Cyclamen persicum

PMDA Updates

October, 2015

News

1. The 8th IMDRF Management Committee Meeting (September 15 to 17)

The 7th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting was held in Kyoto from September 15 to 17, at which Japan takes the chair for 2015. The meeting was presided by Dr. Toshiyoshi Tominaga, Associate Executive Director (for International Programs), while Mr. Soichiro Isobe, Director, Medical Device and Regenerative Medicine Product Evaluation Division, Ministry of Health, Labour and Welfare (MHLW), and a staff member of Office of International Programs (OIP) attended as the MC members, and one each from MHLW and OIP served as secretariat. The first and the third day of the meeting were dedicated to the closed sessions for regulators and officially invited observers only, and Dr. Tatsuya Kondo, the CEO of PMDA, gave a welcome speech at the start of the meeting. During the closed sessions, the guidance documents developed by each working group as well as the proposed new working items have been scrutinized, while the IMDRF Strategic Plan 2020, on which Japan has led the discussion, and which is mid-term strategy has been adopted. On September 16, IMDRF Stakeholders Forum, which is open to all stakeholders with approximately 170 participants including members from MC and industry was held, where updates of the activities of working groups, et.al. were provided and active discussions ensued.

Dr. Kondo

The next IMDRF MC Meeting will be held in Brasilia, Brazil from March 8 to 10, 2016.

Group photo at MC Meeting including
Dr. Tominaga (the 6th from the right at middle row)

The details of the 8th IMDRF MC Meeting and Press release from MHLW are available at following URL:
http://www.imdrf.org/meetings/meetings.asp
http://www.mhlw.go.jp/stf/houdou/0000098265.html (Japanese only)

2. Japan-US HBD East 2015 Think Tank Meeting (September 18)

The Harmonization By Doing (HBD) East 2015 Think Tank Meeting, the meeting for reporting the activities of HBD, which is the regulatory harmonization effort for medical devices among industries, academia and regulators of the US and Japan, was held in Kyoto on September 18, and 7 members from PMDA, including Dr. Toshiyoshi Tominaga, Associate Executive Director; Dr. Yuka Suzuki, Office Director of Office of Medical Devices II, and staff members from Office of Medical Devices I and Office of International Programs, participated in the meeting. The meeting was held under the theme of "Moving Far Beyond – Next Decade", where the achievements of HBD in the past 10 years as well as the challenges for the future were introduced, and a panel discussion under the theme of "What to expect to HBD activities for the next 10 years" was held. Approximately 100 people participated in the meeting and active discussion took place.

Attendees of the Think Tank Meeting including
Dr. Tominaga (the right end at upper row)

3. The 6th International Meeting of World Pharmacopoeias/2015 ChP Annual Scientific Symposium (September 21 to 23)

From September 21 to 22, the 6th International Meeting of World Pharmacopoeias was held in Suzhou City, Jiangsu Province, China in which Dr. Toru Kawanishi, Director General, National Institute of Health Sciences (NIHS), and Mr. Naoyuki Yasuda, Office Director, Office of International Programs, and 2 staff members from Office of Standards and Guidelines Development, PMDA participated as the representatives of Japanese Pharmacopoeia (JP). The representatives of JP co-chaired and expressed opinions as the member of working group for drafting Good Pharmacopoeial Practices (GPhP) to review and address public comments on the proposed draft on GPhP and consequently edit the GPhP document. In the meeting, the first draft including monographs as chemical drugs and pharmaceutical preparations was generally agreed and will be finalized by the Expert Committee on Specifications for Pharmaceutical Preparations in October. On September 23, 2015 ChP Annual Scientific Symposium was held where updates on each pharmacopoeia including JP were provided.

The 7th International Meeting of World Pharmacopoeias is to be held at PMDA in Japan in September, 2016 co-hosted by JP and WHO, where new development after the completion of preparing monographs for chemical drugs will be discussed. Also, JP 130th Anniversary Symposium is being planned at the same time, and discussions among world representatives on general topics on pharmacopoeias are expected.

4. China International Medical Device Regulatory Forum (September 22 to 24)

China International Medical Device Regulatory Forum (CIMDR) was held in Guangzhou from September 22 to 24, and 3 PMDA staff members from the Office of International Programs, Office of Medical Devices II and Office of Standards and Guidelines Development participated in the forum to give presentations on 1) Updates on the medical device regulations in Japan, 2) Introduction of the guidance document for medical devices using 3-D printing technology, and 3) Current situation of adopting international standards in Japan. CIMDR is a forum for medical devices regulations held by China Center for Food and Drug International Exchange (CCFDIE), a sub-organization of China Food and Drug Administration (CFDA). The forum is held every year, inviting speakers from regulatory authorities and industries in foreign countries to introduce regulations of medical devices in each country to Chinese industries. There were approximately 1,500 participants in the forum, and active discussion took place regarding the regulation of medical devices in each participating country. Next forum will be held in Chengdu in September, 2016.

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
Memary	memantine Hydrochloride	October 2
Forteo	teriparatide (genetical recombination)	October 23

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS, October 20, 2015

- galantamine hydrobromide
- magnesium oxide
- dutasteride (Benign prostatic hyperplasia)/ dutasteride (Male pattern hair loss (androgenetic alopecia) in men only)
- ceftriaxone sodium hydrate (Injection)/ ceftriaxone sodium hydrate Kit

- roxithromycin
- asunaprevir/daclatasvir hydrochloride
- laxative drug containing magnesium oxide (Over the counter drugs)
  http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0003.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
November 2-6	IGDRP (International Generic Drug Regulators Programme) Meeting	Korea
November 10-13	10th International Summit of Heads of Medicines Regulatory Agencies & International Coalition of Medicines Regulatory Authorities (ICMRA) Meeting	Mexico City
November 15-17	12th Annual Meeting DIA JAPAN 2015	Tokyo
December 5-10	ICH Jacksonville Meeting	Jacksonville, FL
December 13-18	APEC Multi-Regional Clinical Trials (MRCT) Regulatory Science Center of Excellence Pilot Workshop	Singapore

Reports from overseas

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

Presentation about International strategies in Berlin

The Organization for Professionals in Regulatory Affairs (TOPRA), an organization to promote discussion and awareness of pharmaceutical regulatory topics around the world, held its annual symposium in Berlin on October 12-14, 2015[1]. More than 300 participants from academia, pharmaceutical industry and European regulators attended and the programme included many topics such as drug development, clinical trials, pharmacovigilance study and HTA. I was invited to the session of globalization of pharmaceutical regulation held on October 13 as a speaker, together with the EMA liaison official stationed at US FDA.

I gave a presentation on MHLW and PMDA international strategies published on June 26, 2015[2], and liaison activities at EMA. In the panel discussion after the presentations, I had a number of questions from the floor such as background of promotion of Japan's international activities, future plan of the regulatory science center, and current situation of Sakigake Designation System, and their high interests on Japan's pharmaceutical regulation were shown. In addition, after the session, the Chair gave me a comment that he thought the session was successful because Japan's International strategies were well explained and we were able to have various discussions with participants.

As the PMDA liaison stationed at EMA, I will continue to attend similar meetings actively and explain Japan's policy and activities.

1) TOPRA symposium:
   http://www.toprasymposium.org/Symposium/About_Symposium/TOPRA/Symposium/About_home.aspx?hkey=8ad7487f-71c9-46c3-b767-f845ce07f701
2) MHLW and PMDA International Strategy:
   http://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/150827-01.html
   http://www.pmda.go.jp/english/int-activities/outline/0017.html

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

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Strategy on biological medicines in USP

USP has been developed standards for biological medicines and there were two expert committees on biologics in USP2010-2015 cycle. In 2015-2020 cycle[1)] which started on July 1, Resolution VI "Standards for biological medicines" was adopted as one of 11 resolutions[2)] that influence USP's strategic direction to promote development of standards. Resolution VI states that "USP will promote alignment with stakeholders to develop quality standards for biological medicines, ensuring that innovation and availability are facilitated and complemented." In accordance with this resolution, the expert committees on biologics was reorganized and divided into four expert committees, which are Biologics Monographs 1-Peptides, Biologics Monographs 2-Proteins, Biologics Monographs 3-Complex biologics such as Anticoagulants, and General Chapters-Biological Analysis, to enable each expert committee to focus on its specific topic. General Chapters for biologics were discussed under the expert committee for General Chapters as well as other general chapters for chemical drugs in the previous cycle. In the new cycle, further progress on development will be expected because the specific expert committee for biologics was organized under the Biologics Collaborative Group. Each expert committee will discuss further details on the work plan at a face-to-face meeting in the near future. JP has started to discuss policies for the next revision while considering importance of biologics. Therefore I would like to continue to gather information about strategy on biological medicines in USP and contribute to strengthen the JP in a manner consistent with the international pharmacopoeia.

1) USP 2015 Convention
   http://www.usp.org/2015-convention
2) USP 2015-2020 Resolutions
   http://www.usp.org/about-usp/our-vision/2015-2020-resolutions

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

Looking to the future

What is the biggest difference between the U.S. FDA and PMDA? I was asked this question many times during my one-year dispatch to the U.S. FDA. I observed many differences between the U.S. FDA and PMDA, especially in each agency's organizational structure and the impact of that structure on approaches to work. For example, the U.S. FDA's approach to scientific review work is more heavily based on multidisciplinary teamwork than is PMDA's. However, I'd like to emphasize that the U.S. FDA and PMDA have much in common in the conduct of scientific review work. For example, each organization places a high value on scientific rigor. In my opinion, we both can aim to improve our organizations if we keep collaborating and learning from each other, since both the U.S. FDA and PMDA have unique strengths. Now that I am back at PMDA, I'll try my best to use my one-year experience at the U.S. FDA to be a catalyst to enhance our future collaborations. Finally I'd like to thank all those who made this dispatch possible.

Ms. Sekine with Dr. Janet Woodcock (Director of the Center for Drug Evaluation and Research) on the right and Dr. Gerald J. Dal Pan (Director of Office of Surveillance and Epidemiology, the Center for Drug Evaluation and Research) on the left

Ms. Shohko Sekine
PMDA's Officer at CDER, U.S. FDA in the U.S.A.

Impression of my dispatch to Division of Pharmacometrics, CDER, U.S. FDA

I finished one-year dispatch as a visiting scientist to Division of Pharmacometrics, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA) in September 2015. I was here to learn utilizing the modeling and simulation techniques in clinical pharmacology area. I learned various review cases where modeling and simulation techniques were utilized and also improved my understanding of modeling methodology through participating the new drug reviews and conducting regulatory science researches.

It is planned that PMDA receives electronic data for new drug applications and starts the new drug review using submitted electronic data after October 2016. Since utilizing modeling and simulation techniques using submitted electronic data is considered to contribute to effective new drug review and efficient drug development, I would like to use my knowledge and experiences obtained from this dispatch at FDA for the new drug review using submitted electronic data and establishment of advanced review in PMDA.

I express my gratitude to Dr. Ping Zhao, Dr. Vikram Sinha and every reviewer at Division of Pharmacometrics. I would like to keep good communications with the reviewers at Division of Pharmacometrics and contribute to strengthen the collaboration between PMDA and FDA.

Dr. Masanobu Sato
PMDA's Officer at CDER, U.S. FDA in the U.S.A.

Completion of station at U.S. FDA CDRH

My name is Nobuhiro Handa. I am a principle reviewer of Office of Medical Device III. I have been stationed at Division of Epidemiology (DEPI)/OSB/ CDRH/FDA since August 1, 2015. During my stay for more than 2 months at DEPI, I have learned that DEPI is promoting to form the coordinated registry network (CRN) which integrates registry data, electronic health records in health care providers, and hospital claim data. The ultimate goal of CRN is to facilitate the device development of next generation as well as to utilize it for post-market safety measure. In addition, I have learned that FDA/CDRH initiates the idea of "Ecosystem" which combines regulators, industries and healthcare providers as a single group sharing the common destiny. I do appreciate the FDA staff who have provided outstanding support and friendship to me to complete the dispatch for 12 weeks.

Dr. Nobuhiro Handa
Visiting scientist, Division of Epidemiology, Office of Surveillance and Biometrics at CDRH, U.S. FDA in the U.S.A.
