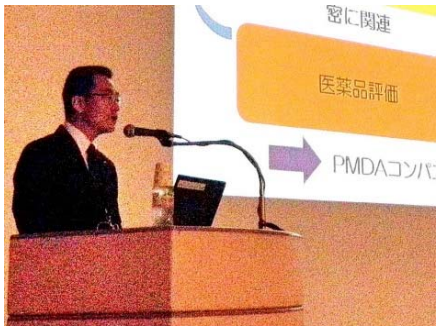
Callicarpa japonica

PMDA Updates

October, 2014

News

1. PMDA Workshop "Companion Diagnostics (CoDx) - regulatory perspective and challenges on development and evaluation - " (September 1)



Dr. Yamori

On September 1, PMDA Workshop "Companion Diagnostics (CoDx) – regulatory perspective and challenges on development and evaluation" hosted by the Companion Diagnostics project team in PMDA was held in Tokyo, and Dr. Takao Yamori, Director of Center for Product Evaluation, Mr. Takeyuki Sato, Associate Executive Director, Dr. Mayumi Shikano, Associate Center Director, and many staff members from PMDA participated in the workshop. In response to the Administrative Notice, "Technical Guidance on Development of In Vitro Companion Diagnostics and Corresponding Therapeutic Products", issued on December 26, 2013, this workshop was held in order to promote further efficient development and review in the future by exchanging views among industry, academia and government based on the specific development cases as well as showing contents and backgrounds of notice and technical guidance relevant to CoDx, etc. and points to consider in their development. A total of 428 people from industry/academia/government including 296 participants from pharmaceutical and diagnostic agent industries, participated in the workshop, and had a very active exchange of views on cooperation among stakeholders in CoDx development, on "me-too" CoDx development, and on future challenges including emerging diagnostic methods such as next generation sequencing, etc.

Please refer to the following web site for more information on this workshop.
http://www.pmda.go.jp/english/service/in_vitro_e.html (English)
http://www.pmda.go.jp/operations/shonin/info/report/workshop20140901.html (Japanese)

2. The 6th IMDRF Management Committee Meeting (September 16 to 18)

The 6th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting was held in Washington D.C. from September 16 to 18, and Dr. Toshiyoshi Tominaga, Associate Executive Director, and two staff members from Office of International Programs, as well as one member from the Ministry of Health, Labour and Welfare (MHLW), participated in the meeting. Closed sessions exclusively for regulators and officially invited observers, and an open session with stakeholders including industry were held, and progress of working items, such as Regulated Product Submission, Medical Device Single Audit Program, and Software as a Medical Device were reported and discussed. In addition, new working items were discussed, and the new working group for Medical Device Patient Registries was formally approved. In 2015, Japan will be the chair country of IMDRF MC and host semiannual MC meetings in Tokyo and Kyoto.

The workshop on the internationally recognized standards was held along with IMDRF, hosted by International Congress of Diagnostic Imaging and Therapy Systems Trade Association (DITTA). Two staff members from Office of International Programs participated in the workshop, and delivered a presentation on the current utilization of international standards in Japan, and served as moderators in individual sessions and panel discussions. Further, Dr. Yuka Suzuki, Director, Office of Medical Devices II, participated in the Global Harmonization Summit hosted by Advanced Medical Technology Association on September 18 and 19, and delivered a presentation on the activities of Harmonization by Doing (HBD).

Please refer to the following web site for the details of the IMDRF MC Meeting.
http://www.imdrf.org/meetings/meetings.asp

3. Kazakhstan Forum of World Pharmacopoeias (September 18 to 19)

From September 18 to 19, Kazakhstan Forum of World Pharmacopoeias, hosted by Ministry of Health and Social Development of the Republic of Kazakhstan, was held in Almaty. Two staff members from the Office of Standards and Guidelines Development, PMDA, participated in the forum as representatives of Japanese Pharmacopeia (JP), and delivered a lecture and took part in a panel discussion. This forum was held in commemoration of the newly published third edition of Kazakhstan Pharmacopoeia. The representatives of Pharmacopoeias from various nations and over 150 general public participated, and proactive discussion took place on necessity of establishment of a cooperative platform among pharmacopoeias and international harmonization of pharmacopoeias. The participation to the Kazakhstan Forum is a part of the international activities contributing to "Globalization of JP" stated in Road Map for the PMDA International Vision, and was a valuable opportunity to introduce JP to foreign countries.

4. Japan-US HBD West 2014 Think Tank Meeting (September 19)

The HBD West 2014 Think Tank Meeting, the meeting for reporting the activities of HBD, was held in Washington D.C. on September 19. Ms. Tomiko Tawaragi, Chief Safety Officer; Dr. Toshiyoshi Tominaga, Associate Executive Director; Dr. Yuka Suzuki, Office Director of Office of Medical Devices II, and 4 staff members collectively from Office of Safety I, Office of Medical Devices I, and Office of Office of International Programs, participated in the meeting. The meeting was held under the theme of "HBD Past, Present, Future", and a panel discussion under the theme of "Outlook of Bi-lateral Collaboration in Light of Multi-lateral Collaboration", inviting the original members at the start of HBD as panelists, as well as progress reports from each working group, were presented. Approximately 70 people participated in the meeting and active discussion took place. Next meeting will be held in September, 2015, in Kyoto.

Please refer to the following web site for the details of HBD.
http://www.jfmda.gr.jp/hbd/e/index.html

5. CEO of United States Pharmacopeia visits PMDA (September 24)

On September 24, Dr. Ronald Piervincenzi, Chief Executive Officer of United States Pharmacopeia (USP), who has assumed the position in last February, visited PMDA to pay a courtesy call on Dr. Tatsuya Kondo, Chief Executive; Dr. Taisuke Hojo, Senior Executive Director; Dr. Kazuhiro Shigetoh, Executive Director; Dr, Tetsuo Nagano, Executive Director; Mr. Tetsuo Yoshioka, Deputy Executive Director; Dr. Toshiyoshi Tominaga, Associate Executive Director; and Mr. Teruyoshi Ehara, Director, Office of International Programs, and had a meeting with executives who are in charge of the Japanese Pharmacopoeia (JP) including Dr. Takao Yamori, Director of Center for Product Evaluation; Dr. Mayumi Shikano, Associate Center Director; and Dr. Seiko Miyazaki, Director, Office of Standards and Guidelines Development. In the meeting, opinions were actively exchanged concerning the situation of on-going project between PMDA (secretariat of JP) and USP, and future cooperative projects between the two authorities. Dr. Piervincenzi delivered a special lecture entitled "Pharmacopeial Harmonization" to PMDA staff members and mutual understanding was deepened through proactive discussion after his lecture. On the same day, Dr. Piervincenzi also paid courtesy visits to the organization related to JP, including the National Institute of Health Sciences,MHLW, and Pharmaceutical and Medical Device Regulatory Science Society of Japan. He deepened understanding regarding the structure of JP organization and opinions were exchanged on future collaboration between JP and USP.

6. Vice Minister, Ministry of Health, Vietnam, calls on PMDA and PMDA's training program provided (September 25)

On September 25, Dr. Nguyen Thanh Long, Vice Minister, Ministry of Health, Vietnam, and the 11 staff members, and Dr. Kohei Toda, Medical Officer for EPI, country office for Vietnam, WHO, paid a call on Dr. Tatsuya Kondo, Chief Executive; Dr. Kazuhiro Shigetoh, Executive Director; Ms. Tomiko Tawaragi, Chief Sefety Officer; Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; Mr. Teruyoshi Ehara, Director, Office of International Programs, and others.

Dr. Nguyen Thanh Long expressed his mission to learn established vaccination system in Japan in order to reflect it to future policy in Vietnam. Dr. Kondo assured PMDA's cooperation by giving information and sharing experience on the vaccination system in Japan.

After the call, staff members from the offices of PMDA including Office of International Programs, Office of Vaccines and Blood Products, Office of Safety II, Office of GMP/QMS Inspection, and Office of Relief Funds, provided presentations to the Vietnamese delegation on 1) Outline of PMDA, 2) Review of vaccines, 3) Post-marketing safety measures of vaccines, 4) Quality control and GMP inspection of vaccines, and the participants actively exchanged their views in the discussion session.

7. The delegation of Ministry of Public Health, Thailand, visits PMDA (September 26)

A delegation representing Department of Medical Sciences, Ministry of Public Health, Thailand, which manages Thai Pharmacopoeia, made a courtesy call on Dr. Tatsuya Kondo, Chief Executive; Dr. Taisuke Hojo, Senior Executive Director; Dr. Tetsuo Nagano, Executive Director; Dr. Toshiyoshi Tominaga, Associate Executive Director; Dr. Mayumi Shikano, Associate Center Director; Dr. Seiko Miyazaki, Director, Office of Standards and Guidelines Development; and Mr. Teruyoshi Ehara, Director, Office of International Programs. The delegation consisted of Deputy Director Generals, Dr. Wanchai Sattayawuthipong and Dr. Varunee Jinaratana, and 9 staff members. PMDA staff members explained PMDA's organization and activities, outlines of JP and Japanese regulatory affairs to the delegation and answered the questions from them. In addition, in the course of opinion exchange on specific future cooperation plans between JP and Thai Pharmacopoeia, contact points of both parties were set up and agreed on having a bilateral meeting in October in Bangkok.

8. RAPS 2014 (September 27 to October 1)

The Regulatory Affairs Professionals Society (RAPS) 2014 annual conference and associated workshops were held in Austin, Texas, from September 27 to October 1. Dr. Takao Yamori, Director of Center for Product Evaluation; 10 staff members collectively from Office of International Programs, Office of Medical Devices I, Office of Medical Devices III, Office of GMP/QMS Inspection, and Office of Safety I; and a staff member from MHLW, participated in the meeting.

On September 28, Japan Workshop was held whole day. The workshop was chaired by staff members of Office of International Programs, and presenters from regulatory authorities including 4 staff members from PMDA and from industry delivered presentations on the current situations of revised Pharmaceutical Affairs Act, regulatory and industry efforts toward the revise, challenges in the global clinical trials, and regulations for regenerative medicines, etc. On September 30, plenary session was held. In the session entitled "What's New in Japanese MD/IVD Regulation", Dr. Yamori and representatives from MHLW and industry delivered presentations on the update of the third Mid-term Plan of PMDA, overview of revised Pharmaceutical Affairs Act, and current efforts of industry to cope with the revision, respectively. In addtion, Dr. Yamori participated in the session entitled "Regulatory Science: How the Science is Applied to Practice?" held on the same day togetherwith officials from FDA and EMA. Dr. Yamori introduced regulatory efforts on the application of regulatory science in the pharmaceutical administration in Japan. There were about a hundred audience both in the workshop and in the plenary session, and active discussions took place. PMDA ran an exhibition booth for the second year in a row at the exhibition hall, and welcomed about 250 visitors. There was an active communication among PMDA staff members and visitors to promote 1) the publicity of Japanese pharmaceutical affairs regulations, 2) recognition of PMDA, 3) reliability of Japanese pharmaceuticals and medical devices, as well as of review and post-marketing safety measures operation at PMDA.

Upper: 1st from left, Dr. Yamori
Lower: PMDA booth

The next RAPS annual conference will be held in Baltimore, Maryland, from October 24 to 28, 2015.

Please refer to the following web site for the details of RAPS 2014.

http://connect.raps.org/2014raps/2014raps-home/

9. PMDA officer dispatched to CDER, U.S.FDA (October 1)

On October 1, PMDA sent Ms. Shohko Sekine, Regulatory Cooperation Officer, Office of International Programs (concurrently positioned in Office of Safety II), to the Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), U.S. FDA. She will take part in various projects related to safety measures for pharmaceuticals in OSE. She will also provide information on post-marketing safety measures in Japan to CDER. The term of the dispatch is for one year.

10. The 2nd Thailand-Japan Symposium (October 15 to 16) and Thai FDA-PMDA bilateral meeting (October 17)

The 2nd Thailand-Japan Symposium was held in Bangkok from October 15 to 16, co-hosted by Thai Food and Drug Administration (Thai FDA) and PMDA. From PMDA, Dr. Kazuhiro Shigeto, Executive Director; Dr. Mayumi Shikano, Associate Center Director; Mr. Kaoru Misawa, International Coordination Officer for Pharmaceuticals; staff members from Office of GMP/QMS inspection, Office of Safety I and Office of International Programs, 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. In the symposium, presentations were delivered by staff members from Thai FDA and PMDA under the theme of new drug review, GMP inspection and post-marketing safety measures of pharmaceuticals.

Left: from left, Dr. Shigeto, Dr. Somboonsook, Dr. Sawanpanyalert
Right: Dr. Shigeto

In addition, a bilateral meeting between Thai FDA and PMDA was held in Bangkok on October 17, and promotion of continued collaboration in the field of pharmaceuticals regulation was confirmed.

The details of the symposium are available at following web site.
http://www.pmda.go.jp/english/events/2014thailand_sympo.html

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.316, September 30, 2014

1. Project of Japan Drug Information Institute in Pregnancy
2. Effects of Angiotensin II Receptor Blockers and Angiotensin Converting Enzyme Inhibitors on Pregnant Women and Foetuses
3. Revision of Precautions (No. 259)
   (1) Pramipexole Hydrochloride Hydrate (and 9 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of September 2014)

http://www.pmda.go.jp/english/service/precautions_2014.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
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 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

Reports from overseas

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

Publication of clinical trial data

Publication of clinical trial data was covered in the letters from the liaison officers three times so far in December 2012, May 2013 and June 2014. EMA Management Board in June 2014 on 2nd October again discussed this issue and reached to the final decision.

The policy will apply to clinical reports contained in applications for centralised marketing authorisations submitted after 1st January 2015. The publication will be implemented through a stepwise approach and as a first phase publication of clinical overview, clinical summary, clinical study reports, and appendices (protocol and its amendments, sample case report form, and documentation of statistical methods) will start in January 2015. In future, EMA plans to explore publication of individual patient data as a second phase. EMA will consult patients, healthcare professionals, academia and industry with regard to legal and technical issues linked with the access to patient data. At the same time, it is critically important for EMA that the privacy of patients is adequately protected.

EMA expects the policy to increase trust in its regulatory work as it will allow the general public to better understand the Agency's decision-making. In addition, academics and researchers will be able to re-assess data sets, which could lead to avoidance of duplication of clinical trials and contribute to development of new medicines. The policy will be reviewed in June 2016 at the latest. We need to continue to pay attention to this issue including its implementation from next year.

The information of publication of clinical trial data as of 2nd October 2014 is:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500174378.pdf

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

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The 50th Anniversary of EDQM

Quality standard for active substance and excipients of pharmaceuticals are described in pharmacopoeia. It serves as keeping the quality and thereby contributing to secure the safety and the effectiveness of pharmaceuticals. Although each country has own pharmacopeia, consolidated pharmacopeia was made by the European Directorate for the Quality of Medicines and Healthcare (EDQM) in Europe.

In Switzerland, the Pharmacopoeia consists of the European Pharmacopoeia (Pharmacopoeia Europaea; Ph. Eur.) and the Swiss Pharmacopoeia (Pharmacopoeia Helvetica; Ph. Helv.) Ph. Helv. includes description of pharmaceuticals which are available only in Switzerland, and Ph. Helv. is used to complement Ph. Eur. Ph. Helv. is often used as reference draft of Ph. Eur., and once the description of a certain substance/excipient is added in Ph. Eur., the same description is deleted from Ph. Helv.

Currently, as much as 37 countries are supporting as members for editing Ph.Eur. Switzerland is one of the seven founding member countries of the Ph. Eur. when it was decided to compile pharmacopoeia 50 years ago. Since then, continuous contribution has been committed by Switzerland. In addition, Switzerland is a member of the Official Medicines Control Laboratories (OMCL) network which performs quality control of marketed pharmaceuticals in Europe which is one of the activities of EDQM. You will find the activities on Swissmedic web site. Because of the above mentioned relationship between Switzerland and EDQM, exhibition of posters, etc., introducing the activities of EDQM was carried out in Swissmedic in May, 2014, to celebrate 50th anniversary of EDQM. The year 2014 is the 50th anniversary of EDQM as well as the 20th anniversary of OMCL. To celebrate the anniversary year, international meeting was held from October 6th to 8th at Strasbourg, France. Swissmedic also contributed to the meeting by sending presenters and moderators. Thus, the organizations are operating under the close cooperative relationship to contribute to each other's activities.

On the other hand, Japan also proactively contributes to the activities of Pharmacopoeias in other countries. For example, this year, representatives from secretariat of JP (including PMDA staff members as representatives of JP committee) participated in the 3rd International Meeting of World Pharmacopoeias hosted by Medicines and Healthcare Products Regulatory Agency (MHRA) in London on April 10 and 11. Also, when the adverse health effect caused by heparin contaminated with impurities occurred in 2008, the organizations in Europe, the United States and Japan worked in collaboration to describe a new test method of heparin in each pharmacopeia.

Nowadays, manufacture and distribution of pharmaceuticals are increasingly globalized. Accordingly, the harmonization of Pharmacopoeias is growing its importance and the international activities toward the harmonization have been continued among Ph. Eur., USP and JP. The pharmacopeias are used as domestic standards, but in some cases, it is used as reference standards in other countries. Under such circumstance, further collaborative activities among organizations of the pharmacopeias are increasingly required. I would like to work for promoting further cooperation among JP, Ph. Eur. and Ph. Helv. in my dispatch period.

For the details of the 50th Anniversary of international meeting of EDQM and its related activities of Swissmedic, please refer to the following web sites.

https://www.edqm.eu/en/Conference-50th-Anniversary-of-the-EDQM-1617.html
https://www.swissmedic.ch/ueber/00134/00590/00591/02387/index.html?lang=en

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

