



Cerasus

PMDA Updates

April, 2019

News

1. Message from New Chief Executive of PMDA

The Pharmaceuticals and Medical Devices Agency (PMDA) plays three key roles—relief services for persons injured by adverse reactions to drugs and regenerative medical products, product reviews, and safety measures. To provide patients and healthcare professionals with rapid access to safer, more effective drugs, medical devices, and regenerative medical products, the PMDA is engaged in ensuring quality, efficacy, and safety from development to post-market stages.

Since its inception in 2004, the PMDA has steadily improved its outcomes based on regulatory science. Those include significantly diminishing its review time frame for new products. With the emergence of innovative products, an increasing number of cases will have no precedents to refer to, propelling the PMDA to be the first in the world to make regulatory decisions. Quality at the PMDA will be even more important.

The PMDA will promote regulatory science, assess risks and benefits from scientific perspectives while remaining vigilant of timeframes, with the spirit of Safety First. The PMDA will also further transparency, to better convey grounds for its decisions to healthcare professionals, patients, and the public.

Relief services for persons injured by adverse reactions to drugs and regenerative medical products are highly regarded internationally and is the source of Japanese pride, our precious asset. The PMDA will carry on with offering support to people who have suffered injuries related to drugs and regenerative medical products.

Today, the PMDA is recognized as a regulatory authority standing shoulder-to-shoulder with its counterparts in Europe and the United States. We look forward to playing an active role in discussions on international harmonization of regulations, and will contribute to raising standards at Asian and other regulatory authorities.

Without being bound by precedents, the PMDA will proactively pursue new initiatives and contribute to the advancement of the public health and safety of all people in Japan.

Yasuhiro Fujiwara, MD, PhD
Chief Executive
Pharmaceuticals and Medical Devices Agency



2. The 10th International Meeting of World Pharmacopoeias

From March 4 to 5, the 10th International Meeting of World Pharmacopoeias (IMWP) was held in Geneva, Switzerland. Two staff members from Office of Review Management, PMDA participated as the representatives of Japanese Pharmacopoeia (JP). Each-participating pharmacopoeia shared recent updates and all participants discussed common interests and concerns on pharmacopoeias. JP presented the outline of Supplement II to the JP 17 edition to be published around May 2019.

Regarding individual projects, the meeting discussed the contents and finalizing schedule for “a white paper on the added value of having pharmacopoeial standards for public health”



Group photo of participants

which was prepared by a drafting team which includes JP as one of drafting members. The meeting also discussed and reached a consensus on the standard working procedure of future projects at IMWP.

3. The 15th IMDRF Management Committee Meeting

From March 19 to 21, the 15th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting was held in Moscow, Russia, and three staff members from Office of International Programs, PMDA along with a staff member from Ministry of Health, Labour and Welfare (MHLW) attended as the MC Members. On the first day, an open IMDRF Stakeholder Forum was held with approximately 200 participants including members from MC and industry, and the participants discussed issues on interest to industries such as next generation sequencing. The MC members from Japan provided an outline of recent Japanese regulatory challenges, and a progress report of the Adverse Event Terminology WG (AE WG), chaired by Japan. The second and the third day of the meeting were dedicated to the closed sessions for regulators and official and invited observers only, where, in addition to the guidance documents developed by each WG, new work items were discussed. In this meeting, the final documents of Principles of Labeling submitted by the Good Regulatory Review Practices WG, Terminologies for Categorized Adverse Event Reporting submitted by AE WG and UDI System Application Guide submitted by the UDI WG were approved. The documents for public consultation submitted by the Medical Device Clinical Evaluation WG and the Personalized Medical Devices WG were also approved.

On March 18, prior to the IMDRF meeting, a workshop sponsored by DITTA (The Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association) was held under the theme of optimizing standards for regulatory use. Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC) meeting was also held in the afternoon and Japan delegates attended as a member country.

The next IMDRF MC Meeting will be held in Ekaterinburg, Russia, in September 2019. The details of the 15th IMDRF MC Meeting will be available at the following web site.

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

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>

Lorbrena

lorlatinib

April 4

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS, March 19, 2019

- Quetiapine fumarate (tablets, fine granules)
- Quetiapine fumarate (extended release tablets)
- Clozapine
- Vonoprazan fumarate
- Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- Vonoprazan fumarate/amoxicillin hydrate/metronidazole
- Denosumab (genetical recombination) (120 mg product)
- Intravenous injection preparations containing sorbitol as excipient
- Intravenous injection preparations containing fructose as excipient

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

Pharmaceuticals Revisions of PRECAUTIONS, March 28, 2019

- Amobarbital
- Secobarbital sodium
- Pentobarbital calcium
- Sodium valproate
- Cefmenoxime hydrochloride

- Ceftibuten hydrate
- Cefaclor
- Cefazolin sodium
- Cefazolin sodium hydrate
- Cefalexin
- Cefalotin sodium
- Cefixime hydrate
- Cefepime dihydrochloride hydrate
- Cefozopran hydrochloride
- Cefotiam hydrochloride
- Cefoperazone sodium/sulbactam sodium
- Cefcapene pivoxil hydrochloride hydrate
- Cefditoren pivoxil
- Cefdinir
- Ceftazidime hydrate
- Ceftizoxime sodium
- Cefteram pivoxil
- Ceftriaxone sodium hydrate
- Cefpirome sulfate
- Cefpodoxime proxetil
- Cefminox sodium hydrate
- Cefmetazole sodium
- Cefroxadine hydrate
- Flomoxef sodium
- Latamoxef sodium
- Hydroxyethylated starch 70000
- Hydroxyethylated starch 70000/sodium chloride/potassium chloride/calcium chloride hydrate/sodium lactate
- Penicillamine (50 mg, 100 mg)
- Vancomycin hydrochloride (injectable dosage form)
- Benzylpenicillin benzathine hydrate
- Benzylpenicillin potassium
- Amoxicillin hydrate
- Amoxicillin hydrate/potassium clavulanate
- Ampicillin hydrate
- Ampicillin sodium
- Ampicillin sodium/sulbactam sodium
- Sultamicillin tosilate hydrate
- Bacampicillin hydrochloride
- Piperacillin sodium
- Ampicillin hydrate/cloxacillin sodium hydrate
- Ampicillin sodium/cloxacillin sodium hydrate
- Imipenem hydrate/cilastatin sodium
- Tebipenem pivoxil
- Doripenem hydrate
- Panipenem/betamipron
- Biapenem
- Faropenem sodium hydrate
- Meropenem hydrate
- Cefotaxime sodium
- Cefuroxime axetil

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

Risk Information which some safety measures might be taken (March 29, 2019)

- Sumatriptan succinate
- Naratriptan hydrochloride

- Eletriptan hydrobromide
- Zolmitriptan
- Rizatriptan benzoate
- Ipragliflozin L-proline
- Dapagliflozin propylene glycolate hydrate
- Tofogliflozin hydrate
- Luseogliflozin hydrate
- Canagliflozin hydrate
- Empagliflozin
- Tenepliptin hydrobromide hydrate/canagliflozin hydrate
- Sitagliptin phosphate hydrate/ipragliflozin L-proline
- Empagliflozin/linagliptin
- Dulaglutide (genetical recombination)
- Lenvatinib mesilate
- Nivolumab (genetical recombination)
- Influenza HA vaccine

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

Pharmaceuticals and Medical Devices Safety Information No. 362, April 16, 2019

1. Guidelines for Prescription Drug Marketing Information Provision
2. Revision of Package Inserts of Intravenous Injection Products Containing Sorbitol or Fructose as Excipient for Use in Patients with Hereditary Fructose Intolerance
3. Important Safety Information
 1. Baloxavir marboxil
 2. Quetiapine fumarate
 3. (1) Vonoprazan fumarate
(2) Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
(3) Vonoprazan fumarate/amoxicillin hydrate/metronidazole
4. Revision of Precautions (No. 302)
Oseltamivir phosphate (and 7 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
May 15-16	6th Thailand – Japan Symposium	Bangkok
May 20-23	11th DIA China Annual Meeting	Beijing
June 1-6	ICH Week	Amsterdam
June 23	International Coalition of Medicines Regulatory Authorities (ICMRA) Meeting	San Diego
June 23-27	DIA 54th Annual Meeting 2019	San Diego

Reports from overseas

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

New support program for developing countries funded by USAID (PQM+)

The United States Pharmacopeial Convention (USP) collaborates with United States Agency for International Development (USAID)¹⁾ and provides support program named as "Promoting the Quality of Medicine (PQM)"²⁾, in order to improve and assure pharmaceutical quality for developing countries since 2009 to 2019³⁾. In March, USAID published a new support program "PQM+" as a follow-on program to the PQM, and is receiving concept papers from public⁴⁾.

PQM+ anticipated start date is on or about July 31, 2019, and is not expected to exceed 5 years in duration. USAID anticipates need for medical product quality assurance systems strengthening in 55 priority countries⁵⁾ as well as at the global level. The expected total amount will be up to \$160 million. The goal of PQM+ is to sustainably strengthen medical product quality assurance systems in low and middle-income countries. To achieve this goal, 5 objectives are settled as follows;

- Governance for medical product quality assurance systems improved
- Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved
- Financial resources for medical product quality assurance optimized and increased
- Supply of quality-assured essential medical products of public health importance increased
- Global medical product quality assurance learning and operational agenda advanced

1) <https://www.usaid.gov/>

2) <https://www.usp-pqm.org/>

3) <http://www.pmda.go.jp/files/000228949.pdf>

4) <https://www.grants.gov/grantsws/rest/opportunity/att/download/282668>

5) <https://www.usaid.gov/sites/default/files/documents/1864/USAID-Global-Health-Report-Brochure-508.pdf>

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