



Hydrangea

PMDA Updates

June, 2019

News

1. IMDRF Working group face-to-face meeting

From May 7 to 10, a face-to-face meeting of IMDRF (International Medical Device Regulators Forum) GRRP (Good Regulator Review Practices) Working Group was held in Singapore. Staffs from Office of International Programs, Office of Standards and Compliance for Medical Device, and Office of Manufacturing Quality and Vigilance for Medical Devices attended the meeting. This working group works on single review and has currently developed a guidance related to recognition of Conformity Assessment Bodies conducting medical device regulatory reviews. In the meeting, we discussed a draft of the guidance for public comments.

From May 13 to 16, a face-to-face meeting of IMDRF Standard Working Group was held in Brussels, Belgium. Staffs from Office of International Programs, and Office of Standards and Compliance for Medical Device attended the meeting. The working group mainly discussed the results of a survey on the recognition status of each country for international standards including ISO. Additionally, a draft procedure was prepared for establishing and maintaining liaisons between IMDRF and each international standards body such as ISO. These working groups will continue to discuss these drafts.

2. The 6th Thailand-Japan Symposium

The 6th Thailand-Japan Symposium was held in Bangkok, Thailand on May 15, co-hosted by Thai Food and Drug Administration (Thai FDA) and PMDA, and attended by 208 people in total. The participants from Japan included Dr. Yasuhiro Fujiwara (Chief Executive), Dr. Nobumasa Nakashima (Senior Director for International Programs), Dr. Kensuke Ishii (Office Director of Office of Medical Devices II), as well as staff from Office of Medical Devices II, Office of In Vitro Diagnostics, Office of Pharmacovigilance II, and Office of International Cooperation of PMDA and staff of Ministry of Health, Labour and Welfare. From Thai FDA, Dr. Tares Krassanairawiwong (Secretary-General), Dr. Surachoke Tangwiwat (Deputy Secretary-General), and many other staff participated in the symposium.

Dr. Krassanairawiwong and Dr. Fujiwara were made opening remarks in this symposium and then VTR session was held for looking back on the 1st-5th symposiums and the favorable cooperation between Thailand and Japan. After that, at sessions on pharmaceuticals as well as those on medical devices, presentations and discussions were held by the participants from both countries to share regulatory updates on pharmaceuticals and medical devices.

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

<http://www.pmda.go.jp/english/symposia/0149.html>



Group photo of Participants. From right to left, Dr. Krassanairawiwong (5th), Dr. Fujiwara (6th), Dr. Nakashima (7th), and Dr. Ishii (8th).

3. DIA China Annual Meeting

From May 20 to 23, DIA China Annual Meeting was held at Beijing International Convention Center in Beijing, China. Dr. Tatsuya Kondo, Honorary Chief Executive of PMDA, and 3 other staffs were attended to the meeting and delivered presentations. In the Opening Plenary, Dr. Kondo delivered a presentation as Keynote Lecture on Regulatory Science that he promoted while in office. In the same session, Dr. Junko Sato, Office Director, Office of International Programs, participated a Panel Discussion regarding future prospectives of Regulatory Science with US FDA, EMA, and Chinese academia. It was a lively meeting with more than 150 exhibitors and over two thousand participants.

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	Non-proprietary Name	Posting date
Jivi [Initial Approval]	damoctocog alfa pegol (genetical recombination)	May 28
Cymbalta [Partial Change Approval]	duloxetine hydrochloride	June 13

Regenerative Medical Products

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html>

Brand Name	Generic Name	Posting date
Stemirac [Initial Approval]	human (autologous) bone marrow-derived mesenchymal stem cells	May 31
JACC [Initial Approval]	human autologous tissue for transplantation	June 13

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (June 4, 2019)

- Eletriptan hydrobromide
- Zolmitriptan
- Naratriptan hydrochloride
- Rizatriptan benzoate
- Sumatriptan
- Sumatriptan succinate (oral dosage form)
- Sumatriptan succinate (injectable dosage form, ampules)
- Sumatriptan succinate (injectable dosage form, kit)
- Avelumab (genetical recombination)
- Nivolumab (genetical recombination)
- Pembrolizumab (genetical recombination)
- Baloxavir marboxil

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

Pharmaceuticals and Medical Devices Safety Information No. 363 (June 4, 2019)

1. Direct Patient Reporting System for Adverse Drug Reactions
2. Research Project on Development of Educational Programs for Healthcare Professionals who Engage in Interviews with Patients about Sensitive Matters
3. Important Safety Information
 1. Dulaglutide (genetical recombination)
 2. Empagliflozin
 3. Nivolumab (genetical recombination)
 4. Lenvatinib mesilate
 5. Influenza HA vaccine
4. Revision of Precautions (No. 303)
Dulaglutide (genetical recombination) (and 11 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/0017.html>

Medical Devices Revisions of PRECAUTIONS (June 7, 2019)

- Revision of Precautions to the Package Inserts of Gel-filled Breast Implant

<https://www.pmda.go.jp/english/safety/info-services/devices/0002.html>

Risk Information which some safety measures might be taken (June 14, 2019)

- Epoprostenol sodium
- Nivolumab (genetical recombination)
- Pembrolizumab (genetical recombination)
- Febuxostat
- Standardized cedar pollen extract (liquid)
- Allergen extract (1) (tablet)
- Allergen extract (2) (tablet)
- Cedar pollen extract
- Palbociclib

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

Pharmaceuticals Revisions of PRECAUTIONS (June 18, 2019)

- Metformin Hydrochloride(preparations with a daily maximum dose of 2 250 mg)
- Metformin Hydrochloride(preparations with a maximum daily dose of 750 mg)
- Anagliptin/metformin hydrochloride
- Alogliptin benzoate/metformin hydrochloride
- Pioglitazone hydrochloride/metformin hydrochloride
- Vildagliptin/metformin hydrochloride

<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
July 8-11	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2019	Tokyo
July 16	4th Korea-Japan Joint Symposium on Medical Products	Seoul
July 22-26	PMDA-ATC & WHO Pharmaceuticals Review Seminar 2019	Tokyo
August 15-16	APEC-LSIF-RHSC SOM3 meeting	Puerto Varas