



Mt Fuji and *Prunus Cerasus*

PMDA Updates

April, 2018

News

1. Unit Manager GLP GCP GDP & Head GLPMA of UK's MHRA visits PMDA

On March 14, Dr. Andrew Gray, Unit Manager GLP GCP GDP & Head GLPMA, Medicines and Healthcare Products Regulatory Agency (MHRA), the UK's regulator of medicines medical devices and blood components for transfusion, made a courtesy visit to PMDA, where he exchanged opinions with Dr. Tatsuya Kondo, Chief Executive; Mr. Haruo Akagawa, Senior Executive Director (as of March 2018); Mr. Seiichi Inoue, Executive Director; and Dr. Takao Yamori, Executive Director as well as PMDA staff in GxP area. In this meeting, current trends in the UK and Japan, and future cooperation between the two agencies were discussed.

Also, we exchanged opinions on technical aspects of inspections. This was particularly worthwhile as mutual understanding was achieved, and also cooperation possibilities were enhanced at operational level.



Dr. Kondo and other PMDA executives with Dr. Gray from MHRA

2. The 13th IMDRF Management Committee Meeting

From March 20 to 22, the 13th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting was held in Shanghai, China, and three staff members from PMDA's Office of International Programs as well as a staff member from Ministry of Health, Labour and Welfare (MHLW) attended as the representatives from the MC Member jurisdiction. The first and third day of the meeting were dedicated to the closed sessions for regulators, official observers and invited observers only, where, in addition to the guidance documents developed by each working group, new work items were discussed. In this meeting, the MC approved the draft on "registry assessment tool" proposed by the Medical Device Patient Registries Working Group as well as the draft on "Table of Contents" proposed by the Regulated Product Submission (RPS) Working Group as final documents.



Group photo of participants

On the second day, an open Stakeholder Forum was held with approximately 500 participants including members from MC and industry, and active discussions were held on issues of interest to industry, particularly the use of artificial intelligence (AI). The MC members from Japan provided an outline of recent regulatory efforts, and a progress report of the Medical Device Adverse Event Terminology Working Group which Japan takes the chair.

On March 19, prior to the IMDRF meeting, DITTA (Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association) Workshop on Cybersecurity was held, where MHLW staff member presented current efforts for cybersecurity in Japan. Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC) meeting was also held in the afternoon and Japanese delegates attended as a member country.

The next IMDRF MC Meeting will be held in Beijing, China, in September 2018.

The details of the 13th IMDRF MC Meeting are available at the following web site.

<http://www.imdrf.org/meetings/meetings.asp>

3. 4th Self-CARER

From March 20 to 22, the 4th Self-CARER (Self-Medication Collaborative ASIAN Regulator Expert Roundtable) was held in Taipei, Taiwan and attended by about 30 regulators from 10 regulatory agencies in Taiwan, India, Indonesia, Japan, Malaysia, New Zealand, Singapore, Thailand and Vietnam to discuss international cooperation in the Asia Pacific region in the area of self-care medicines. This roundtable was arranged following the previous 3rd Self-CARER held in October 2016 in Nagoya, and it was chaired by Japan (Mr. Naoyuki Yasuda, Office Director, Office of International Programs, PMDA), co-chaired by Thailand and Taiwan, and participated by 3 other staff members from PMDA.

International Conference of Self-Medication Trends and Regulations was held during this roundtable period. In this conference, achievements of Self-CARER to date were outlined by the co-chair-Thailand, and each country's regulatory system for self-care medicines was outlined by its regulator. To wrap up the conference, the outcome of the 4th Self-CARER as well as the future of Self-CARER was presented by the chair-Japan, and expectations for Self-CARER were expressed by the participants.

4. ICH interim meeting

From March 26 to 27, ICH interim meeting was held at the European Medicines Agency (EMA) Conference Room in London to bring together New Topics Subcommittee, Implementation Subcommittee, Training Subcommittee and Communication Subcommittee. Streamlining the process of New Topics proposals was initiated a year ago, but coordination was not sufficient to accomplish this especially in terms of the process for selection of new topics.

To reflect on the situation, the interim meeting was convened to facilitate coordination required for the Assembly. The meeting resulted in efficient discussions ahead of the Kobe meeting in June, which was regarded as very productive.

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
Mikeluna	carteolol hydrochloride/latanoprost	March 14
Feburic [Initial Approval]	febuxostat	March 15
Feburic [Partial Change Approval]	febuxostat	March 15
Kenketu Glovenin-I	freeze-dried polyethylene glycol-treated human normal immunoglobulin	March 15
Hemangioli	Propranolol Hydrochloride	March 15

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS, March 27, 2018

- Propofol
- Adrenaline (preparations indicated for emergency supplemental treatment of anaphylactic reactions caused by allergens in vespid venom, food, drugs and other allergens)
- Adrenaline (preparations indicated for emergency supplemental treatment of acute hypotension or shock associated with various diseases or conditions)
- alpha blocking antipsychotics (see the link for details)
- antimicrobials indicated for pharyngolaryngitis, tonsillitis, acute bronchitis, infectious gastroenteritis, or

sinusitis (Notification: 'Revision of PRECAUTIONS for antimicrobials', PSEHB/PSD Notification No. 0327-1, dated March 27, 2018)

<http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0005.html>

PMDA Medical Safety Information No. 53 (March, 2018)

Introduction of Connectors that Prevent Misconnection

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

Risk Information which some safety measures might be taken (March 30, 2018)

- Tosufloxacin tosilate hydrate (for oral use)
- Omarigliptin
- Trelagliptin succinate
- Saxagliptin hydrate
- Pembrolizumab (genetical recombination)
- Cladribine

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

Pharmaceuticals and Medical Devices Safety Information No. 352, April 17, 2018

1. Introduction of the International Standards (ISO [IEC] 80369 series) Related to Connectors for Prevention of Interconnection

- Switching of small-bore connectors for neuraxial anesthesia -

2. Important Safety Information

(1) Tolvaptan

(2) Anagliptin, linagliptin, teneligliptin hydrobromide hydrate, teneligliptin hydrobromide hydrate/canagliflozin hydrate

(3) Anagliptin

(4) Sterile talc

3. Revision of Precautions (No. 293)

Tolvaptan (and 5 others)

4. List of Products Subject to Early Post-marketing Phase Vigilance

<http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0016.html>

Pharmaceuticals Revisions of PRECAUTIONS, April 19, 2018

- Omarigliptin
- Saxagliptin hydrate
- Trelagliptin succinate
- Cladribine
- Pembrolizumab (genetical recombination)
- Tosufloxacin tosilate hydrate (for oral use)

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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
June 2-7	ICH week	Kobe

June 11-14	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2018	Tokyo
June 18-22	PMDA-ATC Pharmaceuticals Review Seminar 2018	Tokyo
June 18-22	DIA 54th Annual Meeting 2018	Boston

Reports from overseas

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

Second EMA International Awareness Session

Following the successful first EMA International Awareness Session in September 2017, a second session was held on 8-9 March 2018. In addition to continued strong interest from international regulators, there were many participants from academia and non-profit organizations (NGOs) at the session among an enlarged number of attendees.

The contents of the Session were similar to last time and provided a good opportunity to comprehensively learn not only about the EMA's business but also the whole EU regulatory framework. By updating the order of topics and contents themselves to make the session more accessible for academics and NGOs, the attendees were allowed to understand it more easily and join the discussions more actively.

Mr. Akihiro Manaka and Mr. Kento Takamura from Product Evaluation Division in the Ministry of Health, Labour and Welfare, Japan, attended the Session and collected latest information. In addition, they were able to use the margins of the meeting to promote building cooperative relationships, for example, by exchanging opinions with EMA staff and providing regulators from other countries with information on regulations in Japan.

The next session is being planned in September 2018. I expect that these regular sessions will allow Japan to strengthen communications with Europe and other countries.

Mr. Hideyuki Kondo

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