



Helianthus annuus

PMDA Updates

August, 2014

News

1. The Japan-Brazil seminar on medical care regulations, joined by Prime Minister Abe (August 2)

On August 2, the Japan-Brazil seminar on medical care regulations, an open seminar to the public, co-hosted by PMDA, the National Health Surveillance Agency (ANVISA), the Japan External Trade Organization (JETRO), and Japanese-Brazilian Charity Organization of São Paulo (ENKYO), was held in São Paulo.

The Japanese government is promoting international cooperation in the medical and insurance field with the major foreign countries, and Shinzo Abe, the Prime Minister of Japan, participated in the meeting to make a special speech. Many experts from the regulatory authorities and industries participated in the meeting, including Dr. Tatsuya Kondo, Chief Executive; Ms. Tomiko Tawaragi, Chief Safety Officer; Mr. Masanobu Yamada, Associate Center Director for New Drug; Dr. Mayumi Shikano, Associate Center Director for Advanced Review with Electronic Data Promotion and Science Board; Dr. Nobumasa Nakashima, Director, Office of International Programs, from PMDA, and Dr. Dirceu Brás Aparecido Barbano, President Director, from ANVISA.

The Seminar consisted of the following topics: 1) Brazil/Japan update and future collaboration in medical field, 2) Efficiency of product review on medical devices and pharmaceuticals, 3) Topics from pharmaceutical industries, 4) Medical devices/pharmaceuticals inspection on manufacturing and quality control standards, 5) Topics from medical devices industries, 6) Pharmacopoeia, and active discussions took place by more than 300 participants. Continued cooperation between Japan and Brazil is anticipated in the future.

On August 3 and 4, a bilateral meeting between ANVISA and MHLW/PMDA was held. In the meeting, specific areas and direction of the cooperation were discussed, and promotion of the cooperative works between both regulatory agencies was agreed.

For the details of the Japan-Brazil seminar on medical care regulations, see following PDF file.

<http://www.pmda.go.jp/kokusai/file/seminar20140714.pdf>



From left, Prime Minister Abe, Dr. Kondo, group photo

2. The 8th ICCR Meeting (July 8 to 10)

The 8th International Cooperation on Cosmetics Regulations (ICCR) Meeting was held in Ottawa, from July 8 to 10. Two staff members each from Ministry of Health, Labour and Welfare (MHLW), and the Office of OTC/Generic Drugs, PMDA, participated in the meeting. ICCR is a voluntary international group consisting of cosmetics regulatory authorities from Japan, Canada, EU, and the US, discussing the safety and regulation of cosmetics. In the meeting, active discussions took place on allergens, *in silico* approaches for safety assessment of cosmetic ingredients, alternatives to animal testing, traces, and microbial contaminants, etc., as main topics.

Next ICCR Meeting will be held in Rome, in 2015.

Press statement of the 8th ICCR Meeting are available at the following web sites.

http://www.iccrnet.org/files/4114/0603/8824/press_statement_iccr8_en.pdf

www.iccrnet.org (ICCR official web site)

3. CVIT 2014 HBD Town Hall Meeting (July 26)

Six PMDA members, including Dr. Yuka Suzuki, Director, Office of Medical Devices II, participated in the Harmonization By Doing (HBD) Town Hall Meeting held in Nagoya on July 26, in conjunction with the 23rd Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics Meeting (CVIT 2014). In this session, presentations were given on the experience obtained from the global clinical trial through 10 years of HBD's activities, the on-going clinical trials, the approach for transcatheter aortic valve implantation (TAVI) post-marketing registry by academia and regulators of both the US and Japan, and the evaluation of medical devices for the treatment of Critical Limb Ischemia (CLI), followed by active discussions.

HBD Steering Committee is planning to hold HBD West 2014 Think Tank Meeting on September 19 in Washington D.C.

4. APEC-LSIF-RHSC (August 13 to 16)

APEC- Life Science Innovation Forum (LSIF) Regulatory Harmonization Steering Committee (RHSC) Meeting was held in Beijing from August 13 to 16, and Mr. Naoyuki Yasuda, International Planning Director, MHLW, and a staff member from the Office of International Programs, PMDA, participated in the meeting.

RHSC Meeting aims for "Promotion of the strategic framework for the convergence of medical products regulation." There are 9 working areas, including Multi-Regional Clinical Trials in which Japan plays its leadership role, Good Clinical Practice inspection, Good Review/Submission Practice, Cell Therapy, and Pharmacovigilance, and the progress of each working area was explained. Furthermore, future operations, such as proactive participation from academia were discussed, based on opinions including requests to RHSC from industries.

Next APEC-LISF RHSC Meeting will be held in Philippines, in January to February, 2015.

5. Call for application to the 5th PMDA Training Seminar starts

PMDA will hold the 5th PMDA Training Seminar for officials of foreign regulatory agencies from October 6 to 10, 2014. In this seminar, the outline of PMDA's operations and the current status regarding review of new drugs, including biopharmaceuticals and cellular and tissue-based products, will be addressed. In addition, group work on case studies is scheduled in the program.

For the details of the 5th PMDA Training Seminar, see following web site.

http://www.pmda.go.jp/english/seminar/5th_pmda_training_seminar.html

6. The Second Thailand-Japan Symposium

The Second Thailand-Japan Symposium will be held in Bangkok, from October 15 to 16, 2014. The event will be co-hosted by PMDA and the Thai Food and Drug Administration (ThaiFDA). This symposium aims to promote better understanding of both regulatory systems among the regulatory agencies and pharmaceutical industries of Thailand and Japan, thereby contributing to enhance mutual cooperation and drug development in the two countries. Sessions will be held under the themes of New Drug Review, GMP Inspection, and Pharmacovigilance.

For the details of the symposium, see following web site (Available from September 1).

http://www.pmda.go.jp/english/events/2014thailand_sympto.html

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.314, July 29, 2014

1. Revision of Report Form in Drugs and Medical Devices Safety Information Reporting System
2. Revision of Precautions (No. 257)
azilsartan and 7 others
3. List of Products Subject to Early Post-marketing Phase Vigilance (as of July 2014)

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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
August 24-29	International Conference of Drug Regulatory Authorities (ICDRA)	Rio de Janeiro
August 26-29	China International Medical Device Regulatory Forum (CIMDR)	Amoy
September 16-18	International Medical Device Regulators Forum (IMDRF)	Washington D.C.
September 19	US-Japan HBD West 2014 Think Tank Meeting	Washington D.C.
September 27 -October 1	Regulatory Affairs Professionals Society (RAPS) Annual Meeting	Austin
October 6-10	5th PMDA Training Seminar (Pharmaceuticals)	Tokyo
October 15-16	The Second Thailand-Japan Symposium	Bangkok

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
Sovriad	Simeprevir Sodium	August 4

Reports from overseas

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

Public comments on draft rules of procedures on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC)

Recently, EMA launched a public consultation on “draft rules of procedures on the organisation and conduct of public hearings at the PRAC” on the EMA website. The PRAC discusses the necessity of holding a public hearing for each pharmaceutical product under review, from the standpoint of the extent of safety concern, level of public interest, etc. The primary purpose of a public hearing is to hear the views of public on the acceptability of the risks associated with pharmaceutical products concerned, while comparing their therapeutic effects with those of their alternative ones, as well as to receive advices concerning the risk management and minimisation activities. The PRAC conducts further discussions on the safety of medicines referring to those views and advices.

The public hearing is open to the public and all participants are required for registration beforehand. The PRAC invites stakeholders such as representatives of patients, consumers, healthcare professionals and researchers. In addition, the marketing authorisation holders of the pharmaceutical products under discussion have the opportunity to present their views in the public hearing. The outline of discussions at public hearings, list of participants, applications pertaining to Conflict of Interest and submitted materials, etc., will be published on EMA website after the public hearing.

By holding public hearings, not only the regulatory authority hears the opinions of stakeholders such as patients and healthcare professionals, but also patients themselves can deepen their understandings on efficacy and safety of medicines as well, which could lead to expecting merits such as steady implementation and improvement of risk management and minimisation activities. EMA is inviting public comments on the public hearings through its website by October 15, 2014. If you have interests in this topic, how about sending EMA your comments?

The detailed information of the draft rules on procedures for public hearings is shown in the following website.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/07/news_detail_00214_6.jsp&mid=WC0b01ac058004d5c1

Mr. Yoshihiko Sano

PMDA's International Liaison Officer stationed at EMA in the United Kingdom

Program committee meeting for next DIA Euro

As a part of PMDA International Strategic Plan, PMDA is actively participating in meetings such as Drug Information Association (DIA) and Regulatory Affairs Professionals Society (RAPS) and organizing sessions and having exhibition booth for the purposes of promoting Regulatory Science, gaining PMDA's recognition and also increasing the quality level of its review, etc.

Program Committee (PC) meeting for DIA Euro 2015 was held at Paris the other day. In addition to work as an international liaison officer at Swissmedic, my mission here includes to cover pharmaceuticals related matters in whole Europe such as participating this PC meeting.

“Innovation” is the main theme for DIA Euro 2015 which will be held in Paris next spring, PC's task is how to construct program which draw audience's attention and also make them satisfied. Purpose of this PC meeting was to brush up draft program by discussing with other members of PC. Each theme leader of 12 themes which were created at previous PC meeting brought their ideas about configuration of sessions. About 20 members including secretariat from all over European countries had very productive discussions. I, as only one program committee member from Japan, did my best to configure program while considering continuous effort of PMDA for DIA such as organizing Asian session and PMDA town hall and also to include PMDA's recent effort to introduce innovative product for the world such as Science Committee with the idea to involve next year's theme. All members of the program committee will strive to live up to the expectations of everyone. Please keep updated.

Dr. Jun Kitahara

PMDA's International Liaison Officer stationed at Swissmedic in the Switzerland

