



Capricornis Crispus

PMDA Updates

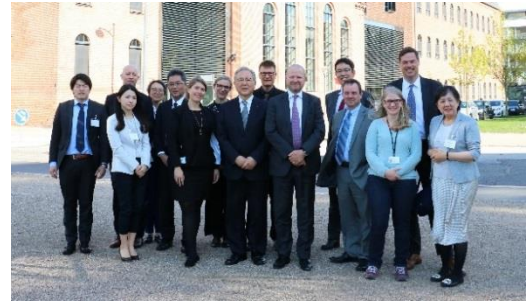
June, 2018

News

1. Exchanging letters of Confidentiality Arrangements with Danish Medicines Agency

On May 2, Danish Medicines Agency (DKMA) and MHLW/PMDA exchanged letters of Confidentiality Arrangements (CA) in Copenhagen, Denmark. From PMDA, Dr. Tatsuya Kondo, Chief Executive, and two staff members from the Office of International Programs; from MHLW, Dr. Nobumasa Nakashima, Office Director, Office of International Regulatory Affairs and one staff from Pharmaceutical Safety division participated in the signing ceremony.

The purpose of this exchange of letters is to facilitate increased access to safe, effective and high quality products, and share confidential information related to these products. DKMA and MHLW/PMDA also had the bilateral meeting and exchanged the latest information on each regulatory challenges and discussed towards future collaboration.



Group photo in front of DKMA

2. Joint New Drug WG - GBO WG Workshop of Taiwan and Japan

On May 8, Joint New Drug WG - GBO WG Workshop of Taiwan and Japan was held in Taipei, Taiwan. Mr. Naoyuki Yasuda, Office Director, Office of International Programs and one staff member from Office of Generic Drugs from PMDA; and Ms. Fumi Yamamoto, Director, Pharmaceutical Evaluation Division and one staff member from MHLW participated in the workshop. Based on the discussion from the 5th Joint Conference of Taiwan and Japan on Medical Products Regulation held in November last year, this was held to share the information on progress in cooperation of new drugs and generic drugs, which Taiwan and Japan regulators work on in collaboration with each other. Presentations including those by MHLW's Ms. Yamamoto on updates of the regulatory environment in Japan, and by a PMDA staff member on generic drug review practices, followed by Q&A exchanges. This enhanced communication with the industries in Taiwan and Japan on this subject.

Building on this, to encourage further collaboration, the 6th Joint Conference of Taiwan and Japan on Medical Products Regulation will be held in this October in Tokyo.

3. The 1st International Pharmaceutical Regulators Programme (IPRP) Working Group Meetings

From May 16 to 17, Working Groups (WGs) for generic drugs under International Pharmaceutical Regulators Programme (IPRP) met in Bern, Switzerland, attended by about 30 participants from 15 countries/regions/organizations. From Japan, 4 staff members from PMDA's Office of Generic Drugs participated in the meetings of Quality WG and the Bioequivalence WG for Generic drugs. These WGs were formerly convened under International Generic Drug Regulators Programme (IGDRP), which was reviewed and consolidated into International Pharmaceutical Regulators Programme (IPRP) as of January 2018. In the meeting, opinions regarding existing projects were shared among participants, papers were finalized as deliverables of the activities, and future directions were discussed.

The next WG meeting will be held in Canberra, Australia.

4. IMDRF GRRP Working Group Meeting

From May 14 to 18, a meeting of IMDRF (International Medical Device Regulators Forum) GRRP (Good Regulatory Review Practice) Working Group (WG) was held in Eindhoven, Netherlands. Attendees from regulatory authorities in Japan included 5 staff members from PMDA's Office of Medical Devices III, Office of In Vitro Diagnostics, Office of Standards and Guidelines Development, and Office of International Programs as well as Ministry of Health, Labour and Welfare.

Since its establishment in December 2015, IMDRF GRRP working group has been working toward harmonization across countries in the review processes, through standardization of requirements for premarket reviews and competence for regulatory reviewers. This WG has published a guidance document on Competence, Training and Conduct Requirements for Regulatory Reviewers. This meeting concentrated on revising GHTF's Essential Principles and GHTF's Label and Instructions for Use documents. A final draft document of the Essential Principles was produced to address the public comments in each member countries. Also, a draft Label and Instructions for Use document for consultation was developed.

IMDRF, especially IMDRF Standards WG, has been promoting collaboration with international standards bodies including ISO and IEC. This meeting was held as a joint meeting with ISO TC210 WG2 which reviews standards similar to those of GRRP WG. The meeting was productive with active discussions from both perspectives.

English translations of review reports

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

Pharmaceuticals

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

Brand Name	Generic Name	Posting date
Loqoa	esflurbiprofen/mentha oil	May 14
Taltz	Ixekizumab (genetical recombination)	May 23
Avastin [Partial Change Approval]	bevacizumab (genetical recombination)	May 31

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS, June 5, 2018

- Amiodarone hydrochloride
- Filgrastim (genetical recombination)
- Filgrastim (genetical recombination, follow-on biologic 1)
- Filgrastim (genetical recombination, follow-on biologic 2)
- Filgrastim (genetical recombination, follow-on biologic 3)
- Pegfilgrastim (genetical recombination)
- Lenograstim (genetical recombination)
- Everolimus (tablets 2.5mg/5mg)
- Everolimus (dispersible tablets 2mg/3mg)
- Eftrenonacog alfa (genetical recombination)
- Metronidazole (oral dosage form)
- Metronidazole (injectable dosage form)
- Lansoprazole/amoxicillin hydrate/metronidazole
- Rabeprazole sodium/amoxicillin hydrate/metronidazole
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole

<http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0006.html>

PMDA Medical Safety Information No. 54 (June, 2018)

Precautions When Using an Indwelling Bladder Catheter

<http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html>

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
July 3	3rd Korea-Japan Joint Symposium on Medical Products	Tokyo
August 22-24	APEC-LSIF-RHSC SOM3 meeting	Brisbane

Reports from overseas

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

Chimeric antigen receptor T-cell therapy registries workshop

The EMA held a chimeric antigen receptor (CAR) T-cell therapy registries workshop on 9 February 2018. For CAR T-cell therapy products, while "Kymriah" had been approved in August 2017 in USA, the product was under assessment in EU at the time of the workshop (there are no other products approved in either region).

The workshop focused on contents and operations of registries where effect and safety data should be collected once CAR T-cell therapy products are marketed. Not only general potential issues related to this kind of registries such as how to ensure data quality and how to collect funds for their operations, but also common data items to be collected for CAR T-cell therapy products were discussed. Such discussions before relevant products marketed would help effective and efficient operations of the registries.

As Japan has also promoted environment arrangements for use of Advanced Therapy Medicinal Products (ATMPs) like the publication of guidelines for registries of ATMPs, it is significant to share experiences related to such registries between Japan and EU.

Mr. Hideyuki Kondo

PMDA's International Liaison Officer stationed at EMA in the United Kingdom