



Citrus junos

PMDA Updates

December, 2013

News

1. Korean health officials visits PMDA Kansai Branch (November 8)

Three Korean officials including Dr. Sun-Hee Lee, Director General of Drug Evaluation Department, Ministry of Food and Drug Safety (MFDS), Korea, visited the Kansai Branch of PMDA on November 8, 2013. Dr. Atsushi Tamura, Chief of Kansai Branch, presented the purpose of establishment of the Kansai Branch and the outline of the Pharmaceutical Affairs Consultation on R&D Strategy. Dr. Lee explained the recent organizational changes and the reason for their visit to the Kansai Branch. Both sides actively exchanged opinions during the meeting. The Korean officials were the Branch's first visitors as an overseas regulator.



Center: Dr. Sun-Hee Lee (MFDS), 2nd from the right: Dr. Tamura (Chief of Kansai Branch)

2. ICH meeting (Steering Committee/Working Groups) held in Osaka (November 9 to 14)

For its 2nd biannual meeting for 2013, the ICH Steering Committee (SC) and Working Groups (WGs) met in Osaka, Japan, on November 9-14, 2013. A total of 28 delegates from PMDA, including Dr. Nobumasa Nakashima, Director of Office of International Programs, and other experts, participated in the SC and WG meetings.

For the WGs, the S10 Guideline, the Annex 6 to Q4B (which is the last Q4B Annex), and M8 "eCTD Change Request/Q&A Version 1.25" reached Step 4 of the ICH process. The ICH SC made productive discussions on the governance and organizational aspects of the ICH and so on. In addition, the ICH SC selected 6 new topics from the Efficacy and Multidisciplinary areas, which will undergo the process of guideline development in the ICH. Likewise, the Safety Brainstorming Group selected 4 topics from the Safety area. Experts will discuss new topics from the Quality area. The WGs plan to work on the development of guidelines on newly selected topics in the order of priority, starting in the next ICH meeting.

The next ICH meeting will be held in Minneapolis, Minnesota, U.S., from May 31 to June 5, 2014.

Please also refer to: ICH Osaka Meeting press release.

<http://www.ich.org/ichnews/press-releases/view/article/ich-steering-committee-osaka-japan-november-2013.html>

3. The 1st meeting of International Pharmaceutical Regulators Forum (November 10 to 11)

The 1st meeting of the International Pharmaceutical Regulators Forum (IPRF) was held on November 10-11, 2013, in conjunction with the ICH meeting in Osaka. Dr. Nakashima, Director of Office of International Programs, and others from PMDA participated in the meeting. The IPRF has been formed based on the former Regulators Forum (RF) which was the forum of regulatory participants of the ICH meeting. The IPRF is intended to allow the regulators to discuss challenges faced by them, support the dissemination of ICH guidelines, and exchange



opinions to develop new guidelines. At the meeting, the participants discussed the Terms of Reference of the IPRF and updated the activities of RF taken over by the IPRF. In addition to regulators of the ICH regions, those of many non-ICH countries including Asia and Africa took part in the discussion. Currently, the IPRF is chaired by Dr. Petra Dorr of Swissmedic and co-chaired by Mr. Naoyuki Yasuda, International Planning Director of the Ministry of Health, Labour and Welfare (MHLW).

4. Head of Management Services & Networking of Swissmedic visits PMDA (November 18 to 22)

Dr. Petra Dorr, Head of Management Services & Networking of Swissmedic, the Swiss regulatory agency, visited PMDA from November 18 to 22, 2013. At PMDA, Dr. Dorr received briefings on PMDA's operations including new drug review, GxP inspections, safety measures with a view to the future personnel exchange between Swissmedic and PMDA. In addition, she delivered a presentation to explain the outline of Swissmedic, the regulation of medical products in Switzerland, and current efforts and future directions of Swissmedic. During her visit, Dr. Dorr discussed several issues and exchanged views with PMDA experts.



From left, Dr. Tatsuya Kondo (Chief Executive) and Dr. Petra Dorr (Swissmedic)

5. PMDA Forum on Pharmaceutical Affairs Consultations on R&D Strategy (November 19)

The 1st PMDA Forum on Pharmaceutical Affairs Consultations on R&D Strategy was held in Tokyo, Japan, on November 19, 2013. Dr. Tatsuya Kondo, Chief Executive of PMDA, delivered an opening address and Dr. Takao Yamori, Director of the Center for Product Evaluation of PMDA, chaired the panel discussion at this Forum. In addition, Mr. Yasunori Yoshida, Director of Office of Review Management acted as a speaker. The Forum was concluded with closing remarks by Dr. Hideo Utsumi, Executive Director. Since the launch of the Pharmaceutical Affairs Consultation on R&D Strategy in July 2011, PMDA has promoted the provision of the consultations. Some of the products for which advice was given by PMDA in a consultation are paving the way for commercial development. To highlight the achievements of the last two years, academic and medical professionals, who had actually used the consultations, were invited to give presentations at the Forum. Moreover, all the participants discussed what approach should be taken for further provision and improvement of the Pharmaceutical Affairs Consultation on R&D Strategy.

6. The 1st AHWP-RAPS Joint Conference (December 2 to 3)

The Asian Harmonization Working Party (AHWP) and the Regulatory Affairs Professionals Society (RAPS) held the 1st AHWP-RAPS Joint Conference, in Kuala Lumpur, Malaysia, on the days preceding the 18th AHWP Annual Conference. From PMDA, Mr. Nobuo Uemura, International Liaison Officer and a staff member participated in the conference, with representatives from the MHLW. The conference gathered approximately 320 participants from not only ASEAN member countries including Malaysia (the host country), but also India, Saudi Arabia, the U.S. and Europe. Topics addressed in this conference included: Regulatory Convergence, Building a Regulatory Framework, Activities of International Medical Device Regulators Forum (IMDRF), Structural improvement and education for implementing regulations, and the presentations were made by representatives from the regulatory agencies in participating countries, RAPS and WHO, as well as experts from the industry. The MHLW and PMDA introduced the trend in Japanese regulation and the post-marketing safety measures. The 2nd AHWP-RAPS Joint Conference is scheduled to be held in Korea next year, followed by the 19th AHWP Annual Conference.

7. The 8th International Summit of Heads of Medicines Regulatory Agencies (December 3 to 6)

The 8th International Summit of Heads of Medicines Regulatory Agencies hosted by the Dutch Medicines Evaluation Board was held in Amsterdam, the Netherlands, from December 3 to 6, 2013. From PMDA, Dr. Tatsuya Kondo, Chief Executive, and Dr. Nobumasa Nakashima, Director of Office of International Programs, participated in the Summit. The topics covered in the Summit were regulatory science, adaptive licensing, global health and inspections, which are common important issues faced by each medicines regulatory agency. Dr. Kondo acted as a speaker in the panel discussion on regulatory science, along with Dr. Margaret A. Hamburg, Commissioner of the United State Food and Drug Administration (FDA), while expressing opinions on other topics on behalf of the Japanese regulatory agency. Ahead of the participation in this International Summit, Dr. Kondo and Dr. Nakashima visited the Agence Nationale de Sécurité du Médicamen (ANSM), the French regulatory agency, to hold a bilateral meeting between PMDA and ANSM on December 2. The views on regulatory science and safety measures were exchanged during the meeting.

Please also refer to FDA Voice.

<http://blogs.fda.gov/fdavoiced/index.php/tag/8th-international-summit-of-heads-of-medicines-regulatory-agencies/>

8. CMC Strategy Forum Japan 2013 (December 9 to 10)

On December 9 and 10, 2013, the 2nd CMC Strategy Forum Japan was held in Tokyo, following the success of the last year's inaugural event. The Forum series, which were started in the U. S. and Europe, in 2002 and 2007, respectively, provide an arena for discussions about issues and emerging knowledge on quality aspects of biologics and their regulation. About 140 representatives from regulatory agencies including the U.S. FDA and the European Medicines Agency, as well as pharmaceutical companies and academia in and outside Japan participated in the Forum. PMDA supported the organization of this Forum in Tokyo, and Dr. Hideo Utsumi, Executive Director; Mr. Jun Sakamoto, Director of the Office of Cellular and Tissue-based Products; and other experts from PMDA joined the sessions as speakers or panelists.

9. The 5th Science Committee meeting (December 10)

On December 10, 2013, the 5th Science Committee meeting was held. In the meeting, the report entitled "Summary of WG meetings on the evaluation of non-clinical pharmacological studies of anticancer drugs" which had been prepared by the Pharmaceuticals Subcommittee and the Cellular and Tissue-based Products Subcommittee, was discussed and acknowledged. The Science Board submitted the report to PMDA. The board members also exchanged opinions on the future activities to be addressed in the Science Committee.

The Meeting Agenda and handout materials are available at:

(J) <http://www.pmda.go.jp/guide/kagakuinkai/kagakuinkai/h251210gijishidai.html>

(E) <http://www.pmda.go.jp/english/scienceboard/scienceboard/20131210.html>

10. Two PMDA Training Seminars and PMDA Forum to be held

PMDA will offer its 4th Training Seminar (on pharmaceutical affairs) from February 3 to 7, 2014, under the theme of reviewing generic drugs. In addition, the 1st PMDA Medical Devices Training Seminar will be held from March 3 to 7, 2014. The both seminars are intended to provide an opportunity for officials of regulatory agencies outside Japan. Following the 4th Training Seminar, the PMDA Forum will be held at the Hitotsubashi Hall in Tokyo, Japan, on February 8, 2014, to commemorate the 10th anniversary of PMDA.

For details, please visit the following URLs:

4th Training Seminar

http://www.pmda.go.jp/english/events/4th_pmda_training_seminar.html#7

1st Medical Devices Training Seminar

http://www.pmda.go.jp/english/events/1st_pmda_medical_devices_training_seminar.html

PMDA Forum

<http://www.pmda-forum.jp>

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.307, November 28, 2013

1. Summary of the Relief System for Sufferers from Adverse Drug Reactions and the Cases of Non-payment of Relief Benefits Due to Improper Use of Drugs
2. Important Safety Information
 - (1) Axitinib
 - (2) Bevacizumab (Genetical Recombination)
3. Revision of Precautions (No. 251)
 - (1) Clobazam (and 9 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of November 2013)

http://www.pmda.go.jp/english/service/precautions_2013.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/service/drugs.html>

Name	Active Ingredient	Posting date
Xeljanz	tofacitinib citrate	December 6
Nourias	Istradefylline	December 17

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
February 3-7	4th PMDA Training Seminar –Reviewing of Generic Drugs-	Tokyo
February 8	PMDA Forum	Tokyo
March 3-7	1st PMDA Medical Devices Training Seminar	Tokyo
March 10	EMA/FDA/MHLW-PMDA Orphan Product Designation Workshop	London
March 25-27	26th Annual EuroMeeting Vienna 2014	Vienna

Letters from the liaison officers

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

EMA, FDA and MHLW/PMDA will hold joint orphan product designation workshop on 10 March 2014. MHLW/PMDA and EC/EMA have several clusters in areas of mutual interest. Orphan drug is one of them. We have regular communication to accelerate the development of orphan products as described in 'Report on interactions between the Japanese Ministry of Health, Labour and Welfare (MHLW)/Pharmaceuticals and Medical Devices Agency (PMDA) and the European Medicines Agency (EMA)'.

In the workshop, the regulation of orphan designation in each region and international collaboration among regulators will be shared with participants. EMA/FDA/MHLW-PMDA will also hold dedicated one to one meetings with participants to discuss on a draft application based on a medicine under development that holds promise for the treatment of a rare disease. I would like to suggest developers of orphan products to participate at the workshop and obtain the helpful comparative information.

<http://www.pmda.go.jp/english/international/pdf/ema/ema201205.pdf>

Dr. Junko Sato

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

