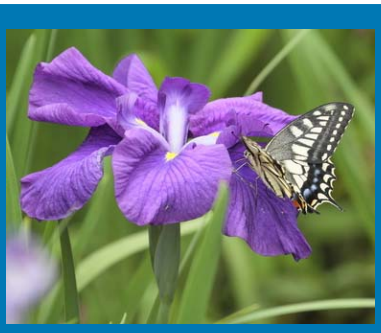

Iris laevigata

PMDA Updates

May, 2013

News

1. World Health Summit Regional Meeting - Asia, Singapore 2013 (April 8-10)

Dr. Tatsuya Kondo, Chief Executive of PMDA participated in the World Health Summit Regional Meeting - Asia (WHSRMA) 2013 held from April 8 to 10 in Singapore to give a presentation. In the Challenges in Drug and Device Regulation session chaired by Assoc. Prof. John Lim, Chief Executive Officer of the Health Sciences Authority of Singapore , Dr. Kondo delivered a speech titled "Challenges in Drug and Device Regulation : Japan's perspective." His fellow speakers were Sir Alasdair Breckenridge, Immediate Past Chairman of the Medicines and Healthcare Products Regulatory Agency; Prof. Ranga Krishnan, Dean of the Duke-NUS Graduate Medical School; and Dr. Ling Su, President of the Drug Information Association (DIA). In his speech, Dr. Kondo introduced PMDA's efforts to solve the drug lag and the results thereof as well as the Japanese regulatory review of medical devices. During the panel discussion following the presentations, lively discussions were held on topics such as how to advance the infrastructure improvement and capacity building in the ASEAN region and what should be done in the next five to ten years, from the perspective of regulatory agencies

2. Cellular and Tissue-based Products Subcommittee meeting held (April 25)

The Cellular and Tissue-based Products Subcommittee, one of the four subcommittees of the Science Board, had its 5th meeting on April 25. The tumorigenicity of cellular products that had been addressed at the previous meeting was disscussed again. Dr. Yoji Sato from the National Institute of Health Science, a temporary member of the subcommittee, gave a presentation on the topic.

The meeting agenda and list of the handouts are available at:
http://www.pmda.go.jp/english/scienceboard/cell_and_tissue-based/20130425.html
The handout materials are available only in Japanese:
http://www.pmda.go.jp/guide/kagakuiinkai/saibou/h250425gijishidai.html

3. China ICH Workshop on the ICH E11 Guideline (April 26)

PMDA sent two representatives to the "ICH E11 Guidelines Workshop on Clinical Investigation of Medicinal Products in Pediatric Population" (April 26, 2013 in Beijing), upon China's request that was made through the ICH Global Cooperation Group activities. The PMDA experts gave presentations on "Overview of ICH" and "Current research situation and challenge of pediatric clinical study in Japan." Under the situation where China has been focusing on the development of drugs for pediatric use, a number of questions on the current status of pediatric drugs in Japan were raised among approximately 70 workshop attendees from the industry, government, and academia in China and opinions were actively exchanged between speakers and attendees.

4. Road map for the PMDA International Vision (April 30)

While PMDA presently conducts its international activities based on the "PMDA International Strategic Plan" and the "PMDA International Vision", the agency has decided to establish a "Road map for the PMDA International Vision"(RM) for more specific action plans to achieve the goals indicated in the Strategic Plan and the Vision prior to the development of the Third Mid-Term Plan in order to meet future challenges in the constantly evolving international environment.

In order to achieve the status of world leader in the coming years, the agency recognizes that it has an urgent need to restructure its internal systems and organization. With this in mind, the following five assignments were selected for the RM as important areas in the PMDA's international activities.

1) Response to advanced science and technology
2) Improvement of international operation basis (e.g., fostering of human resources)
3) Dissemination of English information on the review process of medical products, especially English translations of review reports
4) Dissemination of information and international cooperation on safety measures
5) Increasing leverage of Japanese Pharmacopoeia (JP)

Each RM includes a "Background" section explaining the need it is intended to fill and specifies "Objectives and Goals" and "Measures and Milestones" to achieve the objectives.

Pharmaceuticals and medical devices are now developed, manufactured, distributed and sold worldwide, and the life cycle of medical products cannot be domestically completed within Japan. In this circumstance, no medical regulatory authority is able to fulfill its obligation and protect public health without cooperating with overseas authorities as a member of international community of drug regulators. Therefore,

PMDA is keen to build close cooperative relations with foreign regulatory agencies including the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and agencies in Asian countries that are rapidly gaining significance in clinical development and manufacturing. The agency is committed to following this roadmap, with every PMDA staff member working together to contribute to global development in medical product regulation as a leader among Asian regulators and a leading regulatory agency in a global context.

Please click on the link for more details.

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
May 21-25	IMDRF RPS WG	Washington D.C., U.S.
May 23-24	IGDRP	Canberra, Australia
June 1-6	ICH meeting	Brussels, Belgium
June 23-27	DIA 2013 49th Annual Meeting	Boston, U.S.
June 25-27	Pharmacopoeial Discussion Group Meeting	Strasbourg, France

Letters from the liaison officers

Our liaison officers deliver lively reports for thier activities at their statined overeas authorities.

As I wrote in PMDA update December 2012, the EMA is planning to publish clinical trial data and 'Workshop on clinical trial data and transparency' was held at the EMA in November 2012. The update was posted in EMA website on 30 April. Following the workshop, the EMA issued a call for nominations to join advisory groups to inform the EMA on five specific aspects: protecting patient confidentiality, clinical-trial-data formats, rules of engagement, good analysis practice and legal aspects. More than 200 people from all stakeholder groups, including patients group, pharmaceutical companies, academia and regulators, participated in one or more advisory group. The groups had meetings taking place via teleconference and submitted final advices to EMA last month.

The EMA will now be drafting a policy on proactive access to clinical-trial data to publish it on 30 June. The Agency expects the policy on proactive publication of clinical-trial data to come into force on 1 January 2014.

Multi-regional drug development is getting major in Japan. It means proactive publication of clinical trial data in EU must have big impact to Japan. We might discuss Japanese direction on it with stakeholders.

1) European Medicines Agency publishes final advice from clinical trial advisory groups
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/04/news_detail_001778.jsp&mid=WC0b01ac058004d5c1

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

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ExcipientFest Americas 2013 was held on April 30th and May 1st. This event features technical talks on excipient technology, new drug applications and regulatory issues. Talks on the points to be considered for manufacturing, quality control, risk assessment, distribution of excipients, as well as the talks on new excipient development process were provided. USP gave a lecture on excipient monograph modernization, and the progress of international harmonization projects. Many organizations and enterprises from around the world run booths at the event, and they offer a platform to exchange information.

The participants can collect information on the hot topics or trends in this area, and which was so informative for me to consider future international harmonization item.

Dr. Eriko Fukuda
PMDA's International Liaison Officers stationed at USP in the United States

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