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# PMDA Updates

July, 2015

## News

### 1. “PMDA International Strategic Plan 2015” announced (June 26)

On June 26, 2015, PMDA announced the development of “PMDA International Strategic Plan 2015” in both Japanese and English, which outlines the international activities that will be conducted in the period defined in the 3rd and 4th Mid-term Plans, ending in FY 2023.

The Strategic Plan was developed taking into consideration the changes in the regulatory environment, as well as the Regulatory Strategy Initiative set forth by the MHLW in June 2015.

Below are the key international actions set forth in the “PMDA International Strategic Plan 2015”.

1. Establish the “Regulatory Science Center” for conducting first-in-the-world product reviews, implementing safety measures, and undertaking other activities, as well as disseminating the information to the world.
2. Launch the “Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs” to share PMDA’s accumulated knowledge and experience in product reviews, implementation of safety measures, and provision of relief services with Asian and overseas regulatory authorities.
3. Cooperate with overseas regulatory authorities for expansion of harmonization activities [e.g., ICH, International Medical Device Regulators Forum (IMDRF)] and work-sharing (e.g., GMP/QMS inspections)

On September 3, 2015, PMDA and MHLW will cohost the meeting entitled Celebrating MHLW’s and PMDA’s International Strategic Plan “Toward further promotion of regulatory science and global capacity building” to share the International Strategic Plan, as well as have invited speakers from regulatory authorities in Asia, the US and EU as well as Japan Agency for Medical Research and Development (AMED), Japan Pharmaceutical Manufacturers Association (JPMA), and Japan Federation of Medical Devices Associations (JFMDA) make presentations and share expectations for PMDA/MHLW.

PMDA International Strategic Plan 2015 announcements:

<http://www.pmda.go.jp/english/int-activities/outline/oo17.html>

Announcement for Celebrating MHLW’s and PMDA’s International Strategic Plans “Toward further promotion of regulatory science and global capacity building”:

<http://www.pmda.go.jp/english/symposia/oo8o.html>

### 2. DIA2015 51st Annual Meeting (June 14 to 18)

The DIA 2015 51st Annual Meeting was held in Washington D.C. from June 14 to 18. Dr. Tatsuya Kondo (Chief Executive), Dr. Takao Yamori (Director of Center for Product Evaluation), Ms. Tomiko Tawaragi (Chief Safety Officer), Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs), Dr. Mayumi Shikano (Associate Center Director for Advanced Review with Electronic Data Promotion and Science Board), Dr. Daisaku Sato (Office of Cellular and Tissue-based Products), Dr. Naoyuki Yasuda (Office of Non-clinical and Clinical Compliance), Dr. Junko Sato (International Coordination Officer), Dr. Yoshiaki Uyama (Associate Center Director for Advanced Review with Electronic Data Promotion and Science Board), and 14 other staff members, participated in the meeting.



From right, Dr. Tominaga, Dr. Kondo, Dr. Nakashima, Dr. Yamori and Ms. Tawaragi at PMDA Toan Hall session

Dr. Kondo participated in the "International Regulatory Convergence" session, chaired by Ms. Emer Cooke (Head of International Affairs, EMA), together with Dr. Guido Rasi (Principal Adviser, EMA), Dr. Stephen M. Ostroff (Acting Commissioner, U.S. FDA), Dr. Anil Arora (Assistant Deputy Minister, Health Products and Food Branch, Health Canada), as a panelist, and introduced Strategy of SAKIGAKE, Time-limited Conditional approval of regenerative medical products, and PMDA's recent efforts, etc. At the PMDA Town Hall Session, chaired by Dr. Tominaga, Dr. Kondo, Dr. Nakashima (Ministry of Health, Labour and Welfare), Dr. Yamori, and Ms. Tawaragi, delivered presentations. In total, PMDA staff members participated in 8 sessions as a chair or speaker made a poster presentation, and operated PMDA's exhibition booth. There were about 7,000 participants in the DIA2015 51st Annual Meeting.



PMDA's exhibition booth

The DIA2016 52nd Annual Meeting will be held on June 26 to 30, 2015, in Philadelphia.

### 3. Pharmacopoeial Discussion Group ( PDG ) Meeting ( June 30-July 1 )

From June 30 to July 1, Pharmacopoeial Discussion Group (PDG) Meeting was held at PMDA in Tokyo, co-hosted by PMDA and Ministry of Health, Labour and Welfare (MHLW). PDG is an international council which aims to harmonize general chapters and excipient monographs in Europe, the U.S. and Japan, consisting of representatives from the European Directorate for the Quality of Medicines and Healthcare (EDQM), the United States Pharmacopoeial Convention (USP), PMDA and MHLW. In this meeting, 5 items in the monographs were agreed for revision. So far, 29 items in 36 general chapters, 48 items in 62 excipient monographs have been agreed for harmonization. In addition, an effective process of harmonization was discussed, and it was agreed to seek comments from relevant people from world pharmacopoeias on the PDG's harmonized proposal. The next face-to-face meeting of PDG will be held at USP on November 3-4, 2015.

Please see the press release at the following link:

<http://www.pmda.go.jp/files/000206333.pdf>

### 4. 4th DIA CMC Forum in Japan ( July 2 )

On July 2, the 4th DIA CMC Forum entitled "The Revision of Japanese Pharmacopoeia (17th Edition) and Perspective of Generic Drugs Assessment " was held directly after the Pharmacopoeial Discussion Group (PDG) meeting. The forum opened with a keynote by Dr. Toru Kawanishi, Director General, National Institute of Health Sciences entitled "Purpose of the 17th Edition of the Japanese Pharmacopoeia and Impact on Generic Drugs Assessment" followed by the presentations by Mr. Kenichi Mikami, Director, Office of Generic Drugs, and Dr. Andre Raw, Office of Lifecycle Products, FDA highlighting the current situation of generic drugs assessment and future plan in the U.S. and Japan. In addition, updates of the current situation and issues of each pharmacopoeia was provided by Dr. Seiko Miyazaki, Director, Office of Standards and Guidelines Development, and USP and EDQM who participated in the PDG meeting. The international forum was very worthwhile for the participants, with an active panel discussion among those from government, industry and academia, on the appropriate establishment of standards by the pharmacopoeia and their smooth application during the drug review process.

## Safety Information

### Pharmaceuticals and Medical Devices Safety Information No. 324, July 7, 2015

1. Risk Management Plan
2. Important Safety Information
  - (1) crizotinib
  - (2) technetium (<sup>99m</sup>Tc) hydroxymethylenediphosphonate injection, kit for the preparation of technetium (<sup>99m</sup>Tc) hydroxymethylenediphosphonate injection
3. List of Products Subject to Early Post-marketing Phase Vigilance (as of May 31, 2015)

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

### Medical Devices Revisions of PRECAUTIONS

- Small-intestinal capsule endoscope (June 19, 2015)
- Drug-eluting coronary stent or Drug-coated balloon dilatation catheter for coronary angioplasty (July 15, 2015)

<http://www.pmda.go.jp/english/safety/info-services/0015.html>

### Medical Devices Notification on self-check

- Electric massage devices for home use (June 30, 2015)

<http://www.pmda.go.jp/english/safety/info-services/0017.html>

## Events

### Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
Aug 1	CVIT2015 HBD Town Hall Meeting	Fukuoka
August 18	The 8th Japan-China Medicine Manufacture Exchange Meeting	Beijing
August 27-29	APEC LSIF RHSC	Cebu
September 3	Celebrating MHLW's and PMDA's new International Strategic Plans "Toward further promotion of regulatory science and global capacity building"	Tokyo
September 10	The 2nd Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices	Tokyo
September 14-18	IMDRF MC Meeting, HBD Think Tank	Kyoto

## Reports from overseas

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

### Webinar on publication of clinical data

With regard to publication of clinical trial data covered in the letters from the liaison officer several times before, a webinar was held on June 24 to update on EMA's current situation. The webinar was targeted towards stakeholders such as pharmaceutical companies to deepen their understanding of requirements and procedures for publication of clinical reports. In addition, the concept of commercially confidential information was explained. The questions and answers sessions between presentations were the points that intrigued me. Various questions were sent from the participants to EMA with regard to the scope of information necessary for publication and the procedures for anonymisation. Responsible EMA officers orally responded to these questions during the webinar. EMA plans to summarize these questions and publish them in the form of a Q&A later. Based on the global nature of clinical trials, the start of publication of clinical trial data by EMA may have a strong influence on the international stage, not only in Japan. As a liaison officer stationed at EMA, I consider we need to continue to pay attention to this issue.

Meeting materials and video recordings in the meeting are available on the EMA website as shown below. If you have interests in this topic, how about having a look at them?

(Reference)

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/events/2015/06/event\\_detail\\_001163.jsp&mid=WCobo1aco58004d5c3](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/06/event_detail_001163.jsp&mid=WCobo1aco58004d5c3)

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

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### **DIA 2015 51st Annual Meeting**

DIA 2015 51st Annual Meeting was held on June 15 -18 in Washington, DC. I attended the meeting to gather information on trends of CMC including new drug products in the United States. The session related to CMC in this meeting covered a wide variety of topics such as control strategy, life cycle management and GMP inspection. Among those, the session related to Office of Pharmaceutical Quality (OPQ) which was newly established in U.S. FDA in 2015 seemed to attract the high interest of the participants. Although there was no session related to pharmacopoeia in this meeting, the speaker from a pharmaceutical company stated that the USP will implement its new general chapter(s) related to elemental impurities in line with the timing of ICH Q3D guideline implementation. The speaker also made a favorable comment on collaboration between regulators and the USP. With regard to ICH Q3D guideline, the EP, JP and USP exchanged information on the status of each pharmacopoeia in Pharmacopoeial Discussion Group (PDG) meeting held on June 30 and July 1 in Tokyo, Japan. Cooperation among the PMDA, MHLW and JP regarding to information transmission is expected in the future in Japan.

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

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### **A means to provide drug developers with regulatory authority's consideration of drug interaction to be evaluated during drug development**

Using a website is considered to be one useful means for a regulatory authority to disseminate information. FDA provides its current understanding of how to conduct drug interaction studies during drug development and resulting labeling on its website<sup>1)</sup>. The database of drug-drug interaction in renal and hepatic impairment, which is created by the collaborative work among the FDA, University of Washington, and University of Tokyo, has been also published on the website on June 30, 2015.

PMDA currently does not have such mechanism using website. However, PMDA may as well share the PMDA's consideration of drug interaction with the public by using PMDA's website in a similar way as FDA, in addition to the drug interaction guideline that PMDA is to finalize. Drug-drug interaction cases are accumulated when a new drug is approved and frequent updates may be useful for the communication between PMDA and drug developers. Considering electronic study data will be accumulated in PMDA in near future, I am thinking that PMDA may carefully consider what means would be desirable for providing the latest drug interaction cases and PMDA's consideration of drug interaction

- 1) Drug Development and Drug Interactions  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm080499.htm>

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

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### **The Productive Dispatch to Center for Devices and Radiological Health (CDRH), U.S. FDA**

I have finished a three-month dispatch program at the U.S. FDA CDRH, Office of Device Evaluation (ODE), Division of Cardiovascular Devices (DCD) as a visiting reviewer, which was scheduled from April 13 to July 7. I actively joined in review and policy discussions and led information sharing on PMDA's review process for specific device areas. Through these experiences I was able to learn a lot, especially that our concerns and challenges have more in common more than I had expected. Also, I was able to

have many special opportunities for discussions on topics that we were particularly interested in and asking questions to the directors and managers in person. Thanks to those precious experiences, I could learn how FDA was making tremendous efforts to protect public health both strategically and dynamically but also carefully. I am determined to continuously contribute to the improvement of PMDA's review process by leveraging what I have learned from the dispatch at CDRH and strengthening the two agencies' relations of trust and collaboration.

Ms. Rie Fukaya  
Visiting Reviewer at CDRH, U.S. FDA in the U.S.A.

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### **The results of my dispatch to the U.S. FDA**

I was at the Center for Devices and Radiological Health (CDRH), U.S.FDA from April to July 7 2015. Three months of dispatch was very short, but every day was fulfilling and a productive learning experience. I am very grateful to the people of the U.S. FDA who took care of me during this period.

I was part of the Contact Lens and Retinal Devices Branch in the Division of Ophthalmic and Ear, Nose, and Throat Devices (DOED) in the Office of Device Evaluation. However I also discussed the review of a number of ophthalmic and ear, nose and throat devices with DOED reviewers (e.g., contact lenses, retinal devices, intraocular lenses, glaucoma implants, ophthalmic optical coherence tomographs, capsular tension rings, LASIK surgery machines and cochlear implants). The review approach of the PMDA is not so different from that of the U.S.FDA; furthermore we share the same problems and concerns with respect to decorative contact lenses.

The personal connection with the U.S.FDA staff combined with what I learned during my stay will be a valuable asset. The PMDA and the U.S.FDA could make use of the connection and collaborate in the future on issues of mutual interest.

Mr. Takehiro Ichikawa  
PMDA's International Officer at CDRH, U.S. FDA in the U.S.A.

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PMDA Website: <http://www.pmda.go.jp/english/index.html>

Contact: <http://www.pmda.go.jp/english/contact/0001.html>