the symposium are available at the following website.

<http://www.pmda.go.jp/english/symposia/o156.html>

4. PMDA-ATC CMC/GMP Seminar 2019 in Hanoi, Vietnam

On October 9, PMDA held a seminar entitled "PMDA-ATC CMC/GMP Seminar 2019 in Hanoi, Vietnam". This seminar is the course for regulatory agencies, Drug Administration of Vietnam (DAV). A total of 33 regulators from Vietnam (10 DAV staff and 23 external experts) participated in the seminar.

The seminar opened with remarks by Dr. Nakashima. The program of the seminar included lectures by staff members from PMDA, DAV and the external expert on the topics of the Review of Chemistry, Manufacturing and Control (CMC) and Overview of Good Manufacturing Practice (GMP) inspection. Besides the lectures, case studies of the GMP inspection were conducted.

At the end of the seminar, the course completion certificates were handed to participants by Dr. Nakashima.

Please refer to the following website for the details of PMDA-ATC CMC/GMP Seminar 2019 in Hanoi, Vietnam.

<https://www.pmda.go.jp/english/symposia/o151.html>



Group photo of Participants. From left to right, Dr. Anh (Deputy Director, Drug Registration Division) (4th), Mr. Dong (Deputy Director-General) (5th), Dr. Fujiwara (Chief Executive) (6th), Dr. Nakashima (Senior Director for International Programs) (7th).



Group photo of participants and PMDA directors.
Back row from left to right, Dr. Nakashima (Senior Director for International Programs) (8th).

5. ICMRA Summit Rome Meeting

The ICMRA (International Coalition of Medicines Regulatory Authorities) Summit meeting was held in Rome, Italy, from October 28 to 30. About 100 members from 26 nations and regions participated. From PMDA, Dr. Fujiwara, Dr. Nakashima, and one staff member from the Office of International Programs, and from MHLW, Mr. Yasuda and one staff member participated in this meeting. On the first day, there were discussions on building reliance among regulatory authorities. On the second day, heads of agency level discussions were held in panel discussion and free discussion format on the digitalized healthcare, clinical trials in separate populations, a comprehensive policy framework for regenerative medicines, and regulation on medical use of Cannabis. From PMDA, Dr. Fujiwara participated as a panelist for the session on the reliance and regenerative medicines. On the third day, Dr. Fujiwara led the discussion as a Vice-Chair collaborating with EMA (Chair) and TGA (Vice-Chair). The ICMRA Innovation Project, AMR, future topics of ICMRA, and other topics were discussed. PMDA/MHLW presented interim results on regulator's horizon scanning analysis as part of the Innovation project co-led by Japan, as well as the ICMRA website which is maintained and hosted by PMDA.



Group photo of participants

The next ICMRA meeting will be held on the margins of the DIA Annual Meeting in Brussels, Belgium on March 16, 2020

6. Australian Regulatory Authority announced to include Japan as a reference country for expedited review for prescription medicines

Therapeutic Good Administration (TGA), Australia announced that PMDA is included to the Comparative Overseas Regulators (CORs) for prescription medicine if an applicant submits NDA dossier together with PMDA review report in English. This is because there is sufficient similarity of pharmaceutical evaluation between TGA and PMDA.

Accordingly, if a company intends to apply its application approved in Japan to TGA, the review period will be shorten to 120 or 175 working days, which will lead to an early launch in Australia. This is expected to accelerate access to drugs developed in Japan and contribute to promoting export of Japanese medicinal products and improving the quality of health care in Australia.

MHLW and PMDA continuously enhance to collaborate with TGA for the international regulatory convergence through bi-lateral meeting, etc.

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 |
|---------------------------------------|---|--------------|
| Keytruda [Partial Change Approval] | pembrolizumab (genetical recombination) | October 17 |
| Soliris [Partial Change Approval] | eculizumab (genetical recombination) | October 17 |
| Goofice [Initial Approval] | elobixibat hydrate | October 30 |

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 367 (October 23, 2019)

1. Publication of Risk Management Plan (RMP) Materials on the PMDA website
2. Summary of the Relief System for Adverse Drug Reactions and Request for Cooperation with the System
3. Important Safety Information
 1. Baricitinib
 2. Osimertinib mesilate
4. Revision of Precautions (No. 307)
Baricitinib (and 14 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>

Pharmaceuticals Revisions of PRECAUTIONS (October 29, 2019)

- Methylphenidate hydrochloride (sustained-release tablets)
- Vonoprazan fumarate
- Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- D-Sorbitol (urologic irrigating solution)
- Belimumab (genetical recombination)

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

Pharmaceuticals Revisions of PRECAUTIONS (November 12, 2019)

- Urokinase (60 000 units)

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

Pharmaceuticals Revisions of PRECAUTIONS (November 15, 2019)

- Apalutamide
- Enzalutamide

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

Events

Conferences/Meetings PMDA hosts or participates in:

| Date | Title | Location |
|----------------|---|----------|
| December 10-12 | PMDA-ATC Quality Control (Herbal Medicine) Seminar 2019 | Toyama |
| December 11 | Japan-US HBD East 2019 Think Tank Meeting | Tokyo |
| January 20-23 | PMDA-ATC MRCT Seminar 2020 | Tokyo |

Reports from overseas

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

USP Workshop on peptide and oligonucleotide therapeutics

The United States Pharmacopeia (USP) held "USP Workshop on Peptide and Oligonucleotide Therapeutics: Regulations, Standards and Quality" from November 4 to 5, 2019¹. Although this series of WS were focused on only peptide therapeutics till the last year², discussion about oligonucleotide (ON) therapeutics was included from this year.

About peptide therapeutics, the analytical technology and assessment of impurity profile, which would be important discussion points to explain the "Sameness" between products, were mainly discussed based on the US Food and Drug Administration (FDA)'s draft guidance³ related to generic drug development of synthetic peptide therapeutics published in 2017. There were also other presentations related to control strategy and the necessity of bioassay.

Regarding ON, it was stated that there are challenges to apply concepts of existing ICH guidelines on impurity-control etc. to ONs, because characteristics of ONs are intermediate between small molecules and large molecules. Considering the challenges, assessment approach and control strategy of impurities, new solution of identification, and new analytical technology were mainly discussed.

- 1) <https://www.usp.org/events-training/workshops/therapeutic-peptides-oligonucleotides>
- 2) <https://www.usp.org/events-training/workshops/5th-workshop-therapeutic-peptides>
- 3) <https://www.fda.gov/media/107622/download>

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