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# PMDA Updates

February, 2014

## News

### 1. PMDA Forum (February 8)

PMDA was founded on April 1, 2004 and will celebrate its 10th anniversary this year. In commemoration of the 10th anniversary, PMDA hosted the anniversary symposium, "PMDA Forum" on February 8, 2014 in Tokyo.

The purposes of the symposium are, to widely publicize and improve the people's awareness and understanding on PMDA's activities and efforts; to deepen the people's recognition on significance and role of drugs and medical devices; and to strengthen collaboration with foreign regulatory agencies.



In the Part 1 of the Forum which titled "Globalization of PMDA", Ms. Shinako Tsuchiya, Senior Vice Minister of Health, Labour and Welfare, delivered an opening address and Dr. Tatsuya Kondo, Chief Executive of PMDA, made a speech as a representative of the host, followed by a keynote speech and presentations by guest speakers. In the Part 2, a panel discussion was made under the theme of "Got to Know! Japanese Pharmaceuticals". The Forum came to a huge successful close with a large number of audience, despite a record snowfall in Tokyo on the day. Outlines of the Part 1 and Part 2 are as mentioned below.

#### Part 1: "Globalization of PMDA"

Dr. Kondo made a presentation entitled "10-year Achievements of PMDA" and Dr. Fumimaro Takaku, president of the Japanese Association of Medical Sciences (JAMS), gave a keynote speech on "Pharmaceutical Innovation and Expectations for PMDA". The guest speakers including Prof. Guido Rasi, Executive Director of European Medicines Agency (EMA); Mr. Jüng H. Schnetzer, Executive Director of Swiss Agency for Therapeutic Products (Swissmedic); A/Prof. John C W Lim, Chief Executive of Health Sciences Authority (HSA); Dr. Chung Seung, Minister of Food and Drug Safety (MFDS); Dr. M. Hayatie Amal, Permanent Secretary of National Agency of Drug and Food Control (NADFC); and Mr. Kees de Joncheere, Director of Essential Medicines and Health Products, World Health Organization (WHO), delivered speeches on "PMDA from the International Perspective - Future Collaboration and Expectation for PMDA". Dr. Margaret A. Hamburg, Commissioner of Food and Drug Administration (FDA), could not make her trip to Japan due to sudden unavoidable official duties and a video presentation was delivered.



From left: Ms. Tsuchiya (MHLW), Dr. Kondo (PMDA), Dr. Takaku (JAMS), Prof. Rasi (EMA)



From upper left: Dr. Hamburg (FDA), Mr. Snetzer (Swissmedic), A/Prof. Lim (HAS)  
 From lower left: Dr. Chung (MFDS), Dr. Hayatie (NADFC), Mr. de Joncheere (WHO)

**Part 2: “Got to Know! Japanese Pharmaceuticals”**

In the Part 2, a panel discussion was made having Mr. Akira Ikegami, journalist, as its coordinator and active discussions were made. The panelists were Dr. Kondo (PMDA); Dr. Tomomitsu Hotta, President of National Cancer Center; Prof. Mayumi Mochizuki, Dean of the Faculty of Pharmacy, Keio University; and Mr. Jugo Hanai, Chairman of the Japan Federation of Drug-induced Sufferers Organizations.

It is introduced that there are many patients whose quality of lives are improved significantly by new medicines, while many patients suffer from adverse drug reactions. The panelists exchanged their views on how drugs should be managed from their respective positions. Responding to greater responsibilities PMDA is supposed to take on in the future, in order to deliver safe and effective pharmaceutical products to the people, Dr. Kondo stated PMDA’s determination to perform duties based on ethics to protect public health and the lives of the citizens.



**2. Promotion of cooperative relationship with USP (January 27)**

Dr. Takao Yamori, Director of Center for Product Evaluation (PMDA), visited Dr. Roger Williams, Chief Executive Officer, and several executives of the United States Pharmacopeial Convention (USP) on January 27, 2014. At the meeting, both sides shared mutual understanding on promoting personnel exchange and communication to further enhance the cooperative relationship.

Both parties agreed on dispatching staff members once in a half year in terms of personnel exchange, and on having teleconferences on a regular basis in regard to enhancing communication. These actions will enable PMDA and USP to have more active discussions and opinion exchanges in general tests, international harmonization of excipients standards, and other ongoing issues, which are under the discussion in the Pharmacopoeial Discussion Group.

Dr. Yamori paid respect to Dr. Williams, who was scheduled to retire as of January 31, for his contribution in development of USP and various achievements as a head of the world-leading organization in the area of Pharmacopoeia over a long period of 14 years.



The 4th left: Dr. Williams, the 5th left: Dr. Yamori

### 3. 4th PMDA Training Seminar (February 3-7)

PMDA held the 4th PMDA Training Seminar from February 3 to 7, 2014, under the theme of reviewing of generic drugs. A total 13 officials from 6 regulatory agencies (Taiwan, Korea, Indonesia, Yemen, Saudi Arabia and Russia) and WHO participated in the seminar. The participants learned Japanese pharmaceutical administration system through the lectures and active discussions during the group works, as well as deepened exchange with staff members of PMDA. In the seminar, the participants also visited the manufacturing factory of generic drugs to observe the latest facilities and methods of manufacturing management and quality control.

Additionally, 4 WHO fellows (Vietnam) and 9 trainees of the Japan International Cooperation Agency (China, Malaysia, Mali, Myanmar and Sri Lanka) participated in some parts of the programs.

Please refer to the following URL for the details.

[http://www.pmda.go.jp/english/events/4th\\_pmda\\_training\\_seminar.html](http://www.pmda.go.jp/english/events/4th_pmda_training_seminar.html)

In March, the 1st PMDA Medical Devices Training Seminar is scheduled, under the theme of reviewing of medical devices.

The details are available on the following web page:

[http://www.pmda.go.jp/english/events/1st\\_pmda\\_medical\\_devices\\_training\\_seminar.html](http://www.pmda.go.jp/english/events/1st_pmda_medical_devices_training_seminar.html)

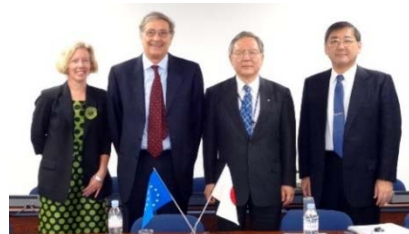


Left: with participants, Right: presentation of certificates

### 4. Bilateral Meetings and Special Presentation (February 7)

Prior to the PMDA Forum, Ministry of Health, Labour and Welfare (MHLW) and PMDA had bilateral meetings with EMA, HSA, NADFC and WHO and the importance of promoting collaborative relationship was confirmed.

After the bilateral meeting, Prof. Guido Rasi (EMA) gave a special presentation to PMDA staff members and mutual understanding between EMA and PMDA was deepened.



From left: Ms. Emer Cooke (EMA), Prof. Rasi (EMA), Dr. Kondo (PMDA), Mr. Masatoshi Narita (Councilor for Pharmaceutical Affairs, MHLW)

### 5. DIA Special Symposium (February 9)

The DIA Special Symposium was held on February 9, 2014 in Tokyo, on the sidelines of PMDA Forum commemorating the 10th anniversary of its foundation. In the Symposium, regulators who took part in the PMDA Forum including Dr. Tatsuya Kondo (PMDA); Prof. Guido Rasi, (EMA); A/Prof. John C W Lim (HSA); Ms. Ratna Irawati, Director of Therapeutic and household products Distribution Control (NADFC); Mr. Kees de Joncheere (WHO), were invited and participated as speakers and panelists together with the representatives from the pharmaceutical industries. The theme of this Special Symposium was "How Can We Deliver Innovative Products to Patients Expeditiously?" and speakers delivered speeches on global policies and environmental arrangement for innovative drug development from their respective positions. In the subsequent panel discussion, in-depth discussions were made between panelists and attendees.

## Safety Information

### Pharmaceuticals and Medical Devices Safety Information No.309, January 29, 2014

1. Precautions for Use of Closure Devices at Puncture Site
2. List of Products Subject to Early Post-marketing Phase Vigilance (as of January 2014)
  - (1) Bosentan Hydrate

[http://www.pmda.go.jp/english/service/precautions\\_2013.html](http://www.pmda.go.jp/english/service/precautions_2013.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/service/drugs.html>

Brand Name	Generic Name	Posting date
Metreleptin	metreleptin (genetical recombination)	January 29
Perjeta	pertuzumab (genetical recombination)	February 19

## Events

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

Date	Title	Location
February 18-21	APEC LSIF RHSC Meeting	Ningbo
February 22-24	CRT2014 HBD Session	Washington D.C.
March 3-7	1st PMDA Medical Devices Training Seminar	Tokyo
March 10	EMA/FDA/MHLW-PMDA Orphan Product Designation Workshop	London
March 17-19	APEC MRCT CoE Pilot training	Singapore
March 25-27	26th Annual EuroMeeting Vienna 2014	Vienna
March 25-27	IMDRF Steering Committee Meeting	San Francisco

## Letters from the liaison officers

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

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Do you know the page of 'Public consultations'<sup>i</sup> in the EMA public website?

EMA makes public consultations at each step of development of guidelines. In this year, the agency has already started six public consultations including 'Draft Guidance on the investigation of subgroups in confirmatory clinical trials'. The EMA publishes the comments submitted with submitter's name after the expiration of the consultation period. You may wonder why you cannot find PMDA as a comment submitter. PMDA makes its comments and discuss with EMA in the teleconference and/or face-to-face meetings. EMA also makes comments to Japanese guidelines if English version of the guideline is prepared before/during consultation period. I join such discussions between PMDA and EMA as a Liaison Officer, and always realise there are a lot in common between PMDA's and EMA's considerations more than I expected. More frankly discussion between the agencies will make more deeply understanding of each other, and it must lead to efficient medicinal product developments.

<sup>i</sup> <http://www.ema.europa.eu/ema/>, Click 'Public consultation' Tab

Dr. Junko Sato

PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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