Acer palmatum

PMDA Updates

November, 2015

News

1. Global Coalition for Regulatory Science Research and Global Summit on Regulatory Science 2015 (October 11 to 13)

During the period from October 11 to 13, the 3rd Global Coalition for Regulatory Science Research (GCRSR) and the Global Summit on Regulatory Science 2015 (GSRS2015) were held in Parma, Italy, and Dr. Mayumi Shikano, Associate Center Director, Mr. Naoyuki Yasuda, Office Director of International Programs and 1 staff member from PMDA, and Dr. Nobumasa Nakashima, International Planning Director, Ministry of Health, Labour and Welfare participated.

GCRSR was established as a place for discussion in 2013 in response to the call from Dr. Margaret A. Hamburg, former Commissioner of US FDA, aiming to newly establish an international collaborative framework to enhance education, scientific trainings and information exchange in the field of regulatory science. In the meeting, activity status of existing topics such as "Nano Technology", "Genomic Evaluation" and "Bioinformatics" were confirmed and the future direction of training and collaborative research for the GCRSR activities was discussed.

In addition, GSRS2015 was held following GCRSR under the theme of "Regulatory Bioinformatics". Experts from regulatory authorities, industries and academias gathered for the GCRSR, and discussed technical issues and utilization in Regulatory systems. In the meeting, the staff member of PMDA made a presentation on "MIHARI, MID-NET and its implementation issues" to foster better understanding of those projects.

The next GSRS is scheduled to be held in the suburbs of Washington D.C. in autumn, 2016.

2. The 6th PMDA Training Seminar (October 19 to 23)

PMDA held the 6th PMDA Training Seminar on pharmaceuticals from October 19 to 23. The seminar was targeted for regulatory authority officials. A total 13 officials from 7 countries (Indonesia, Iran, Korea, Myanmar, Philippines, Thailand, and United States) joined the seminar.

PMDA staff members delivered lectures on the outline of the pharmaceutical administration system in Japan, and the actual works. More in-depth and detailed lectures were made on the post-marketing safety measures and relief services, the theme of this seminar, in addition to the 1.5-day group works on scientific assessment of the adverse reactions, and case study on relief services.

Group photo of participants and Dr. Kondo (the 3rd left on the front line) and Dr, Tominaga (the second left of the 3rd line)

The participants of the seminar learned the pharmaceutical regulations in Japan through the lectures, group works, and case studies. Mutual understanding of each other's regulations was achieved through active exchange of opinions throughout the seminar.

The details of the 6th PMDA training seminar are available at the following URL.
http://www.pmda.go.jp/english/symposia/0082.html

3. Regulatory Affairs Professionals Society (RAPS) 2015 (October 24 to 28)

The Regulatory Affairs Professionals Society (RAPS) 2015 annual conference and associated workshops were held in Baltimore, U.S.A., from October 24 to 28. Dr. Toshiyoshi Tominaga, Associate Executive Director (for International Programs); 13 staff members collectively from Office of International Programs, Office of Medical Devices I, Office of Medical Devices II, Office of Manufacturing/Quality and Compliance, Office of Standards and Guidelines Development, Office of In Vitro Diagnostics and Office of Review Management; and a staff member from MHLW, participated in the meeting.

Dr. Tominaga

On October 25, a full-day Japan Workshop was held, chaired by Dr. Tominaga and a staff member of Office of International Programs, with presentations delivered by industry and regulatory authorities including 4 PMDA staff members on such topics like the current situations of medical device and in vitro diagnostics regulations, the overview of approval review and QMS inspection and the combined efforts of industry and regulators therein, the comparison of cellular and tissue-based products regulations of US, EU and Japan, and updates of IMDRF (International Medical Device Regulators Forum) and HBD (Harmonization By Doing) programs.

The formal sessions of RAPS were held from October 26 to 28, and in the session entitled "What's New in Japanese MD/IVD Regulation" held on October 26, Dr. Tominaga delivered a presentation on PMDA International Strategic Plan 2015 and the effort of PMDA towards accelerated review, along with the presentations by the staff member of MHLW on the overview of revised Pharmaceutical Affairs Act and Sakigake Designation System for prioritized review, and by the industry representative on the current situations of industry effort during this past year after the enforcement of the revised Act. In addition, one member each from Office of International Programs and MHLW participated in the session entitled "Interaction with Health Authorities" held on October 26 and 27 as panelists, where informal Q&A session took place between the participants and the regulators. On October 28, a special session focused on Medical Device Single Audit Program (MDSAP) Pilot was held, and a staff member from Office of Manufacturing/Quality and Compliance introduced current situation regarding Japan's participation in the pilot program. There were a great number of participants both in the workshops and formal sessions, and vigorous discussions took place throughout the conference.

PMDA also ran an exhibition booth for the third year in a row at the exhibition hall, and welcomed more than 250 visitors. There was an active communication among PMDA staff members and visitors for the promotion of 1) the publicity of Japanese pharmaceutical affairs regulations, 2) recognition of PMDA, and 3) reliability of Japanese pharmaceuticals and medical devices, as well as of review and post-marketing safety measures operation at PMDA.

The next RAPS annual conference will be held in San Jose, California, from September 17 to 21, 2016.

4. 2nd International Generic Drug Regulators Programme (IGDRP) Meeting (November 2 to 5)

From November 2 to 5, the 2nd International Generic Drug Regulators Programme (IGDRP) meeting was held in Seoul, South Korea, where about 40 participants from 15 countries/regions/organizations attended. Mr. Naoyuki Yasuda, Office Director of International Programs and a staff member from Ministry of Health, Labour and Welfare (MHLW) participated in the steering committee meeting, and 4 staff members from Office of Generic Drugs participated in the Biowaivers and Active Substance Master File (ASMF)/Drug Master File (DMF) working group meetings. The updates on activities of such working groups were provided by participating regulatory agencies, and the future action policy was discussed in the steering committee meeting.

The next IGDRP meeting will be held in Strasbourg, France in May, 2016.

The details of the IGDRP are available at the following URL.

http://www.igdrp.com/

5. The Science Board Activity Update (April 2015 to October 2015)

The activities from April 2015 to October 2015 of the five subcommitees of the second term of the Science Board, which statred in April 2014, are as follows. Please refer to the following web sites for the meeting agenda and handouts.

1) Subcommittee on Placebo-controlled Studies
   http://www.pmda.go.jp/english/rs-sb-std/sb/subcommittees-2nd/placebo/0001.html (English)
   http://www.pmda.go.jp/rs-std-jp/subcomm-2nd/placebo/0004.html (Japanese)
   The 4th Subcommittee meeting was held on May 8, 2015.
   The 5th Subcommittee meeting was held on September 11, 2015.

2) Subcommittee on Non-clinical Studies
   http://www.pmda.go.jp/english/rs-sb-std/sb/subcommittees-2nd/non-clinical-studies/0001.html (English)
   http://www.pmda.go.jp/rs-std-jp/subcomm-2nd/non-clinical-studies/0004.html (Japanese)
   The 5th Subcommittee meeting was held on May 13, 2015.

3) Subcommittee on Application of Numerical Analysis to Non-clinical Evaluation
http://www.pmda.go.jp/english/rs-sb-std/sb/subcommittees-2nd/numerical-analysis/0003.html (English)
http://www.pmda.go.jp/rs-std-jp/subcomm-2nd/numerical-analysis/0004.html (Japanese)
No meetings were held during this period.

4) Subcommittee on Evaluation of Medical Devices in Pediatric Use
http://www.pmda.go.jp/english/rs-sb-std/sb/subcommittees-2nd/devices-in-pediatric-use/0001.html (English)
http://www.pmda.go.jp/rs-std-jp/subcomm-2nd/devices-in-pediatric-use/0003.html (Japanese)
The 4th Subcommittee meeting was held on July 8, 2015.

5) CPC (Cell Processing Center) Subcommittee
http://www.pmda.go.jp/english/rs-sb-std/sb/subcommittees-2nd/cpc/0005.html (English)
http://www.pmda.go.jp/rs-std-jp/subcomm-2nd/cpc/0005.html (Japanese)
The 6th Subcommittee meeting was held on May 14, 2015.

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
Lonsurf	trifluridine and tipiracil hydrochloride	October 28

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 327, October 27, 2015

1. Utilization of Blood Glucose Meters, etc. that Use Enzymatic Electrodes
2. Precautions Concerning Recurrent and Similar Incidents of Medical Accident
3. Important Safety Information
   (1) asunaprevir and daclatasvir hydrochloride
   (2) amantadine hydrochloride
   (3) nivolumab (genetical recombination)
   (4) sodium-glucose co-transporter 2 (SGLT2) inhibitors
4. Revision of Precautions (No. 268)
   Fingolimod hydrochloride and azithromycin hydrate
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of September 2015)

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0013.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
December 5-10	ICH Jacksonville Meeting	Jacksonville, FL
December 8	PMDA-Keio Joint Symposium on Pharmacometrics	Tokyo

Reports from overseas

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

Excipient EMA says no association between HPV vaccines and Chronic Regional Pain Syndrome or Postural Orthostatic Tachycardia Syndrome

EMA announced on 5 November that there was no evidence of a causal link between human papillomavirus (HPV) vaccines and Chronic Regional Pain Syndrome (CRPS) or Postural Orthostatic Tachycardia Syndrome (POTS). This is the result of an assessment by Pharmacovigilance Risk Assessment Committee (PRAC) that thoroughly reviewed the published research, data from clinical trials and reports of suspected side effects from patients and healthcare professionals, as well as data supplied by Member States. Therefore, PRAC concludes that there is no reason to change the way the vaccines are used or amend the current product information, and that the benefit of HPV vaccines continue to outweigh their risks.

As a liaison official, I continue to update on Japan's situation of HPV vaccines to EMA. On this occasion, I had several opportunities to sit in on EMA's discussions on HPV vaccines and it was particularly interesting for me to see 'hot debates' of how EMA was to evaluate the benefits and risks from a scientific point of view as regulatory authorities. As a liaison officer stationed at EMA, I consider we need to continue to pay attention to activities of scientific committees such as PRAC.

Its details are available on the EMA website as shown below.

EMA publication document
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/11/news_detail_002429.jsp&mid=WC0b01ac058004d5c1
Movie of the virtual press conference
https://www.youtube.com/watch?v=6viXoxkhZoA&feature=youtu.be

Mr. Yoshihiko Sano
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

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Excipient Monograph 2 Expert Committee (EM 2 EC) Face-to-face Meeting

Excipient Monograph 2 Expert Committee (EM 2 EC) which is responsible for USP's global harmonization activities held a face-to-face meeting on October 20 at the USP headquarters. Each USP Expert Committee, including EM2, consists of volunteers with global expertise. USP face-to-face expert committee meetings are typically held once a year and this was first time for EM 2 EC to hold its face-to-face meeting in the USP 2015-2020 cycle. Meeting topics included discussion on the new work plan1) which was mainly focused on Pharmacopoeial Discussion Group (PDG) excipient items and bilateral harmonization projects. As a part of introduction of harmonization with other pharmacopoeias, I introduced the overview of JP, USP-JP bilateral projects and its current status and received favorable comments on collaboration between USP and JP by the Expert Committee. Furthermore, as this meeting was held just before the PDG Rockville meeting on November 3-4, USP scientific Liaisons provided an overview with current status for harmonization of each item on PDG activities and received input from the Experts. An executive summary of the EM 2 EC face-to-face meeting will be posted on the USP website in the near future. Future EM 2 EC teleconferences will be held on a monthly basis using WebEx, and I will attend the meetings and gather information to support progress on bilateral projects and PDG activities.

1) 2015–2020 Excipient Monographs 2 Expert Committee Work Plan
http://www.usp.org/excipient-monographs-2-expert-committee-work-plan

Dr. Chie Mizumaru
PMDA's International Liaison Officer stationed at USP in the U.S.A.
