



*Platycodon grandiflorus*

# PMDA Updates

September, 2014

## News

### 1. The 4th Meeting of Society for Regulatory Science of Medical Products (September 5 to 6)

The 4th Meeting of Society for Regulatory Science of Medical Products was held in Tokyo from September 5 to 6. Regulatory Science is the science that serves precise estimation, evaluation, and judgment to regulate fruits of technology so that they assume the most desirable form in harmony with humankind and society to benefit the public and society. To be the world leading country to put innovative medicines, etc., into practical use from now on, it is necessary for Japan to promote regulatory science domestically, as well as to disseminate outcomes of regulatory science from Japan to the world, to establish regulatory science as a global standard. Under the circumstance, this meeting was held under the theme of "Globalization of regulatory science" with Dr. Tatsuya Kondo, Chief Executive, PMDA, as a head of the meeting.



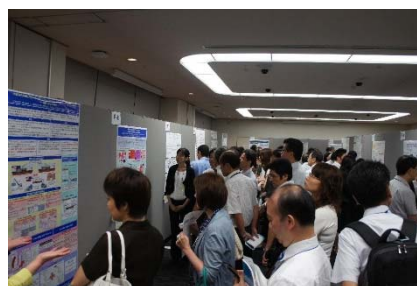
Dr. Kondo

In the special lecture, Dr. Kondo introduced PMDA's past efforts on operations and strategies for globalization. He explained that Japan is required to proactively carry out its responsibilities in the global fields, and emphasized the importance to rally wisdom to fulfill the responsibilities.

During the two-day meeting, 11 symposia were held under the themes such as globalization of regulatory science, trends of medical device software, paradigm shift in digital data submissions and review process, securing the quality of clinical studies, issues in conditional/time-limited authorization of cellular and tissue-based products, and so on. From PMDA, Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; Mr. Masanobu Yamada, Associate Center Director for New Drug Review; Mr. Yasunori Yoshida, Manager, Advanced Review with Electronic Data Promotion Group; Dr. Atsushi Tamura, Branch Chief, Kansai Branch; and Dr. Daisaku Sato, Director, the Office of Cellular and Tissue-based Products, participated as speakers. Total 500 healthcare professionals from industry, government and academia participated in the meeting and lively discussions were conducted.

Details of the 4th Meeting of Society for Regulatory Science of Medical Products is available at the following web site.

<http://www.srsm.or.jp/generalmeeting.html> (Japanese only)



From left, Hitotsubashi hall (venue), Lecture hall, Poster Session

## 2. GCRSR and GSRS2014 (August 21)

On August 21, the Global Coalition for Regulatory Science Research (GCRSR) and the Global Summit on Regulatory Science 2014 (GSRS2014) were held in Montreal, and Dr. Tetsuo Nagano, Executive Director and 2 staff members participated from PMDA.

GCRSR has been established in response to the call from Dr. Margaret A. Hamburg, Commissioner, US FDA, aiming to newly establish an international collaborative framework to enhance education, scientific trainings and information exchange in the field of regulatory science. In the meeting, activity status of existing topics such as "Exposure Assessment" was confirmed and the future direction of GCRSR was discussed.

In addition, GSRS2014 was held following GCRSR under the theme of "Regulatory Genomics and Beyond". Scientists from regulatory authority, industry and academia gathered for the GCRSR, and discussed utilization of Genomics in Regulatory Science. The staff member of PMDA made a presentation entitled "Pharmacogenomics and Regulatory Science in Japan" in the summit. The next GSRS is scheduled to be held in Italy in autumn, 2015.

## 3. The 16th ICDRA (August 24 to 29)

The 16th International Conference of Drug Regulatory Authorities (ICDRA) was held in Rio de Janeiro from August 24 to 29. Mr. Naoyuki Yasuda, former International Planning Director, Ministry of Health, Labour and Welfare (MHLW), and Dr. Taisuke Hojo, Senior Executive Director, Dr. Nobumasa Nakashima, former Director, Office of International Programs, and 2 staff members from PMDA, participated in the meeting. ICDRA is the meeting among pharmaceutical regulatory authorities organized by WHO, which has been held since 1980 to strengthen collaboration among regulatory agencies, to promote international regulations, and to prioritize activities in ICDRA.

In the 16th ICDRA, issues of regulatory system, safety measures, and guidelines on biotechnology and biosimilar were discussed at its pre-meeting (August 24 and 25), and the discussions on strengthening of regulatory system, ensuring safety of medical products, response to advanced technologies and international cooperation took place at its plenary meeting (August 26 to 29). Approximately 300 people from 100 WHO member nations participated, and opinions were actively exchanged during the meeting.

## 4. CIMDR (August 27 to 29)

China International Medical Device Regulatory Forum (CIMDR) was held in Amoy City from August 27 to 29, and PMDA staff members from the Office of International Programs, Office of GMP/QMS Inspection, and Office of Review Management, participated in the forum as speakers. CIMDR is a forum for pharmaceutical regulations of medical devices, held by China Center for Food and Drug International Exchange (CCFDIE), a suborganization of State Food and Drug Administration (SFDA). The forum is held every year, inviting speakers from regulatory authorities and industries in foreign countries to introduce regulations of medical devices in each country to Chinese industries. There were approximately 1,000 participants in the forum, and active discussion took place regarding the regulation of medical devices in each participating country. Next forum will be held in Guangzhou in September, 2015.

## 5. Director, Health Products and Food Branch, International Affairs Division, Health Canada, visits PMDA (September 1 to 4)

Ms. Louise Déry, Director, Health Products and Food Branch, International Affairs Division, Health Canada, visited PMDA from September 1 to 4. During her stay, PMDA staff members explained services of PMDA to Ms. Déry, such as outline of PMDA, international affairs, review of new drugs, review of generic drugs, clinical trial notification, science board, regulatory science, conformity inspection, and promotion of Information Technology.

Ms. Déry, on the other hand, gave a lecture to PMDA staff members regarding the organization and role in pharmaceutical regulations, and international activities of Health Canada.

After the lecture, young staff members inquired on their specialized areas, and deepened mutual understanding through an active discussion.

After the visit, Ms. Déry commented as follows. "The week at PMDA was very useful and well organized. I trust this will facilitate collaboration between PMDA and Health Products and Food Branch of Health Canada. I thank everyone in PMDA for making my visit a wonderful experience and for taking the time to meet me."



A Lecture from PMDA staff to Ms. Déry

## 6. PMDA provides training program to medical doctors from Jiangsu Province (September 2)

PMDA accepted fifteen medical doctors from Jiangsu Province on September 2, and provided them with a training program on reviews of pharmaceuticals, post-marketing safety measures, and relief funding for adverse health effects, etc. This training program was provided upon the request from Japan International Cooperation Center (JICE), a general incorporated foundation, based on the Memorandum of Understanding, regarding friendship and cooperation between JICE and Jiangsu People's Association for Friendship with Foreign Countries. This was the third training course following the first in 2012 and the second in 2013.



## 7. Director-President, ANVISA, visits PMDA (September 3)

Mr. Dirceu Bráz Barbano, Director-President, and Ana Paula S. Jucá S. Silva, Chief of the International Area, from Agência Nacional de Vigilância Sanitária (ANVISA), visited PMDA on September 3, and met with Dr. Tatsuya Kondo, Chief Executive, PMDA; Ms. Tomiko Tawaragi, Chief Safety Officer, PMDA; Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs, PMDA; Mr. Masanobu Yamada, Associate Center Director for New Drug Review, PMDA; Dr. Teruyoshi Ehara, Director, Office of International Programs, PMDA; and Dr. Nobumasa Nakashima, International Planning Director, MHLW. The meeting was held in the presence of Ms. Elaine Humphreys, First Secretary, Embassy of Brazil in Tokyo, and an official from the Ministry of Foreign Affairs.

In the meeting, follow-ups of the Japan-Brazil seminar on medical care regulations and bilateral meeting in São Paulo in last August, such as 1) Cooperation between Brazil and Japan, 2) Plan of the 2nd seminar, and 3) Personnel exchange, was discussed, and further collaboration of Brazil and Japan was confirmed.

After the meeting, Mr. Barbano gave a lecture on the role of ANVISA in the context of national health policies and an attitude as a regulator to PMDA staff members. Active discussion took place, and the participants deepened the understanding of pharmaceuticals regulation in Brazil and ANVISA's role.



Upper: from right, Mr. Barbano, Dr. Kondo, Ms. Silva  
Lower: A lecture by Mr. Barbano

## 8. US FDA official starts training at PMDA (September 3)

Mr. Andrew Durfor, from the Office of Compliance of US FDA, has started his training at PMDA from September 3, as a fellow of the 19th Mike Mansfield Fellowship Program. During the next 8-month training at PMDA, Mr. Durfor is scheduled to learn about the medical device regulations, Quality Management System (QMS) inspection, post-marketing safety measures and review systems, through the actual work of PMDA. After completing the program at PMDA, he will resume his training at MHLW until the end of July 2015.

Mr. Durfor commented as follows, "I am greatly enjoying my time here in PMDA. I came to learn about the Japanese regulatory culture, and the way in which limited resources were used to protect and promote the public health. I am definitely doing that, and trying to find common ground between FDA and PMDA to increase future cooperation and understanding."

## Safety Information

### Pharmaceuticals and Medical Devices Safety Information No.315, August 26, 2014

1. Safety Measures of New Drugs during the Early Post-marketing Phase
2. Important Safety Information
  - (1) Inchinkoto
  - (2) Simeprevir sodium
  - (3) teriparatide (Genetical Recombination)
  - (4) Loratadine
3. Revision of Precautions (No. 258)  
Paroxetine Hydrochloride Hydrate (and 3 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of August 2014)  
[http://www.pmda.go.jp/english/service/precautions\\_2014.html](http://www.pmda.go.jp/english/service/precautions_2014.html)

## Events

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

Date	Title	Location
September 27 -October 1	Regulatory Affairs Professionals Society (RAPS) Annual Meeting	Austin
October 6-10	The 5th PMDA Training Seminar (Pharmaceuticals)	Tokyo
October 15-16	The 2nd Thailand-Japan Symposium	Bangkok
October 31 -November 1	The 2nd Joint Conference of Taiwan and Japan on Medical Products Regulation	Tokyo
November 2-6	International Generic Drug Regulators Pilot (IGDRP)	Singapore
November 8-13	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)	Lisbon
November 12-13	Pharmacopoeial Discussion Group meeting (PDG)	Strasbourg
November 16-18	The 11th Annual Meeting Drug Information Association (DIA) Japan	Tokyo
November 18-21	Asia Harmonization Working Party (AHWP) Annual Meeting	Seoul
November 19-21	The 9th Summit of Heads of Medicines Regulatory Agencies	Beijing

## 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
Alabel/Alaglio	Aminolevulinic Acid Hydrochloride	September 12
Kadcyla	Trastuzumab Emtansine (genetical recombination)	September 25

## Reports from overseas

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

### Submission of PSUR single assessment for medicines authorized by EU member nations

EMA announced on its web site on 1st September that submission of single assessment Periodic Safety Update Report (PSUR) is also required for nationally authorised medicines. As for EMA, so far, single assessment PSUR had been requested for centrally authorised medicines until March 2013 and for medicines authorised in more than one Member State regardless of the types of approval since April 2013. Now the single assessment PSUR also applies to medicines, including nationally authorised ones, with data lock points (final day of PSUR reporting interval) falling on or after 1st September 2014. Meanwhile, for those medicines not listed in EU reference dates (EURDs), the assessment of the PSUR will remain at national level.

EMA will start single assessment procedures for all concerned medicines from October 2014. The Agency uses the information in PSUR to determine if there are new risks identified for medicines or whether the balance of benefits and risks of a medicine has changed, and decides if further investigations need to be carried out to take actions to protect the public from the risks identified such as updating the information provided for healthcare professionals and patients.

Marketing authorisation holders (MAHs) have been required to pay a fee for assessment of PSURs through this procedure as of 26th August 2014. This is derived from the concept that fees of pharmacovigilance actions at EU level should be paid by the MAHs, based on the EU regulation (No 658/2014) set in June 2014. EMA plans to publish guidance on the fees and we need to pay attention to this issue.

The detailed information as of 1st September with regard to the submission of PSUR is:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2014/08/news\\_detail\\_002160.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/08/news_detail_002160.jsp&mid=WC0b01ac058004d5c1)

For fees of safety actions is as a web site below:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2014/06/news\\_detail\\_002132.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002132.jsp&mid=WC0b01ac058004d5c1)

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

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## Knowledge transfer – a proactive way of transforming knowledge into benefits

Not only qualified health care professional such as pharmacists, medical doctors, dentists, veterinarians and also IT experts, engineering experts, etc., a variety of different knowledge will support the work of the regulatory authorities. If you know who has what kind of knowledge, you will be able to leverage it in the business of your own.

Since October, 2013, Swissmedic has been actively involved in the "Knowledge management" Community of Practice (CoP). "Knowledge management" is the method of management, aiming effective works by sharing and clarifying individual's knowledge. One representative from each sector of Swissmedic provides support, from their own perspectives, practical knowledge management in the institute. The members of the CoP meet monthly in order to share experiences, discuss ideas and issues from the front line, and to implement knowledge management initiatives. The Swissmedic Knowledge Management CoP develops competencies, and brings the latest developments into the organisational structure. Results are noted, and issues requiring management decisions are forwarded to the competent unit in the reporting line. Reports are submitted to its management on a twice-yearly basis.

In order to highlight best practices with CoP in the organisation and thus to provide employees with simple tips and tricks for managing and transferring knowledge, the CoP organised the first so-called "Knowledge Management Fair" (WiMaMe) in August, 2014. During a lunch break, topics relating to knowledge management issues were made accessible by means of an informal exchange such as presentation by the staff members and interactive exhibition among participants. In addition to reflections regarding the handling of knowledge, WiMaMe also fostered informal exchange among the participants.

All participants were asked to write their specialty and it was posted on the wall to share the knowledge. The feats varied from ordinary things like "I can make fine pastries without recipe" to highly specialized "In utero electroporation of mice". I wrote "I can speak Japanese." since no one else in Swissmedic could speak Japanese as fluently as me!

I learned that knowledge transfer is a proactive way of transforming knowledge into benefits, and contributes towards improved understanding and cohesion within an institution. If PMDA could arrange the opportunity for knowledge transfer, and share the knowledge of individuals to transfer to benefits, it would promote each operation and activate communication among sections.

Dr. Jun Kitahara  
PMDA's International Liaison Officer stationed at Swissmedic in the Switzerland

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