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PMDA Updates

April, 2014

News

1. The fourth PMDA Advisory Council Meeting of fiscal year 2013 (March 14)

On March 14, the fourth PMDA's Advisory Council meeting, the last meeting for the fiscal year 2013, was held. This Advisory Council has been established as a place for exchanging opinions broadly on PMDA's operations with external qualified members who are stakeholders of drugs and medical devices, including academic experts, healthcare professionals, representatives from relevant industries, consumer representatives, and representatives of people who have suffered from adverse health effects caused by drugs. Since the fiscal year 2013 fell under the last targeted year of PMDA's Second 5-year Mid-Term Plan, the members have looked back on the year-round PMDA's operations along with the plan and lively exchanged opinions toward the development of next 5-year Mid-Term Plan. The PMDA's Third 5- year Mid-Term Plan reflecting the opinions in this meeting has been released on PMDA web site.

http://www.pmda.go.jp/guide/jyohokokai/kohyo.html#keikaku (Japanese text only)

2. DIA 26th Annual EuroMeeting (March 25 to 27)

Dr. Tatsuya Kondo, Chief Executive, and total 11 delegates including 7 chair/speakers from PMDA attended the DIA 26th Annual EuroMeeting held in Vienna from March 25 to 27. In the PMDA Update session chaired by Dr. Nobumasa Nakashima, Director, Office of International Program, PMDA's performance was updated as follows. 1) Dr. Kondo explained about PMDA's holistic operations focusing on the Amendment of Pharmaceutical Affairs Act and PMDA's Third 5-year Mid-Term Plan under the enforcement of the Amendment, 2) Dr. Takao Yamori, Director of Center for Product Evaluation, explained PMDA's challenges on its review including Pharmaceutical Affairs Consultation on R&D Strategy and the Science Board, and 3) Mr. Hiroshi Yamamoto, Chief Safety Officer, explained Safety Measures with a focus on the Risk Management Plan. In the "Current Status and Future Challenges of Asian Regulatory Environment" session chaired by Dr. Nakashima, Mr. Yamamoto delivered a speech representing PMDA, and representatives from regulatory agencies of China, Korea, and Thailand delivered speeches. In addition, other speakers from PMDA proactively transmitted information from PMDA, such as 1) reinforcement of cooperation with overseas regulatory authorities, 2) Quality by Design approach and its review, and 3) initiatives and challenge for creating innovative drugs. About 70 and 100 people came to PMDA Update session and Asian Regulatory Environment session, respectively, and lively exchanged their views between the audience and the speakers.

From left: Venue of DIA EuroMeeting, PMDA Updates session, Asian Regulatory Environment session, Booth of PMDA

3. The 5th IMDRF Management Committee Meeting (March 25 to 27)

Three members including Mr. Nobuo Uemura, the International Coordination Officer for Medical Devices, and one staff member each from PMDA and Ministry of Health, Labour and Welfare (MHLW) attended the 5th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting held in San Francisco from March 25 to 27. The first and the third days were closed sessions exclusively for regulators and officially invited observers, while the second day was the open session inviting stakeholders including industry. Each working group reported and discussed progress of working items, etc. On March 24, prior to the IMDRF MC Meeting, Medical Device Epidemiology Network Initiative (MDEpiNet) Think Tank session entitled "Regulatory Science & Sustainable Implementation of National & International Medical Device Registries"

hosted by FDA was held to discuss the potential new work item for IMDRF. Mr. Uemura and two other staff members from PMDA participated in the session as panelists. The next IMDRF MC Meeting is scheduled from September 16 to 18, 2014 in Washington D.C. In 2015, Japan will be a chair country of IMDRF MC and semi-annual MC meetings will be held in Japan.

The report of the IMDRF meeting is available at the following PDF file.

http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-140327-sanfran-outcome-statement.pdf

4. The 63rd ACC Annual Meeting (March 29 to 31)

Mr. Nobuo Uemura, the International Coordination Officer and two staff members from PMDA attended the 63rd Annual Meeting of American College of Cardiology (ACC) held in Washington D.C. from March 29 to 31. On March 30, Mr. Uemura, and staff joined the session entitled "Device Approval Processes Around the World: Which is better?" as a presenter and as a panelist, and gave a presentation. Representatives from Japan, the US, Brazil, and India introduced medical device regulations in their own countries in this session and panel discussion was conducted subsequently. There were about 50 participants and the active discussion took place.

5. Special training given by Director, Division of Ophthalmic, Ear, Nose and Throat Devices, FDA (April 2)

On April 2, Dr. Malvina B. Eydelman, M.D., Director, Division of Ophthalmic, Ear, Nose and Throat Devices, Center for Devices and Radiological Health, FDA, visited PMDA and gave the special training intended for PMDA staff members, which was entitled "Regulations of Ophthalmic Products in the United States of America". In the training, Dr. Eydelman explained product application, review standards, and guidance for ophthalmic products in FDA. All the participants gained a further understanding of FDA's regulations.

From left, Ms. Tawaragi (Associate Executive Director), Dr. Kondo (Chief Executive), Dr. Eydelman, Dr. Sugawara (Principal Reviewer, Office of Medical Devices II), Dr. Suzuki (Director, Office of Medical Devices II).

6. Secretary – General of Thai FDA visits PMDA (April 9)

On April 9, Dr. Boonchai Somboonsook, Secretary – General of Thai FDA, and Mrs. Prapassorn Thanaphollert, Acting Director, Bureau of Drug Control of Thai FDA, visited PMDA and met Dr. Tatsuya Kondo, Chief Executive; Dr. Taisuke Hojo, Senior Executive Director; Dr. Kazuhiro Shigetoh, Executive Director; Mr. Masaki Matsuoka, Deputy Executive Director; Mr. Yasunori Yoshida, Director of Office of Review Management, and Dr. Nobumasa Nakashima, Director of Office of International Programs. In the meeting, regulatory administration in Thailand and current PMDA's activities were explained by Thai FDA and PMDA, respectively. Dr. Somboonsook showed keen interests especially in i) the purpose of establishing PMDA, ii) the policy and management system, iii) the organizational structure and cooperation among departments, iv) the electronic applications and IT system, v) the review system, vi) the regulatory science. The discussions were lively continued more than estimated time for the meeting. Thailand and Japan have been working on holding joint symposium and bilateral cooperative programs. The both parties confirmed again to pursue further cooperative relationships in the future.

Left: From left, Dr. Nakashima, Mr. Matsuoka, Dr. Hojo, Dr. Somboonsook, Dr. Kondo, Mrs. Thanaphollert, Dr. Shigetoh and Mr. Yoshida, Right: From left, Dr. Somboonsook, Dr. Kondo

7. Director of DAV visits PMDA (April 9)

Dr. Truond Quoc Coung, Director, and Mr. Chu Dang Trung, Head of Department of Drug Evaluation and Licensing, Drug Administration of Vietnam (DAV), visited PMDA on April 9 and met Dr. Tatsuya Kondo, Chief Executive; Dr. Taisuke Hojo, Senior Executive Director; Dr. Kazuhiro Shigetoh, Executive Director; Mr. Masaki Matsuoka, Deputy Executive Director, and Dr. Nobumasa Nakashima, Director, Office of International Programs, PMDA. In the meeting, DAV introduced the pharmaceutical regulations in Vietnam, and PMDA explained PMDA's efforts for Road map for the PMDA International Vision and collaborations with Asian regulatory agencies. After the meeting, Dr. Coung took a tour of PMDA's offices and deepened his understanding of PMDA's operations by receiving explanation at each department. The information and opinions were actively exchanged through the meeting and the tour of PMDA. The first visit of Director of DAV to PMDA became a very meaningful visit to strengthen future collaboration between DAV and PMDA.


Left: From left, Dr. Nakashima, Mr. Matsuoka, Mr. Trung, Dr. Hojo, Dr. Coung, Dr. Kondo, Dr. Shigetoh,
Right: From left, Dr. Coung, Dr. Kondo

8. The 3rd APAC (April 10 to 11)

The 3rd Asia Partnership Conference of Pharmaceutical Associations (APAC) was held in Tokyo from April 10 to 11. Dr. Tatsuya Kondo, Chief Executive; Mr. Shinobu Uzu, Director, Office of New Drug I; Mr. Yasunori Yoshida, Director, Office of Review Management; Dr. Nobumasa Nakashima, Director, Office of International Programs and other four staff members participated in the conference from PMDA. In this meeting, presentations and panel discussions were delivered under the theme of "To Expedite the Launch of Innovative Medicines for the Peoples in Asia". In the panel discussion, Mr. Uzu participated as a chair and lively discussion was developed on the subject of "Collaboration between Regulatory Agencies and Industries to Achieve Regulatory Convergence Smoothly in Asia". The next APAC is scheduled for next spring in Tokyo.


From left: Venue of the 3rd APAC Meeting, Panel discussion, Dr. Uzu

9. PMDA Expert Dispatched to Health Canada (April 14)

On April 14, PMDA sent Dr. Kosuke Haneda, Reviewer, PMDA, Office of Safety II (concurrently positioned in Office of International Programs) to Health Canada. He is expected to be stationed in Health Canada for three months to promote collaborative relationships between MHLW/PMDA and Health Canada.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.311, March 26, 2014

1. Modified Adverse Reaction Reporting System for Quasi-drugs and Cosmetics
2. Important Safety Information
3. Revision of Precautions (No. 254)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of March 2014)

http://www.pmda.go.jp/english/service/precautions_2013.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
May 8-10	APEC MRCT WS/GCP inspection WS	Qingdao
May 11-14	The 6th DIA China Annual Meeting	Shanghai
May 20-21	The 2nd Japan-Indonesia Symposium	Jakarta
May 22-23	The 8th DIA Annual Conference in Japan for Asian New Drug Development	Tokyo
May 26-28	IGDRP	Taipei
May 31-June 5	ICH US meeting	Minneapolis
June 13	ICMRA	Washington D.C.
June 15-19	The 50th DIA Annual Meeting	San Diego
June 25-26	PDG	Rockville

Letters from the liaison officers

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

Nice to meet you. I am Yoshihiko Sano who was dispatched to EMA as the third liaison officer of PMDA on April 7, succeeding the first liaison officer, Mr. Yoshikazu Hayashi (November 2009 – April 2012), and the second liaison officer, Dr. Junko Sato (May 2012 – April 2014).

Globalization of development and distribution of medical products has been advanced and medicines first approved in Japan have emerged. In such circumstances, it is important to establish harmonious relationship with overseas regulatory authorities including EMA. I believe that the desired and pivotal roles as a liaison officer are facilitating cooperative framework with overseas regulatory agencies on notifications and guidelines from initial drafting stage, and jointly take safety measures at an early stage by sharing and evaluating safety information, as stated in the "Road map for the PMDA International Vision". I would like to take over the predecessors' work steadily and to further strengthen cooperation between EMA/EC and MHLW/PMDA.

Yoshihiko Sano
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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"Problem of multilanguage country"

I'm Jun Kitahara, International Liaison officer stationed at Swissmedic since the beginning of March. Some of you might have already realized, since it was informed in previous PMDA updates in March. I would like to provide you some information about Switzerland and Europe, probably a little different point of view as that from EMA.

Four different languages are used officially here in Switzerland including German, French, Italian and Romansh. Swissmedic should use German, French and Italian for publishing information. Even though English is not an official language, English information is also important for global information sharing, of course. Although English information provision is also big challenge for PMDA, multilanguage country has its own difficulty even for domestic information sharing.

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

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