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PMDA Updates

March, 2013

News

1. Cellular and Tissue-based Products Subcommittee meeting held (February 6)

The Cellular and Tissue-based Products Subcommittee, one of the subcommittees of the Science Board, had its 4th meeting on February 6. In the meeting, Prof. Hiroyuki Mano, a member of the subcomittee, gave a presenation on "the tumorigenicity of cellular products," which led to a lively discussion among participants. Other meeting topics included the rules and procedures for inviting outside experts into the subcommittee meetings to deeply examine very specialized areas of concerns .

The meeting agenda and list of the handouts are available at:
http://www.pmda.go.jp/english/scienceboard/2012/cell_and_tissue-based/20130206.html
The handout materials are available only in Japanese:
http://www.pmda.go.jp/guide/kagakuiinkai/24saibou/h250206gijishidai.html

English agenda and lists of handouts have been now made available at the newly created web pages for the Science Board.

2. The 1st Indonesia-Japan Symposium (February 13)

The 1st Indonesia-Japan Symposium was held on February 13th in Jakarta, Indonesia. This symposium was co-hosted by PMDA, the Japan Pharmaceutical Manufacturers Association (JPMA), the Indonesian National Agency of Drug and Food Control (NADFC), and Gabungan Perusahaan Farmasi Indonesia (GPFI). The joint event was intended for regulatory officials and pharmaceutical industry professionals of the two countries to enhance understanding of each other's regulatory system,thereby contributing to expansion of bilateral collaboration and development of medical products in both countries. The symposium highlighted pharmacovigilance and Good Distribution Practice (GDP). At the opening of the symposium, Dr. Tatsuya Kondo, Chief Executive of PMDA, introduced PMDA's recent efforts for promoting regulatory science and international activities. His Indonesian counterpart, Dra. Lucky S. Slamet, Head of NADFC, explained the roadmap to improve Indonesia's regulatory system while emphasizing the importance of pharmacovigilance, one of the themes of the symposium. Click here for the presentation materials.

3. Bilateral Communication with Thai Food and Drug Administration (February 18)

On February 18, Dr. Nobumasa Nakashima, Director of Office of International Programs, visited Dr. Pathom Sawanpanyalert and Dr. Paisarn Dunkum, Deputy Secretary Generals, and other officials of the Thai Food and Drug Administration (Thai FDA), which became the first bilateral communication between the Thai FDA and PMDA. The meeting was noted as a start of further mutual cooperation, and as a specific project, the two countries agreed to consider holding a joint symposium within a year.

4. Chief Executive of PMDA visits UK's MHRA (March 4)

Dr. Kondo, Chief Executive of PMDA, visited Sir Kent Woods, Chief Executive, and several executives of the UK Medicines and Healthcare products Regulatory Agency (MHRA) on March 4. At the meeting, both sides shared their recent developments and exchanged views on the common areas of interest, including regulatory science for better public health. PMDA will continue to further enhance the cooperative relationship with the MHRA building on the Memorandum on Information Exchange signed in October 2010.

Dr. Tatsuya Kondo, Chief Executive of PMDA, and Sir Kent Woods, Chief Executive of MHRA

5. DIA 25th Annual EuroMeeting (March 4 to 6)

Dr. Kondo, Chief Executive, and other delegates from PMDA attended the DIA 25th Annual EuroMeeting held in Amsterdam, Netherlands from March 4 to 6. In the PMDA Update session chaired by Dr. Nakashima, Director of Office of International Programs (OIP), the Agency's latest activities were addressed. Dr. Kondo was the lead-off speaker for the session, followed by Dr. Hideo Utsumi, Executive Director, and Mr. Kazuhiko Mori, Chief Safety Officer. Their speeches referred to PMDA's current situation and future direction; PMDA's approach to advanced science and the Science Board to PMDA; and safety measures including Risk Management Plan, respectively.

Moreover, Mr. Shinobu Uzu, Director of Office of New Drug I; Mr. Ira Wolf, Japan Representative of Pharmaceutical Research and Manufacturers of America; and Prof. Werner Knöss, Chairman of the Committee on Herbal Medicinal Products, the European Medicines Agency, took the rostrum in the session which was organized by OIP of PMDA. The Agency's exhibition booth was also open to provide information during the DIA meeting period.

Left: Dr. Kondo makes his speech. Center: From left, Mr. Mori, Dr. Utsumi, Dr. Kondo, and Dr. Nakashima respond to questions from the audience in the PMDA Update session. Right: PMDA exhibition booth.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.299, February 27, 2013

1. Utilization of the PMDA Medical Safety Information
2. Important Safety Information
   (1) Zanamivir Hydrate
   (2) Josamycin, Josamycin Propionate
   (3) Sunitinib Malate
   (4) Ryutanshakanto (for ethical use)
3. Revision of Precautions (No. 243)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of February 2013)

<Reference> Adverse Drug Reaction "Anaphylaxis"

http://www.pmda.go.jp/english/service/precautions_2012.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
April 8-10	World Health Summit in Asia	Singapore
April 15-16	7th DIA Annual Conference in Japan for Asian New Drug Development	Tokyo, Japan
April 26	ICH E11 Guidelines Workshop	Beijing, China
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.

Letters from the liaison officers

Modelling and Simulation Working Group (MSWG)[1] was established in EMA, January 2013. The MSWG will meet monthly and provide support to the EMA's scientific committees and working parties, including the Committee for Medicinal Products for Human Use (CHMP), the Paediatric Committee (PDCO) and the Scientific Advice Working Party (SAWP), on product-related issues but also in more general methodological discussions and qualification procedures regarding modelling and simulation.

PMDA also started internal discussion on modelling and simulation as a part of Statistic Project. I hope these activities in both agencies will contribute development of medicinal products and innovation efficiently.

1)http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000122.jsp&mid=WC0b01ac058063f485

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

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A meeting of the science board to the FDA was held on Feb. 27. The board member consists of experts from academia, medical profession, and industry. The science board provides advice to FDA on scientific and technical issues, and also provides advice that supports FDA in keeping pace with technical and scientific developments. In this meeting, FDA's recent research activities were reported. The research programs are extensive; collecting and analyzing post-marketing safety information on drugs and biologics, genomics work, study on vaccine immunogenicity, and more. Some of them are joint studies with universities or research institutes. The board discussed how these findings could be used efficiently for the regulatory issues at the meeting.

PMDA established the science board in 2012, and a personnel exchange program between PMDA and academia/medical institutions has been started. PMDA thinks that cooperation and communication with academia and medical institutions are necessary to acquire the latest scientific and technical knowledge. Fostering of regulatory scientists is important to deliver safe and effective drugs and medical devices to the people, and it is also important for further promotion of medical innovations. These ideas seem to be common among FDA and PMDA. The results of these efforts are expected to be translated into practical application of innovative technologies, and development of standards and guidelines which contribute to speed-up approval review, and I will make my efforts to support the process.

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

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