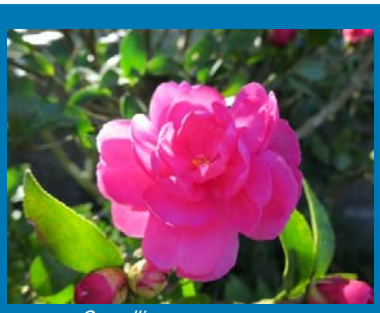

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PMDA Updates

November, 2013

News

1. Thai FDA-PMDA bilateral meeting and the 1st Thailand-Japan Symposium (October 22 and October 24-25, respectively)

On October 22, 2013, a bilateral meeting between the Thai Food and Drug Administration (Thai FDA) and PMDA was held in Bangkok, Thailand. In the meeting, both parties explained the outline of the regulatory system of each country and discussed the future cooperation between the two agencies. In addition, Thai FDA and PMDA co-hosted the 1st Thailand-Japan Symposium in Bangkok on October 24-25. From PMDA, Dr. Tatsuya Kondo, Chief Executive; Mr. Masanobu Yamada, Associate Center Director;and several Office Directors of PMDA participated in the symposium. From Thai FDA, Dr. Boonchai Somboonsook, Secretary General, Dr. Pathom Sawanpanyalert, Deputy Secretary-General and many Thai FDA staff members participated in the symposium. The symposium featured presentaions and discussions on drug safety, GMP inspection, and pharmacopeia. The regulatory agencies confirmed the intention to build the platform of cooperation between Thailand and Japan while helping to enhance the understanding of each regulatory system among the regulators and pharmaceutical industry of the two nations.

Left: Dr. Somboonsook (Secretary General, Thai FDA), right: Dr. Kondo (Chief Executive, PMDA)

2. PMDA experts' participation in the HBD session at TCT 2013 (October 27)

A one-day session on Harmonization By Doing (HBD) activities was held as a part of the Transcatheter Cardiovascular Therapeutics (TCT) conference 2013 in San Francisco, US, and two PMDA experts joined as presenters. The session focused on the past activities and future directions and challenges of HBD, the regulatory harmonization effort among academia, industry and regulators of US and Japan, which celebrates its 10th anniversary this year. The session also addressed the topics discussed between US and Japan under this scheme, such as: (1) the current situations of post-market surveillance and the possibility of mutual utilization of data from the Japanese Registry for Mechanically Assisted Circulatory Support (J-MACS) and the transcatheter aortic valve replacement (TAVR) registry (available in US), (2) the drug-eluting stent study and future collaborative development and approval, (3) the study on the common clinical trial design to be used in the US and Japan to develop devices for the treatment of Critical Limb Ischemia (CLI), and (4) the current status of the Mobile Health.

The experts from academia, industry and regulators of US and Japan highlighted the expectations and visions for the future collaborative scheme between the two countries through the presentations and discussions delivered in the session.

3. The 5th meeting of IGDRP held (October 28-31)

The International Generic Drug Regulators Pilot Project (IGDRP), which is a collaborative scheme among health authorities in generic drug regulation, held its 5th meeting in Geneva, Switzerland, from October 28 to 31, 2013.
Experts from PMDA's Office of OTC/Generic Drugs and other offices took part in this meeting. Representatives from 14 countries/regions, including Japan, as well as the European Union and the World Health Organization (WHO) met to update the reports on the ongoing working group activities, such as the results of regulatory gap analysis among health authorities, the commencement of discussion on differences in the criteria for biowaiver in each participating country, and the launch of discussion on a format required for information sharing as to drug master files. The future activities of IGDRP were also discussed during the meeting. In addition, it was decided that the website and secretariat function for IGDRP will be provided by WHO during the pilot project period.

4. The 11th OECD GLP training course held in Japan (October 28-31)

The 11th Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) training course for GLP inspectors which was co-hosted by PMDA and OECD was held from October 28 to 31, 2013 in Chiba, Japan. This training course is intended to provide a training opportunity for GLP inspectors from the OECD member countries, the participating countries of OECD Mutual Acceptance Data (MAD) and the non-OECD countries that are interested in the MAD, with the aims of training and standardization of GLP inspection, and networking among the participating inspectors. The first training course held in Asia gathered 83 participants from 27 countries and offered training programs, mainly on computer system validation (CSV) and quality assurance (QA). Dr. Tatsuya Kondo, Chief Executive of PMDA, delivered an opening address and emphasized the importance of promotion of international cooperation in harmonizing the procedures related to GLP inspection. Dr. Taisuke Hojo, Senior Executive Director and other Office Directors from PMDA also witnessed the opening of the training course.

Dr. Kondo (Chief Executive, PMDA)

5. Chief Executive of PMDA delivers special speech at 10th DIA Japan Annual Meeting (November 8)

On November 8, 2013, Dr. Tatsuya Kondo, Chief Executive of PMDA, delivered a special speech at the 10th DIA Japan Annual Meeting held in Tokyo, Japan. His speech focused on the future drug development and regulatory science. During the meeting period from 6 to 8 October, over 20 PMDA experts acted as speakers or session chairs in 29 sessions, in which the lively discussions were held. Since this meeting took place shortly before the ICH meeting in Osaka, many ICH professionals also participated in the DIA meeting to make presentations on future activities and globalization of ICH and its new framework of international cooperation. PMDA had its own exhbition booth during the meeting to provide information. Over 250 attendees visited the booth and the PMDA staff members answered questions from the visitors.

6. Pharmacopoeial Discussion Group (PDG) (November 5-6)

The Ministry of Health, Labour and Welfare/PMDA hosted the PDG regular meeting held at the PMDA office in Tokyo, Japan, to discuss the harmonization of general chapters and excipient monographs among the three pharmacopoeias [Japanese Pharmacopoeia, European Pharmacopoeia and the United states Pharmacopeia]. The WHO representative also attended this meeting as the permanent observer. Five revised/corrected monographs and 2 revised/corrected general chapters were harmonized in this meeting. At present, 28 of the 35 general chapters and 45 of the 62 excipient monographs in the current work program have been harmonized. The three pharmacopeias agreed to critically review the harmonization work procedures (procedures of the revision of the excipient monographs) and the discussion toward the next meeting was started. In the future, PDG will make more information on the background, work progress and decision-making available to stakeholders, thereby increasing transparency. The next PDG international meeting will be held in the first half of 2014, in US.

The news release is available on the following web page:
http://www.pmda.go.jp/english/pharmacopoeia/pdf/jpdata/pdg_press_release_en.pdf

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.306, October 30, 2013

1. Adverse Reactions to Influenza Vaccine in the 2012 Season
2. Important Safety Information
   (1) Propylthiouracil
   (2) Bortezomib
   (3) Minocycline Hydrochloride (oral dosage form, injectable dosage form)
   (4) Losartan Potassium
3. Revision of Precautions (No. 250)
   (1) Celecoxib (and 4 others)
   (2) Tracheostomy Masks
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of October 2013)
   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
Votrient	pazopanib hydrochloride	November 15
Ryzodeg	Insulin Degludec (Genetical Recombination)/Insulin Aspart (Genetical Recombination)	November 27

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
December 2-5	AHWP-RAPS Joint Meeting	Kuala Lumpur, Malaysia
December 3-6	8th International Summit of Heads of Medicines Regulatory Agencies	Amsterdam, the Netherlands
December 10	Taiwan-Japan Joint Seminar	Taipei, Taiwan
December 11	2013 TFDA EP／STED Medical Devices Reviewer Training Course (I)	Taipei, Taiwan
December 23-24	Joint Conference between Taiwan and Japan on Medical Product Regulation	Taipei, Taiwan
February 8	PMDA forum	Tokyo, Japan

Letters from the liaison officers

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

On 7 November, EMA released an Addendum to the guideline on the evaluation of medicinal products indicated for the treatment of bacterial infections. The addendum outlines a new approach facilitating the development of antibacterial agents targeted against multidrug-resistant (MDR) pathogens where patients have very limited or no remaining treatment options. It also gives guidance on data-gathering strategies to support the benefit-risk evaluation as part of the marketing-authorisation process for different indications. Infections by MDR bacteria are a major public health burden in not only EU but also other regions/countries including Japan. Generally the number of patients with infectious disease caused by MDR bacteria is very limited. Therefore, it must be an area which multi-regional clinical development is utilized. Unfortunately, such specific guidance to MDR pathogens is not published in Japan today. Global collaboration is necessary to tackle the growing challenge of antimicrobial resistance. We also have to discuss with stakeholders and go forward to provide new agents to patients.

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

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