



Osmanthus fragrans

PMDA Updates

September, 2018

News

1. 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 Brisbane, Australia from August 22 to 24. 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 Mr. Fumihito Takanashi (Deputy director, Office of International Regulatory Affairs, MHLW). RHSC meeting aims for "Promotion of the strategic framework for the convergence of medical products regulation". Regulators from 9 APEC economies, representatives from industry (pharmaceuticals, biopharmaceuticals, medical devices) and academia participated in the meeting. At the meeting, Dr. Nakashima was approved as the new Co-Chair along with the U.S. as the successor to Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs, PMDA at that time). APEC-LSIF-RHSC has established Centers of Excellence (CoE) focusing on seven priority work areas to offer training for regulatory capacity building to regulators and relevant personnel. At the meeting, PMDA reported the result of PMDA-ATC Pharmacovigilance Seminar 2018, a CoE workshop on pharmacovigilance held in February this year. Also, performance indicators were discussed to assess the outcomes of the committee's activities and priority work areas.

The next APEC-LISF RHSC meeting will be held in Chile in the first quarter of 2019.



Dr. Michelle Limoli, U.S. FDA (left) and Dr. Nobumasa Nakashima, Senior Director for International Programs (right), PMDA co-chairing at the meeting

2. 3rd Japan-India Medical Products Regulation Symposium

From August 27 to 28, the 3rd Japan-India Medical Products Regulation Symposium was held in Delhi, India between Ministry of Health and Family Welfare (MoHFW)/Central Drugs Standard Control Organization (CDSCO) of India and MHLW/PMDA of Japan. This symposium was initiated as part of the cooperation activities based on the "Memorandum of Cooperation on Medical Products Regulation Dialogue and Cooperation Framework" signed between CDSCO and MHLW in December 2015.

In this symposium, following the 2nd symposium held in Tokyo in April last year, we shares the best practices in the regulation of pharmaceuticals and medical devices in both India and Japan and discuss the international regulatory harmonization and cooperation. After the symposium, a bilateral meeting was held where regulators of India and Japan exchanged views on future bilateral cooperation.

The details of the symposium are available at the following web site.

<http://www.pmda.go.jp/int-activities/symposia/0072.html> (in Japanese)

3. Call for application to PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2019 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold a seminar entitled "PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2019" from January 21 to 24, 2019. This four-day seminar is designed for new drug application reviewers from overseas regulatory authorities. The seminar includes lectures, group discussions and clinical site tour with the objective of acquainting the participants with the topics or points to consider including: protocol designing and planning of MRCT, clinical operation, clinical data evaluation,

regulatory review based on results of GCP inspections, post-market benefit/risk assessment of approved drugs based on MRCT, international cooperation and regulatory convergence among regulatory authorities.

The seminar is held as a workshop of the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) Center of Excellence; however, the seminar is open to non-APEC economies as well.

Please refer to the following website for the details of PMDA-ATC MRCT Seminar 2019.

<http://www.pmda.go.jp/english/symposia/0138.html>

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 |
|------------|------------------|--------------|
| Ninlaro | ixazomib citrate | September 5 |

Safety Information

Risk Information which some safety measures might be taken (August 24, 2018)

- Ampicillin sodium
- Ampicillin sodium/cloxacillin sodium hydrate
- Ampicillin hydrate
- Ampicillin hydrate/cloxacillin sodium hydrate
- Bacampicillin hydrochloride
- Sultamicillin tosilate hydrate
- Dolutegravir sodium
- Dolutegravir sodium/abacavir sulfate/lamivudine
- Radium (223Ra) chloride
- Sunitinib malate

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

Pharmaceuticals and Medical Devices Safety Information No. 356, September 4, 2018

1. Guidance on Safe and Secure Radio Wave Utilization in Medical Institutions
2. Important Safety Information
 1. Ceftriaxone sodium hydrate
3. Revision of Precautions (No. 296)
 - (1) Apremilast (and 1 other)
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, September 18, 2018

- Radium (223Ra) chloride
- Sunitinib malate
- Ampicillin hydrate
- Bacampicillin hydrochloride
- Ampicillin sodium/cloxacillin sodium hydrate
- Ampicillin sodium
- Sultamicillin tosilate hydrate
- Ampicillin hydrate/cloxacillin sodium hydrate
- Dolutegravir sodium
- Dolutegravir sodium/abacavir sulfate/lamivudine

<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 |
|----------------|---|-------------|
| October 1-4 | RAPS (Regulatory Affairs Professional Society) Annual Conference | Vancouver |
| October 11-12 | 6th Joint Conference of Taiwan and Japan on Medical Products Regulation | Tokyo |
| October 15-16 | PMDA-ATC Pharmaceuticals Review Seminar 2018 in Nay Pyi Taw, Myanmar | Nay Pyi Taw |
| October 22-24 | PMDA-ATC Quality Control (Herbal Medicine) Seminar 2018 | Toyama |
| November 10-15 | ICH week | Charlotte |
| November 12-16 | PMDA-ATC Medical Devices Seminar 2018 | Tokyo |
| November 26-30 | PMDA-ATC GMP Inspection Seminar 2018 | Tochigi |

Reports from overseas

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

Participation in EU GCP Inspectors Working Group meeting from Japan

The EU GCP Inspectors Working Group is composed of EMA staff and GCP inspectors from EU countries, and focuses on harmonisation and co-ordination of GCP-related activities as well as promoting international cooperation. As part of the activities, face-to-face meetings are regularly arranged, and the recent meeting in June 2018 had participants from PMDA GCP relevant divisions.

The topics at the meeting included sharing and addressing of issues observed in real GCP inspection cases, discussing guidelines under consideration and sharing the update and prospective of GCP-related activities, including the impact of Brexit. A topic related to Japan was also held, where PMDA contributed to active discussions by providing its knowledge and experience.

Staff from US FDA also attended the meeting. While regulators from the 3 regions have exchanged opinions via telephone conferences etc., seeing each other in person deepened their relationship. This was also a valuable opportunity to constructively discuss how to progress further collaboration among Japan, EU and USA in a friendly environment.

Mr. Hideyuki Kondo

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

Workshop regarding the grouping and nomenclature of excipients, and Think Innovation

The United States Pharmacopeial (USP) Convention held the workshop discussing on grouping and nomenclature of excipients on Aug 7th¹⁾. One of the major discussion points was how to classify and give names to the polymers which have various molecular weights and characteristics (eg. liquid/semi-solid/solid) or excipients from different origins. Considering the feedback from the stakeholders regarding the integrity of excipients identification system in the US (UNII²⁾), the suppression of UNII codes for excipient monographs will be effective from Nov 1st through the Compendial Notices³⁾ published on the USP website at the end of August. Looking at their rapid action to control the situation, I feel USP's strong ability to make decision and execution.

The second topic is "Think Innovation" which is USP's internal event held quarterly. In the event, each division prepares their ideas for improvement of USP's activity and/or novel operation. After free discussion at their booth, attendees would vote the idea which they think is the best, which is in turn the idea that is executed. I think this interesting event promotes a nice system which makes every employee think about their operation's progression and enable executives to better understand and implement ideas and thoughts from employees.

- 1) <http://www.usp.org/events-training/workshops/getting-excipient-nomenclature-right>
- 2) <https://fdasis.nlm.nih.gov/srs/>
- 3) <https://www.uspnf.com/notices/removal-unii-code-usp42nf37-online>

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

