



Cosmos

PMDA Updates

September, 2019

News

1. Indonesian Health Authorities announced to include Japan as a reference country for 120 days evaluation path for new drug

National Agency of Drug and Food Control (NADFC), Indonesia announced that Japan is included to the reference regulatory authority for 120 days evaluation path for new drug if an applicant submits NDA dossier together with PMDA review report in English. This is because NADFC recognized that the evaluation system of Ministry of Health, Labor and Welfare (MHLW) and PMDA is well established.

Accordingly, if a company intends to apply its new drug approved in Japan to NADFC, the review period will be shorten from the standard of 300 days to 120 days, which will lead to an early access for Indonesian patients to the innovative new drug developed in Japan, and is expected to contribute to the improvement of the quality of health care in Indonesia.

MHLW and PMDA continuously enhance to collaborate with regulatory agencies in Asia for the international regulatory convergence through bi-lateral meeting, training seminar at PMDA-Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, etc.

2. Thai FDA adopts Japanese Pharmacopoeia (JP) as a reference pharmacopoeia

The Food and Drug Administration of Ministry of Public Health of the Kingdom of Thailand (Thai FDA) announced that Thai FDA revised the notification of the Thai Ministry of Health on July 26, 2019, with the initiative of successive secretary generals including Dr. Tares Krassanairawiwong, in order for JP to be a reference pharmacopoeia in Thailand (Its enforcement will take effect 180 days after the day following the official gazette announcement on July 26.).

This is a great result of collaborative relationships between Thai FDA and PMDA/MHLW over the years. We will strengthen cooperation with Thai FDA in the future.

MHLW and PMDA will promote closer collaboration with regulatory agencies in Asia for the international regulatory convergence through bi-lateral meeting, training seminar at PMDA-Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, etc.

3. Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) Meeting

Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) Meeting was held in Puerto Varas, Chile from August 15 to 16. Key participants from Japan included Dr. Nobumasa Nakashima (Senior Director for International Programs, PMDA), Dr. Eriko Fukuda (Office Director, Office of International Cooperation, PMDA) and a staff of MHLW. The APEC-LSIF-RHSC aims to “promote strategic framework for regulatory convergence of medical products regulation”, and is co-chaired by Dr. Nakashima along with Dr. Michelle Limoli from the U.S.FDA from 7 APEC economies, representatives from industry coalition (pharmaceuticals, biopharmaceuticals, medical devices) and academia participated in the meeting. APEC-LSIF-RHSC has established Centers of Excellence (CoEs) focusing on 7 Priority Work Areas (PWAs) to offer trainings for regulatory capacity building to regulators and relevant personnel.



Dr. Nakashima and Dr. Limoli leading as Co-Chair

At the meeting, PMDA was endorsed to hold PMDA-ATC Medical Devices Seminar 2019 in November 2019 (<https://www.pmda.go.jp/english/symposia/0154.html>) as CoE Pilot workshop of Medical device PWA. PMDA expects to have formal certification as a CoE at the APEC-LSIF-RHSC meeting in the first half of 2020. In addition, PMDA reported the result of PMDA-ATC Pharmacovigilance Seminar 2019, a CoE workshop on Pharmacovigilance PWA held in February 2019.

The next APEC-LSIF-RHSC meeting is to be held in Putrajaya, Malaysia in February 2020.

4. The 8th Workshop and Steering Committee of the Regional Alliance for National Regulatory Authorities for Medical Products in Western Pacific Region

From August 27 to 29, Regional Alliance Steering Committee and 8th Workshop for National Regulatory Authorities for Medical Products in the Western Pacific Region were held in Tokyo, Japan. Participants from Japanese government included Dr. Junko Sato (Office Director, Office of International Programs) and 3 other staff members from PMDA; Mr. Naoyuki Yasuda (Director of Office of International Regulatory Affairs) and other staff members from MHLW. In addition, Mr. Hideki Tarumi (Director General, Pharmaceutical Safety and Environmental Health Bureau, MHLW) gave opening remarks for the workshop.

This workshop had total of 41 participants including 28 representatives of the Western Pacific Region countries (Australia, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, Hong Kong, Laos, Malaysia, Micronesia, Mongolia, New Zealand, Papua New Guinea, Philippines, Republic of Korea, Singapore, Tonga and Viet Nam), WHO staff, temporary advisors and observers.

Workshop participants discussed how regulatory competence in the Western Pacific region can be improved, and they visited PMDA as site tour in the afternoon on the 2nd day of the workshop. Taking this opportunity, Dr. Yasuhiro Fujiwara (Chief Executive, PMDA) gave welcome greeting to the workshop participants. Furthermore, Dr. Sato introduced various activities promoted by PMDA's Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs while a staff member of MHLW explained the regulatory systems in Japan. This triggered and resulted in an active discussion among the 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
Afstyla [Initial Approval]	lonoctocog alfa (genetical recombination)	August 27

Medical Devices

<http://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html>

Brand Name	Non-proprietary Name	Posting date
OncoGuide NCC Oncopanel System [Initial Approval]	analysis set for genetic mutations (to acquire comprehensive genomic profiling for cancer)	August 28

Regenerative Medical Products

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

Brand Name	Non-proprietary Name	Posting date
Collatogene [Initial Approval]	beperminogene perplasmid	September 9

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (August 22, 2019)

- Apomorphine hydrochloride hydrate
- Talipexole hydrochloride
- Pramipexole hydrochloride hydrate
- Pramipexole hydrochloride hydrate
- Bromocriptine mesilate
- Pergolide mesilate
- Rotigotine
- Ropinirole hydrochloride
- Cabergoline
- Tofacitinib citrate
- Freeze-dried BCG vaccine

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

Pharmaceuticals Revisions of PRECAUTIONS (September 6, 2019)

- Romosozumab (genetical recombination)
- Trelagliptin succinate

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

Pharmaceuticals and Medical Devices Safety Information No. 366 (September 17, 2019)

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

-Switching of small-bore connectors for enteral application

2. Important Safety Information

1. Freeze-dried BCG vaccine

3. Revision of Precautions (No. 306)

Apomorphine hydrochloride hydrate (and 9 others)

4. 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>

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
October 1-2	The 7th Joint Conference of Taiwan and Japan on Medical Products Regulation	Taipei
October 8-9	The 1st Vietnam-Japan Symposium • PMDA-ATC CMC/GMP Seminar 2019 in Hanoi, Vietnam	Hanoi
October 28-30	ICMRA Summit	Rome
November 10-12	DIA Japan Annual Meeting	Tokyo
November 11-15	PIC/S Committee Meeting and Seminar 2019	Toyama
November 12-15	PMDA-ATC GMP Inspection Seminar 2019	Toyama
November 16-21	ICH & IPRP week	Singapore

November 25-29

PMDA-ATC Medical Devices Seminar 2019

Tokyo

Reports from overseas

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

Multi-Attribute Method (MAM)

MAM is attracting attention in a testing method for quality control of biologics such as therapeutic antibodies¹⁾. MAM is a kind of peptide mapping with a certain degree of quantitativity. Sample proteins are digested by enzymes and the peptide fragments are measured with liquid chromatography/mass spectrometry (LC/MS) using high-resolution mass spectrometry. By characterizing each peak on LC/MS with liquid chromatography/tandem mass spectrometry (LC/MS/MS) in advance, it is thought that MAM can monitor site specific modification (e.g. deamidation, oxidation, glycosylation) quantitatively.

In the US, there is a forum "MAM Consortium" to discuss and share information with the aim of encouraging the development and application of MAM²⁾. The United States Pharmacopeia (USP) and the United States Food and Drug Administration (FDA) has joined this forum as members. At the USP's internal event on July 16th, 2019, a presentation related to MAM was given. FDA also proceeds the evaluation of MAM for quality control of protein therapeutics³⁾.

I've also joined teleconferences of MAM Consortium since March, 2019 based on the mission of Liaison to gather technical information on quality of pharmaceuticals in the US.

- 1) Rogers RS et al, AAPS J 2018; 20: 7.
- 2) <http://mamconsortium.org/>
- 3) <https://www.fda.gov/drugs/science-research-drugs/impact-story-transitioning-powerful-analytical-tool-manufacturing-improve-quality-complex>

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PMDA's Liaison Officer stationed at USP in the U.S.A