



*Chimonanthus praecox*

# PMDA Updates

January, 2016

## News

### 1. PMDA Chief Executive Dr. Kondo's New Year message for 2016

A Happy New Year to you all.

PMDA has grown to be one of the leading regulatory agencies in the world nowadays. PMDA's world leading review service as well as its initiatives including promotion of regulatory science, implementation of SAKIGAKE Designation System, and development of review system for regenerative medical products along with relief system for adverse health effects from them, have been paid close attention, and are highly regarded in the world as an excellent example to follow. Under such circumstances, I am considering PMDA needs to progress new initiatives even further.



Since last year, the big news about revelation of inadequate manufacturing processes of blood products has made an impact on the Japanese society. We must accept this reality and deal with it responsibly to ensure the quality of Japanese drugs.

2016 is the second to third year in the 3rd 5-year mid-term plan of PMDA. PMDA will promote the project for developing the Medical Information Database Network (Mid-net), enhance the service for reliability, and ensure manufacturing/quality and compliance.

Furthermore, through the launch of the "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs", PMDA will enhance regulatory capacity building operations to Asian countries, and contribute to international society.

I wish you all a happy and prosperous year 2016.

### 2. ICH Meeting in Jacksonville (December 5 to 10)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was held in Jacksonville, Florida, U.S.A. from December 5 to 10. This was the first meeting for the new ICH after the organizational changes. Thirty one staffs in total from PMDA, including Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs (who served as Vice-Chair of the Assembly) and Mr. Naoyuki Yasuda, Office Director, Office of International Programs, and also Dr. Nobumasa Nakashima, International Planning Director for Pharmaceuticals and staffs from Ministry of Health, Labour and Welfare (MHLW). In the Assembly, a substantial progress was achieved with the approval of Rules of Procedure for the Assembly of the new ICH association and the application process for new Members. In Working Group meetings at the Jacksonville, the key achievements included ICH E18 on "Genomic Sampling and Management of Genomic Data", which reached Step 2b, and ICH E14 on "Questions & Answers on the Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drug" as well as ICH M8 on "Implementation package Version 1.0 for the electronic Common Technical Document (eCTD) Version 4.0" which reached Step 4.



Group photo of Assembly participants  
(Dr. Tominaga at the 2nd from the left)

The next ICH meeting will be held in June 2016 in Lisbon, Portugal.

### 3. PMDA-Keio Joint Symposium on Pharmacometrics (December 8, 2015)

On December 8, PMDA-Keio Joint Symposium on Pharmacometrics was held, cohosted by PMDA and Keio University.

These days, drug development strategy and quantitative decision making using Modeling & Simulation (M&S) have been given attention from the point of view of more scientific and rationale drug assessment and development. In this symposium, leading experts in pharmacometrics from the U.S. delivered lectures on the most recent findings including M&S methodologies, its clinical application, and its utilization on reviewing and consulting at U.S. FDA, from perspectives of industry, academia and regulatory agencies. Participants from PMDA included: Dr. Takao Yamori, Director of Center for Product Evaluation who brought greetings, Dr. Mayumi Shikano, Associate Center Director (for Advanced Review with Electronic Data Promotion and Science Board) who chaired the meeting, and Dr. Naomi Nagai, Senior Specialist (for Pharmacokinetics) who had a presentation on the current situation of the regulatory agency, entitled "Role of Pharmacometrics in Drug Development and Regulatory Review: PMDA perspectives". In addition, an active opinion exchange on industry-government-academia collaboration took place during the panel discussion.

The details of the symposium including presentation files in English is available at following URL:

<http://www.pmda.go.jp/review-services/reexamine-reevaluate/symposia/0043.html>



Group photo of organizers and speakers  
(Dr. Yamori at the center, Dr. Shikano at the 2nd from the right, and Dr. Nagai at the right end)

### 4. HBD Special Program (December 18, 2015)

On December 18, HBD<sup>1)</sup> Special Program was held under the theme of "From Japan to US!" during Kamakura Live in Yokohama. In this program, regulatory efforts by Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI), U.S. FDA and PMDA, as well as the experiences and viewpoints of industry and academia of the U.S. and Japan were introduced, with the aim of promoting innovative medical devices from Japan to foreign countries this time. In addition, with respect to the medical device post-marketing registry, which is a critical issue in the lifecycle-based product development of medical devices, the participants discussed on the research activities and the tools supporting registries in the U.S. and Japan. In the plenary session, Dr. Tatsuya Kondo, Chief Executive of PMDA, delivered a presentation entitled "Medical Technology from Outside World Into Japan and From Japan Exported to Outside World", while Dr. Yuka Suzuki, Director of Office of Medical Devices II, presented "Lessons Learned from HBD and PMDA's Effort to Encourage Medical Device Innovation" in the following session. The speakers joined in the panel discussions at the end of individual sessions and active discussions took place.



Dr. Kondo

1) Harmonization By Doing (HBD): A joint effort launched in 2003, by the members from academia, industry and regulators of the U.S. and Japan with the aim of promoting global clinical trials and regulatory harmonization for medical devices through discussions based on the actual projects.

## 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
Delytba	delamanid	January 5
Tivicay	dolutegravir sodium	January 8

## Safety Information

### Pharmaceuticals and Medical Devices Safety Information No. 329, January 7, 2016

1. Adverse Reaction to Influenza Vaccine in the 2014 Season
2. Safety of Influenza Antiviral Drugs
3. Important Safety Information
  - (1) Lenvatinib mesilate
4. Revision of Precautions (No. 270)
  - Fomepizole (and 3 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of November 2015) (Reference)
  - Precautions Regarding Handling of Fire During Long-Term Oxygen Therapy (LOT)

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

### Notifications on Early Post-marketing Phase Vigilance for Prescription Drugs

- Implementation Methods, etc. of Early Post-marketing Phase Vigilance for Prescription Drugs
  - Q&A on Early Post-marketing Phase Vigilance for Prescription Drugs (January 8, 2016, originally posted in Japanese on March 24, 2006)
- <http://www.pmda.go.jp/english/safety/regulatory-info/0001.html>

### Pharmaceuticals Revisions of PRECAUTIONS, January 12, 2016

- products containing azilsartan
  - products containing amlodipine besilate
  - nintedanib ethanesulfonate
  - tazobactam/piperacillin hydrate
  - piperacillin sodium
  - products containing atovaquone
  - itraconazole
- <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
February 15-19	The 2nd PMDA Training Seminar (Medical Devices)	Tokyo
February 23-26	APEC LSIF RHSC Meeting	Lima
March 1-4	APEC MRCT/GCP Regulatory Science Centre of Excellence Pilot Program	Singapore
March 8-10	International Medical Device Regulators Forum (IMDRF) MC Meeting	Brasilia
March 16	International Regulatory Forum of Human Cell Therapy and Gene therapy Products	Osaka
March 24-25	The 3rd Thailand-Japan Symposium	Bangkok

## Reports from overseas

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

### EU Medicines Agencies Network Strategy to 2020

On December 18, EMA published EU Medicines Agencies Network Strategy to 2020 in collaboration with Heads of Medicines Agencies (HMA, a network of the heads of the National Competent Authorities). This strategy has four themes: contributing to human health, contributing to animal health and human health in relation to veterinary medicines, optimising the operation of the EU network, and contributing to the global regulatory environment. In the fourth theme, interactions of regulatory authorities outside EU are described. In particular, in the context of globally-approved medicines, the strategy points out the significance of regulatory harmonisation by regulatory authorities through multinational collaboration such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and existing bilateral arrangements. As a concrete example of the bilateral interaction, collaborations between EMA with Japan MHLW/PMDA and US FDA are cited. In addition, the strategy stresses the importance EU authorities give to product supply chain and data integrity. It underlines the necessity of better use of resources of regulatory authorities by promoting information sharing and cooperation between them for GMP and GCP inspections.

As the PMDA liaison stationed at EMA, I will continue to share information and promote interactions between regulatory authorities in EU and Japan.

- 1) Detailed information on the training session  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners\\_and\\_networks/general/general\\_content\\_000318.jsp&mid=WCob01ac0580289efe](http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000318.jsp&mid=WCob01ac0580289efe)
- 2) Activities of representatives of patients' and consumers' working party  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/events/2015/10/event\\_detail\\_001234.jsp&mid=WCob01ac058004d5c3](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/10/event_detail_001234.jsp&mid=WCob01ac058004d5c3)

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

## General Chapters - Biological Analysis Expert Committee Meeting

General Chapters - Biological Analysis Expert Committee Meeting was held on December 16-17, 2015 at the USP headquarters<sup>1)</sup>. This meeting was the first face to face meeting in USP's 2015-2020 Council of Experts cycle started on July 1, 2015. The new strategy based on Resolution VI "STANDARDS FOR BIOLOGICAL MEDICINES", which is one of the activity policies in this 5-year cycle, was introduced in the meeting. In addition, the current status of developing general chapters and achievements of the previous 2010-2015 cycle were reviewed. Main topics of the agenda were Oligosaccharide Analysis, Therapeutic Monoclonal Antibody, Vaccines and Residual DNA Measurement, etc. USP promotes developing new monographs and chapters related to Biologics due to the increase of biopharmaceuticals in the U.S. market. A new general chapter regarding analytical methods for characterization of therapeutic monoclonal antibodies, *Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies*, was released on November 1, 2015 and will be official on May 1, 2016. In order to develop further new chapters and Reference Standards which meet users' needs, two surveys for new standards that could support manufacturers and reviewers of vaccine and monoclonal antibody products were conducted and their results were discussed in the meeting. The next face to face meeting will be held on August 23-24, 2016 and a bioassay workshop will be held in September, 2017 (in collaboration with other USP Expert Committees). Understanding USP's strategy on biologics is very important to develop chapters on biological methods with consideration of international consistency in JP. I will make an effort to get collect information continuously and contribute to international harmonization.

1) General Chapters - Biological Analysis Expert Committee Meeting (Dec 2015)

<http://www.usp.org/meetings-courses/expert-committee-meetings/general-chapters-biological-analysis-expert-committee-meeting-6>

Dr. Chie Mizumaru

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

---



PMDA Updates ©2009-2016 PMDA

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

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