PMDA Updates

June, 2010

< News>

1. The 8th Korea and Japan Joint Seminar held in Tokyo : June 4

The 8th Korea and Japan Joint Seminar co-hosted by the Korea Pharmaceutical Manufacturers Association (KPMA) and the Japan Pharmaceutical Manufacturers Association (JPMA) was held in Tokyo on June 4. Dr. Kawahara, Senior Executive Director of PMDA, delivered a speech titled "Challenges and Initiatives of the PMDA" in session "Pharmaceutical Regulatory" and exchanged views on a broad range of topics of regulation between Korea and Japan.

2. The International Conference on Harmonization (**ICH**) Steering Committee and its Expert Working Groups (EWGs) met in Tallinn, Estonia : June 5-10

Dr. Tominaga, Office Director of International Programs, and other experts of PMDA participated in the ICH Steering Committee and its EWGs meeting in Tallinn, Estonia from 5 - 10 June, 2010. The meeting saw progress in the harmonization of pharmacopeial text in the three regions. Two annexes for the Q4B Guideline (Evaluation and Recommendation of Pharmacopoeial Text for Use in the ICH Regions; Annex 11 on Capillary Electrophoresis and Annex 12 on Analytical Sieving) reached Step 4 and another 2 (Annex 13 on Bulk and Tapped Density and Annex 14 on Bacterial Endotoxin) reached Step 2. The E7 IWG completed a set of Questions and Answers, which reached Step 4.
The next ICH Steering Committee and its EWGs meetings will be held in Fukuoka, Japan from 6-11 November, 2010.
For more details: http://www.ich.org/LOB/media/MEDIA5995.pdf

3. Workshop on Career Development in Clinical Oncology held, at Japanese Embassy in the US : June 11

Dr. Kondo, Chief Executive of PMDA, and Mr. Uemura, International Liaison Officer responsible for U.S. relations, made their speeches on education at the Workshop on Career Development in Clinical Oncology, co-sponsored by the Japanese Embassy, S&R Technology Holdings, LLC and National Cancer Institute (NCI) on June 11. The workshop was intended to assist young investigators in all aspects of designing a compelling, hypothesis-driven clinical trial for novel drug development. The workshop dealt with key concepts underlying cancer therapeutic clinical trials and expanded the network among NCI and Japanese researchers visiting the U.S.

4. DIA 46th Annual Meeting in Washington, DC : June 13-17

Dr. Kondo and PMDA experts attended the DIA 46th Annual Meeting in Washington, DC. and

delivered presentations for sessions including “PMDA town meeting” and “International Cooperation among Regulators Including the Exchange of Confidential Information.” In the latter session, Dr.Kondo and the senior executives from FDA and EMA shared their perspectives on their confidential arrangements on dialogue about medicinal products, regulatory processes and public health issues. The session allowed time for the audience to ask questions and shared feedbacks with regulators on the latest topics of mutual concern.

5. The first PMDA Advisory Council for FY 2010 approved PMDA’s annual report and audited financial statements for FY 2009: June 23

PMDA sought recommendations and opinions on improvement from its third-party advisory bodies, i.e. Review and Safety Measures Operations Committee (held on June 8,) Relief Service Operations Committee (held on June 21) and Advisory Council (held on June 23,) in order to strengthen internal control process and to increase transparency and efficiency in terms of cost control in the PMDA operations. In its first session for FY 2010, the Advisory Council deliberated and approved its annual report and audited its financial statements for FY 2009.

<Notification>

Notification: Guideline - Nonclinical Evaluation for Anticancer Pharmaceuticals (PFSB/ELD notification No.0604-1 dated 4 June 2010)

Notification: Points to consider regarding setting targets for shortening review times for new drugs (PFSB/CND Administrative Notice, dated 6 June, 2010)

Notification: The 2nd Pilot Program Regarding Medical Device Collaborative Consultation and Review of Premarketing Applications (PFSB/ELD/OMDE Notification No. 0615-1, dated 22 June, 2010)

< Safety Information >

●Pharmaceuticals and Medical Devices Safety Information No.269, May 2010

The articles in this issue describe the following information

- Project to Collect and Analyze Medical “Near-Miss” Incidents from Pharmacies
- Important Safety Information (Clopidogrel, Sitagliptin, Tacrolimus etc.)
- Revisions of PRECAUTIONS section of package inserts (Infliximab and 15 others)
- List of products subject to Eeary Post-marketing Phase Vigilance

For more details: http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-269.pdf

●Medical Safety Information: Precautions in Handling of Electric Scalpels (Part 2) No.15, March 2010

The article in this issue describes Precautions in Handling Electric Scalpels in a patient when using an alcoholic antiseptic.
For more details: http://www.pmda.go.jp/english/service/pdf/safety/No15.pdf

●**Medical Safety Information: Precautions in Handling Electric Scalpels (Part 1) No.14, February 2010**
The article in this describes Precautions in Handling Electric Scalpels in a patient with an endotracheal tube.
For more details: http://www.pmda.go.jp/english/service/pdf/safety/No14.pdf

<Events >

1. Conferences/meetings PMDA hosts

Dates	Title	Location
August 26	the 5th PMDA international Symposium on Biologics	Tokyo