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PMDA Updates

March, 2016

News

1. The 3rd PMDA Medical Devices Training Seminar (February 15 to 19)

Group photo of trainees with Chief Executive, Dr. Tatsuya Kondo (the 5th from the left) and Associate Executive Director for International Programs, Dr. Toshiyoshi Tominaga (the 6th from the lefy)

PMDA held the 3rd PMDA Medical Devices Training Seminar for overseas regulators from February 15 to 19. A total of 31 regulators from 11 foreign authorities (i.e. Bahrain, Chinese-Taipei, Ghana, Hong Kong, India, Indonesia, Iran, Malaysia, Myanmar, Saudi Arabia and Singapore) participated in the seminar. Lectures were delivered on an overview of the medical device regulations, review and approval procedures, case studies of reviews, Quality Management System (QMS) inspections, Good Laboratory Practice (GLP)/Good Clinical Practice (GCP) inspections, clinical trials for medical devices and post-marketing safety measures, and utlization of international standards. In addition, overview of the third-party certification system by registered certification bodies and the academia-industry-government collaboration were discussed. Also, the participants of the training gave presentations on the medical device regulations from his/her regulatory authorities. As a part of the seminar, they had a training tour to a medical device facility. The participants and the PMDA staffs actively exchanged their views throughout the seminar and cultivated friendly relationship. At the end of the seminar, Dr. Tatsuya Kondo, Chief Executive, awarded the Course completion certificates to all of the participants.

Please refer to the following web site for the details of the 3rd PMDA Medical Devices Training Seminar.

http://www.pmda.go.jp/english/symposia/0087.html

2. PMDA delivers lectures for the 3rd Japan Medical Innovation Tour (February 18)

On February 18, PMDA delivered lectures for the 3rd Japan Medical Innovation Tour. Nine universities and academic research institution staff members from Chinese Taipei, Indonesia, Malaysia, Mongolia, Singapore, Thailand and Vietnam participated in the training program. PMDA delivered lectures on outlines of PMDA's organization, the role of PMDA in the pharmaceutical affairs, and international collaboration activities in the Asia region. PMDA provided this training upon the request from Kyushu University which has undertaken the publicly-offered program "Japan-Asia Youth Exchange Program in Science" (SAKURA Exchange Program in Science), from Japan Science and Technology Agency (JST).

Group photo of trainees

3. PMDA provides training program to officials from Thai Ministry of Public Health, Thailand (February 22 to 25)

Trainees and lecturer from the Office of Cellular and Tissue-based Products

PMDA accepted two regulators from the Thai Ministry of Public Health, Thailand from February 22 to 25, and provided training on reviews of biological products. Office of Cellular and Tissue-based Products facilitated lectures on regulations for biological and regenerative medicine products, and case studies of reviews. As a part of this training, the participants visited a biopharmaceutical manufacturing facility where they observed manufacturing and quality control processes. Throughout the training, officials of both regulatory authorities exchanged views actively and deepened mutual understandings.

4. Asia-Pacific Economic Cooperation, Life Science Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) (February 23 to 25)

Dr. Tominaga

APEC-LSIF-RHSC meeting was held in Lima, Peru from February 23 to 25. Key participants from Japan were Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs, PMDA), Dr. Junko Sato (Office Director, Office of International Cooperation, PMDA) and Dr. Nobumasa Nakashima (International Planning Director, MHLW).

RHSC meeting aims for "Promotion of the strategic framework for the convergence of medical products regulation". Dr. Tominaga is co-chair of the RHSC along with the US. The meeting was attended by regulators from APEC economies (Canada, People's Republic of China, Indonesia, Japan, Republic of Korea, Mexico, Peru, Philippine, Chinese Taipei, Thailand, and US), industry representatives (pharmaceuticals, bio-pharmaceuticals, medical devices, generics), and representatives from academia. Japan already has a leadership role in one of the 6 work areas for APEC-LSIF-RHSC, 'Multi-Regional Clinical Trials/GCP Inspection (MRCT/GCP)' together with Thailand. At this meeting, it was officially agreed that the discussion on 'Good Registration Management' was also to be led by Japan along with Chinese Taipei.

APEC-LSIF-RHSC has been offering pilot programs to establish Center of Excellence (CoE), aiming at training regulatory officers and relevant officials. It was agreed that PMDA as CoE was to provide the pilot programs in the areas of vigilance and MRCT/GCP.

Next APEC-LISF RHSC meeting will be held in Peru, in August, 2016.

5. APEC RHSC Center of Excellence Workshop "Multi-regional Clinical Trials" (March 1 to 4)

APEC RHSC Center of Excellence Workshop "Multi-regional Clinical Trials" was held from March 1 to 4 in Singapore. 34 participants from 14 countries/regions participated in this workshop targeted for regulators. The workshop was conducted as one of the initiatives from the work area, MRCT/GCP led by Japan in APEC- LSIF-RHSC, using a curriculum developed by Japan and Thailand, in cooperation with Duke-NUS, the proposed site of CoE. In the workshop, topics including points to consider when initiating global clinical trials, assessment methodologies of the results, and the principle for observation during GCP inspections were discussed. From Japan, Dr. Junko Sato, Office Director, Office of International Cooperation, PMDA who is in charge of the curriculum participated and interacted in the workshop.

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
Squarekids	adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (salk vaccine) combined vaccine	February 26
Insulin Glargine BS	insulin glargine (genetical recombination) [insulin glargine biosimilar 1]	February 29
Forxiga	Dapagliflozin Propylene Glycolate Hydrate (JAN*)	March 7
Lenvima	Lenvatinib Mesilate	March 10
Avigan	favipiravir	March 14
Giotrif	afatinib maleate	March 14
Copegus	ribavirin	March 18
Sovaldi	sofosbuvir	March 18

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 331, March 15, 2016

1. "Children and Pharmaceuticals" Data Collecting Network Development Project
2. Important Safety Information
   (1) Eribulin Mesilate
3. Revision of Precautions (No. 272)
   Methylphenidate Hydrochloride (and 2 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance

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

Pharmaceuticals Revisions of PRECAUTIONS, March 22, 2016

- Flunitrazepam (injections)
- Loxoprofen Sodium Hydrate (for oral use)
- Paliperidone Palmitate
- Risperidone (injections)
- Verteporfin
- Furosemide
- Mirabegron
- Products containing Loxoprofen Sodium Hydrate (OTC drugs for oral use)

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
April 6-8	DIA 28th Annual EuroMeeting	Hamburg
April 7	Asia Pacific Healthcare Summit 2016	Singapore
April 7-8	The 5th Asia Partnership Conference of Pharmaceutical Associations (APAC)	Tokyo
April 13-14	10th DIA Asia New Drug Conference	Tokyo
April 28-30	3rd International Conference on the Progress of Regenerative Medicine and Its Cultural Impact	Vatican
May 9-12	3rd International Generic Drug Regulators Programme (IGDRP)	Strasbourg

Reports from overseas

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

Lunchtime talk at the EMA

On March 2, I had the honour to give a presentation to colleagues at the EMA to talk about Japan's recent situation and reflections on my two years as MHLW/PMDA liaison official at the EMA as a lunchtime talk. There was a high level of interest from EMA colleagues in the Japan's pharmaceutical regulation and system, with almost 60 people, some of who stood during the talk. My presentation covered changes in Japan's population, social health expenditure and overview of MHLW and PMDA, followed by regenerative medicines and Conditional Time-limited Authorization, Sakigake, orphan drugs, pricing and HTA, international strategies and the liaison's interactions with the EMA. I received many questions from the floor after my presentation such as the duration of Conditional Time-limited Authorization and the pricing system in Japan. I would like to take this opportunity to thank the EMA for the precious chance to give a presentation.

For recent two years, I have been doing my best effort to promote and strengthen interactions between EMA and MHLW/PMDA as a MHLW/PMDA liaison stationed at the EMA. My term as a liaison will end on April 1, 2016. As there are many similarities between EU and Japan as regulatory authorities, I hope we continue to deepen our interactions by overcoming differences in systems and languages, and to contribute to patients in the world as regulatory authorities.

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

To learn FDA's processes for the Medical Device Single Audit Program (MDSAP)

I have been dispatched to FDA in order to become an effective MDSAP Assessor. Assessors from a coalition of regulatory authorities (Australia (TGA), Brazil (ANVISA), Canada (HC), Japan (MHLW/PMDA) and United States (U.S. FDA)) work together to assess participating Auditing Organizations (AOs) to validate/confirm their abilities to conduct MDSAP audits.

You may wonder how AOs can confirm a company meets the regulatory requirements of five (5) independent regulatory authorities. The MDSAP coalition has established standardized auditor competence requirements and audit procedures to ensure consistent, high quality audits of medical device manufacturers are conducted. For example, MDSAP Subject Matter Expert (SME) Group has established standardized "Audit Model" and "Companion Document". These documents prescribe the method used by AOs to confirm a medical device manufacturer is meeting specified regulatory requirements (e.g. ISO 13485, QMS Ordinance etc.). MDSAP SME Group has also created online training materials for MDSAP auditors as well as procedures and training for the regulatory authority assessment of AOs. MDSAP policies and procedures are based on documents established by the International Medical Device Regulators Forum (IMDRF). These documents are available at the websites cited below[1) 2)].

Recently, I observed the assessment of an MDSAP AO and learned the assessment method. I would like to put this experience to use not only in upcoming MDSAP assessments but also domestic Registered Certification Bodies' assessments.

1) http://www.imdrf.org/documents/documents.asp
2) http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm

Ms. Hiromi Kumada
Visiting assessor, Office of Compliance at CDRH, U.S. FDA in the U.S.A.
