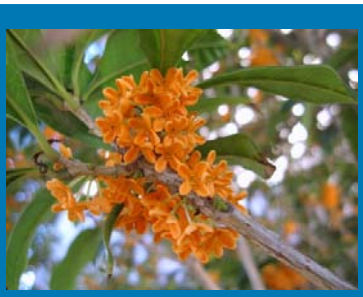

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PMDA Updates

October, 2013

News

1. PMDA joins the 4th CIMDR Forum (September 10 to 13)

Two PMDA experts participated in the 4th China International Medical Device Regulatory Forum (CIMDR) held in Xian, China. There were more than 1,000 participants in the Forum. In the Medical Device Innovation Forum, Dr. Atsushi Tamura, former International Coordination Officer (currently, Chief of Kansai Branch, PMDA) introduced PMDA's recent activities, including the Science Board and the Pharmaceutical Affairs Consultation on R&D Strategy. Also, another PMDA expert gave a presentation on Japan's medical device regulation, overview of medical device review, etc. in the Plenary Session. The 5th CIMDR is scheduled for August 2014 in Amoy, China.

2. Global Summit on Regulatory Science 2013 – Nanotechnology (September 10- 11)

Global Summit on Regulatory Science 2013 – Nanotechnology (GSRS13) was held in Little Rock, USA, on September 10-11, 2013, hosted by the U.S. Food and Drug Administration (FDA)/National Center for Toxicological Research (NCTR). This international conference provides an opportunity to discuss innovative technologies and partnerships with the aim of globally enhancing translation of basic science into regulatory applications. Over 100 attendees from government, industry, and academia gathered for discussion. Dr. Hideo Utsumi, Executive Director of PMDA, and other three PMDA's reviewers participated in the conference with a focus on nanotechnology. On the first day, Dr. Margaret Hamburg, FDA Commissioner, gave a speech on public health and regulatory science, while other scientists made presentations on the present state of nanotechnology standards and the impact of nanotechnology on healthcare. The second day of the conference saw experts' presentations on the evaluation of nanomedicine stability, the biomedical evaluation on pharmacokinetics, and the safety initiative on nanomaterial safety, followed by an active question and answer session. How best to address innovative technologies such as nanotechnology in the regulatory framework is currently under consideration at PMDA, with a strong emphasis on regulatory science. PMDA continues to proactively promote international cooperation in regulatory science research.

3. Dr. Utsumi's speech at 2nd US-Japan Clinical Trials in Oncology Workshop (September 13)

The 2nd US-Japan Clinical Trials in Oncology Workshop was held in Washington DC, USA on September 13, 2013. The workshop was hosted by the Embassy of Japan in Washington DC, and Dr. Naoko Takebe from the National Cancer Institute (NCI) and Dr. Kazuhiko Takabe from Virginia Commonwealth University (VCU) served as the course directors. In the workshop, Dr. Utsumi, Executive Director of PMDA, delivered a speech under the theme of PMDA's role in promoting innovation. This workshop is mainly intended to provide young physician-researchers who are engaged in clinical trials with a forum to discuss the design of clinical studies for novel drug development. The participants are encouraged to review key concepts underlying cancer therapeutic clinical trials and facilitate networking among participating researchers. In addition to providing the overview of PMDA's operations, Dr. Utsumi explained information on innovative drugs that originated from academia and have been approved in Japan and PMDA's initiatives to support innovation. Moreover, active discussions were made on promotion of oncology clinical trials during the workshop.

4. USP-PMDA Bilateral Meeting held (September 16)

On September 16, 2013, Dr. Nobumasa Nakashima, Director of Office of International Programs, PMDA, visited the United States Pharmacopeial Convention (USP) located in Washington DC, USA, and had a bilateral meeting with Dr. Roger L.Williams, CEO of USP, and other executives. PMDA had its International Liaison Officers stationed at the USP from February 2010 to September 2013, thereby promoting a cooperative relationship between the two parties. In this meeting, Dr Nakashima, on behalf of PMDA, expressed the gratitude to the USP for acceptance of the International Liaison Officers over the past three and half years, while providing information on PMDA's recent organizational structure, roles and responsibilities, international activities, and the current state of the Japanese Pharmacopoeia. On the other hand, USP introduced its branches overseas and links with the branches, and also explained the cooperative relationship with other pharmacopoeias. Both parties have agreed to continuously enhance the partnership between USP and PMDA, such as by mutually dispatching experts.

5. PMDA's participation in RAPS 2013 (September 28 to October 2)

A total of 13 delegates from PMDA, headed by Dr. Utsumi, Executive Director, including seven speakers, attended RAPS 2013 (the regulatory covergence provided by the Regulatory Affairs Professionals Society) held in Boston, USA. This year, a whole day workshop titled "Japan Regulatory Essentials, Medical Devices & IVDs" was held, and the representatives from PMDA, the Ministry of Health, Labour and Welfare, and industry gave presentations on the current status of medical device regulation, medical device review and QMS inspection in Japan, from each standpoint. In the session titled "What's New in Japanese MD/IVD Regulation," which

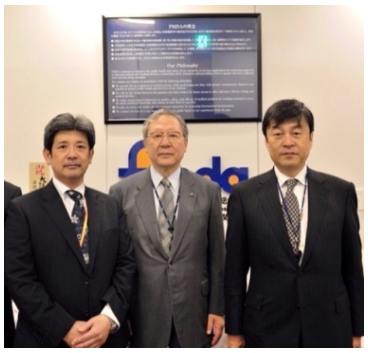
attracted more than 100 audience members, Dr. Utsumi delivered a presentation on the current state and efforts of PMDA, followed by vigorous discussions. Also noted was the first appearance of the PMDA exhibit booth, where a variety of information on the Agency was provided and questions were responded to. The booth had nearly 300 visitors.

6. PMDA expert dispatched to Swissmedic (October 1)

PMDA sent Dr. Junko Komura, Director of Division of Regulatory Science Operation, Office of Regulatory Science to Swissmedic, the Swiss regulatory agency for therapeutic products, on October 1, 2013. Dr. Komura is the first PMDA expert sent to Swissmedic as part of the personnel exchange program and will stay in Switzerland for three months. The major mission of Dr. Komura is to deepen mutual understanding by exchanging opinions on safety measures and reviews of biopharmaceuticals and new drugs. At the same time, she aims to acquire practical knowledge of secretariat's operations from Swissmedic which is the chair of the International Pharmaceutical Regulators Forum (IPRF). Based on the outcome of this dispatch, PMDA and Swissmedic will consider the possibility of a long-term personnel exchange.

7. Establishment of the Kansai Branch of PMDA (October 1)

PMDA launched its first branch office, the Kansai Branch, in the Kansai region (the west of Japan) on October 1, 2013. The inaugural ceremony was held at Tower C, Knowledge Capital, Grand Front Osaka, to celebrate the opening of first branch office with many participants from the national and local governments and industry.



Left: Dr. Tamura (Chief of Kansai Branch), Dr. Kondo (Chief Executive), Mr. Matsuoka (Deputy Executive Director)
Right: Grand Front Osaka, Knowledge Capital

Dr. Tatsuya Kondo, Chief Executive, and Dr. Tamura, Chief of the Kansai Branch, participated in the ceremony as the representatives from PMDA. Dr. Kondo expressed his hope that PMDA will more flexibly respond to the needs in society by taking advantage of this opportunity. The Kansai Branch starts its operation with seven staff members who are responsible for Pharmaceutical Affairs Consultation on R&D Strategy this fiscal year. The branch office will add six GMP inspectors to have a total of 13 staff members in or after April 2014.

Main participants were as follows: Mr.Toshio Imabeppu, Director-General of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; Mr. Ichiro Matsui, Governor of Osaka Prefecture and chairman of regional industrial development committee of Union of Kansai Governments; Mr. Kazuo Sumi, Vice Chairman of Kansai Economic Federation and President of Hankyu Corporation; and Dr. Isao Teshirogi, President of Japan Pharmaceutical Manufacturers Association and President of Shionogi & Co., Ltd.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.305, September 25, 2013

1. Hydroxyethyl Starch-containing Solutions and Renal Impairment
2. Project of Japan Drug Information Institute in Pregnancy
3. Important Safety Information
   (1) Alogliptin Benzoate-containing products
   (2) Valsartan-containing products
   (3) Vildagliptin
   (4) Orengedokuto, Kamishoyosan and Shin'iseihaito
4. Revision of Precautions (No. 249)
   Isoflurane (and 13 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of September 2013)
   http://www.pmda.go.jp/english/service/precautions_2013.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
October 24-25	1st Thailand-Japan Symposium	Bangkok, Thailand
October 24-25	5th IGDRP Meeting	Geneva, Switzerland
October 28-31	11th OECD GLP training course	Chiba, Japan
October 29-30	Asia-Pacific Medical Devices Symposium	Taiwan
November 6-8	10th DIA Japan Annual Meeting	Tokyo, Japan
November 9-14	ICH Meeting	Osaka, Japan
November 12-14	IMDRF MC Meeting	Brussels, Belgium
December 2-5	AHWP-RAPS Joint Meeting/ AHWP Annual Meeting	Kuala Lumpur, Malaysia
December 3-6	8th International Summit of Heads of Medicines Regulatory Agencies	Amsterdam, Netherlands
December 23-24	Joint Conference between Taiwan and Japan on Medical Product Regulation	Taipei, Taiwan

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
Lixiana	edoxaban	October 18

Letters from the liaison officers

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

MHLW/PMDA and EMA improve information sharing in the area of good manufacturing practice using EudraGMDP. EudraGMDP is one of EU databases in GMP area.

Japan has become the first non-European country to start entering the GMP. It means to allow drug regulators in Japan and the EU to use information in EudraGMDP instead of issuing original paper GMP certificates for a number of regulatory procedures, such as marketing authorization applications or variation applications, including the addition of a new manufacturer. This information sharing must contribute to save time for importers, manufacturers and regulatory authorities. The EMA also offers 'read and write' access to EudraGMDP to the regulatory authorities of all countries with which the EU has an MRA or an agreement on conformity assessment and acceptance of industrial products.

The utilization of the database may be one of trigger to consider providing coveted medicinal products efficiently. Let's consider what we can do, and what we should do furthermore.

Junko Sato, Ph.D.
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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