Row of cherry blossom trees

PMDA Updates

April, 2016

News

1. Launch of "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs" (April 1)

On April 1, PMDA launched the "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs", based on the "PMDA International Strategic Plan 2015" published on June 26, 2015.

Group photo of speakers with Mr. Haruo Akagawa, Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (the 4th from the right) and Dr. Kondo (the 5th from the right) and Dr. Sato (the left end)

This Training Center will, by fully utilizing PMDA's accumulated knowledge and experience in response to the demand of Asian regulatory authorities, provide training to regulators in Asia and other countries. The training programs will include basic lectures to provide essential information (e.g. information on reviews of pharmaceuticals and medical devices, risk management, etc.) that are essential for building regulatory capacity, as well as mock GMP inspections with the cooperation with the actual manufacturing facility. Office of International Cooperation was also launched as new administration office of the Training Center.

On April 7, PMDA held the "Commemoration of the Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs" to mark the launch of the Training Center.

In the Commemoration, Dr. Tatsuya Kondo (Chief Executive, PMDA), Mr. Hideaki Nakagaki (Director General, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)) and Dr. Junko Sato (Office Director, Office of International Cooperation, PMDA) explained the importance of international cooperation as well as the objective and the outline of the Center. In addition, the governor of Toyama prefecture and overseas regulators and Japanese industry representatives stated their expectations to the Center.

Through the initiatives of this Center, PMDA will promote regulatory capacity building and harmonization in Asia and other emerging countries, and facilitate further development of cooperation.

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

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

2. PMDA Officer Dispatched to EMA (March 28)

On March 28, PMDA sent Mr. Hideyuki Kondo, Deputy Coordination Director, Office of International Programs to the European Medicines Agency (EMA). Mr. Kondo is expected to be stationed there to further promote collaborative relationships between EMA and MHLW/PMDA through information exchange and scientific communication as the 4th International Liaison Officer to EMA from PMDA. The term of the dispatch is for two years.

3. The 9th IMDRF Management Committee Meeting (March 8 to 10)

The 9th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting was held in Brasilia, Brazil from March 8 to 10, and two staffs from Office of International Programs attended as the MC Members. The first and the third day of the meeting were dedicated to the closed sessions for regulators and officially invited observers only, where the guidance documents developed by each working group as well as the proposed new working items were discussed. On March 9, IMDRF Stakeholders Forum, which is open to all stakeholders, was held with approximately 220 participants including Members from MC and industries, and active discussions on concerns of medical device industries took place. At the forum, up-to-date information of Japanese medical device regulations, as well as the progress report of the Adverse Event Terminology Working Group (chaired by Japan), were provided by the Japanese MC Members.

The next IMDRF MC Meeting will be held from September 13 to 15, 2016 in Brazil (place to be decided).

The details of the 9th IMDRF MC Meeting are available at the following URL:
http://www.imdrf.org/meetings/meetings.asp#historic

4. International Regulatory Forum of Human Cell Therapy and Gene Therapy Products (March 16)

PMDA and The Japanese Society for Regenerative Medicine (JSRM) jointly convened International Regulatory Forum of Human Cell Therapy and Gene Therapy Products in Osaka on March 16, with support from National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN), with regulatory trends in cell therapy and gene therapy products as the theme. The invitees included U.S.FDA and EMA and other regulatory authorities for cell therapy and gene therapy products in Europe and Asia and leading researches from in and outside of Japan. From PMDA, Dr. Tatsuya Kondo (Chief Executive), Dr. Daisaku Sato (Director of Office of Cellular and Tissue-based Products) and 2 staffs of the Office of Cellular and Tissue-based Products attended the forum. Mr. Kazuhiko Mori (Councillor for Pharmaceutical Safety, Minister's Secretariat, MHLW) also attended in addition to 300 participants from regulatory agencies, academic institutions and the industry in and outside of Japan.

Group photo of speakers including Dr. Sato (the 5th from the right on front row)

Dr. Kondo

Nowadays, development of human cell therapy and gene therapy products has been progressed internationally, and efforts have been made to address regulatory challenges in the evaluation of quality, efficacy and safety of the products in clinical trials and reviews. In this forum, updates on the specific challenges in quality, efficacy and safety of cellular and tissue-based products in the views of development in international scale were shared through the exchange of information and opinions among experts from regulatory authorities, academia and industries from in and outside of Japan.

This forum is expected to offer the opportunity to trigger the international dissemination of regulatory science for cellular and tissue-based products and a promotion of international convergence in the evaluation of quality, efficacy and safety of the products through the activities such as IPRF, APEC and WHO.

5. The 3rd Thailand-Japan Symposium (March 24)

The 3rd Thailand-Japan Symposium was held in Bangkok on March 24, co-hosted by Thai Food and Drug Administration (Thai FDA) and PMDA, and was attended by approximately 250 people (including 85 regulators and 103 industry representatives in Thailand).

The participants from PMDA included Dr. Tatsuya Kondo (Chief Executive), Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs), and staffs from Office of Review Management, Office of Standards and Guidelines Development, Office of GMP/QMS inspection, Office of Safety I, Office of International Programs and Office of International Cooperation , who made presentations. From Thai FDA, Mr. Praphon Angtrakool (Deputy Secretary-General) and many other staffs participated in the symposium.

Group photo of speakers including Dr. Kondo (the Center on the front row) and Dr. Tominaga (the left end on the front row)

In this 3rd symposium, session on medical devices was newly allocated in addition to pharmaceuticals session, where presentations and discussions were made by the participants from both countries on topics including regulatory updates on medical devices to share regulatory updates on medical devices.

The details of the symposium are available at following web site.
http://www.pmda.go.jp/english/symposia/0086.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
Nopicor	nalfurafine hydrochloride	March 24
Takecab	vonoprazan fumarate	March 24
Clenafin	efinaconazole	March 24
Inavir (Initial Approval)	laninamivir octanoate hydrate	March 29
Inavir (Partial Change Approval)	laninamivir octanoate hydrate	April 12

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 332, April 2016

1. Notification Regarding Fulminant Type 1 Diabetes Mellitus During Use of Nivolumab (Genetical Recombination)
2. Change in Report Forms for "Drugs and Medical Devices Safety Information Reporting System"
3. Important Safety Information
   (1) Furosemide
4. Revision of Precautions (No. 273)sai
   Flunitrazepam (Injections) (and 7 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0014.html

Pharmaceuticals Revisions of PRECAUTIONS, March 23, 2016 (March 29, 2016 revised)

- Mycophenolate Mofetil (March 23, 2016) (March 29,2016 revised)
  http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0003.html

Pharmaceuticals Revisions of PRECAUTIONS, April 21, 2016

- Gabapentin
- Levodopa
- Levodopa/Carbidopa hydrate
  Levodopa/Carbidopa hydrate/Entacapone
  Levodopa/Benserazide hydrochloride
- Gabapentin enacarbil
- Edoxaban tosilate hydrate
- Rivaroxaban
- Sitagliptin phosphate hydrate
  Vildagliptin
  Vildagliptin/Metformin hydrochloride
- Afatinib maleate
- Trabectedin
- Fexofenadine hydrochloride/Pseudoephedrine hydrochloride
- Oseltamivir phosphate
- Peramivir hydrate
- Sodium chloride/Potassium chloride/Sodium sulfate anhydrous
  Macrogol 4000/Ascorbic acid
  Sodium L-ascorbate
- Products containing pseudoephedrine hydrochloride (OTC drugs)
  Products containing pseudoephedrine sulfate (OTC drugs)
  http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0004.html

Medical Devices Revisions of PRECAUTIONS, April 11, 2016 (originally posted in Japanese on March 31, 2016)

- Medical Devices that Constitute Metal-on-Metal Artificial Hip Prosthesis
  http://www.pmda.go.jp/english/safety/info-services/0015.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
May 9-13	3rd INTERNATIONAL GENERIC DRUG REGULATORS PROGRAMME (IGDRP)	Strasbourg
May 18-19	India-Japan Seminar	New Delhi
June 11-16	ICH Week	Lisbon
June 23	Korea-Japan Symposium	Tokyo

June 26-27	International Coalition of Medicines Regulatory Authorities (ICMRA)	Philadelphia
June 26-30	DIA 2016 52nd Annual Meeting	Philadelphia

Reports from overseas

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

Greetings as a new appointed International Liaison Officer in Europe

I am Hideyuki Kondo and have been working as the 4th International Liaison Officer from PMDA at European Medicine Agency (EMA) office since 29 March 2016. Last year, I understand, was an important milestone for both EMA and PMDA because EMA celebrated its 20th anniversary and PMDA announced its International Strategic Plan 2015. In this new phase for both organisations, I am very pleased at this time to have the opportunity to involve in cooperation activities between EU and Japan, which should result in contributions to better access for patients in each region to excellent medicines. I will make all efforts to maintain and advance the strong trust/cooperative relationship that has been built through a variety of activities between both sides.

I would like to thank many stakeholders for their support from the preparation stage of moving to U.K. I also look forward to working with them in coming activities.

Mr. Hideyuki Kondo
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

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The experience from the temporary dispatch to US FDA CDRH

I have finished the temporary dispatch to U.S. FDA CDRH, Office of Compliance (OC), Division of International Compliance Operations (DICO), Medical Device Single Audit Program (MDSAP) Team from January to April 15. During my dispatch, I had the opportunity to learn a lot, and these three months were very fulfilling. The MDSAP Team members taught me many details of the process of MDSAP. Following my observation of MDSAP assessments of Auditing Organizations (AOs), I assessed an AO as an MDSAP assessor. I also had opportunities to talk with staffs from other divisions of OC, which enabled me to learn about US regulation of medical devices. And above all, the best thing in this dispatch was meeting a lot of staffs in U.S. FDA. I would like to use this experience to contribute to future international activities. Finally I would like to thank everyone in U.S. FDA CDRH.

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