PMDA Updates

July 2011

News

1. 9th Korea-Japan Joint Seminar (June 10)

PMDA Senior Executive Director, Dr. Akira Kawahara delivered a speech titled "MRCT & Korea-Japan Cooperative Relationship" in 9th Korea-Japan Joint Seminar in Seoul jointly hosted by Korea Pharmaceutical Manufacturers Association and Japan Pharmaceutical Manufacturers Association. Dr. Kawahara discussed the importance of promoting multi-regional clinical trials (MRCT) in East Asia and the current status and future direction of bilateral cooperation between the two countries, including training of Korea FDA employees at PMDA.

2. ICH Cincinnati Meeting (Steering Committee/ Working Groups) (June 11 - 16)

22 PMDA experts attended the International Conference on Harmonization (ICH) Steering Committee (SC) and its Working Group held in Cincinnati, USA, June 11-16. In the Meeting, E2B (R3) Implementation Guide (IG) was advanced to Step2. Three sets of Q&A regarding M3 (R2) guideline were finalized (Step4). Three "Points to Consider" documents covering the topics relevant to the implementation of Q8, Q9 and Q10 guidelines were also completed. The next ICH Steering Committee meeting (including Expert Working Groups) will be held in Seville, Spain November 5 -10, 2011. The SC will invite East African Community (EAC) to the next ICH Global Cooperation Group.

3. Pharmacopoeial Discussion Group (PDG) (June 14 - 15)

PDG consists of European Directorate for the Quality of Medicines (EDQM), the United States Pharmacopoeial Convention, Inc (USP) and MHLW/PMDA of Japan. PMDA sent its representatives to the PDG meeting held in Cincinnati to discuss harmonization of general chapters and excipient monographs of the three pharmacopoeias. This time, 4 items of General Chapters and 5 items of excipient monographs were newly harmonized. As a result, the PDG efforts for harmonization have achieved 28 of the 35 General Chapters and 41 of the 62 excipient monographs of the current work programme. The next PDG will be held in Strasbourg, France November 8-9, 2011.

4. Bilateral Meeting with FDA (June 18)

MHLW/PMDA had a bilateral meeting with US FDA in Chicago. The meeting dealt with current

issues of pharmaceutical regulation in the US and Japan. The delegations from both sides exchanged their views on international harmonization, regulatory science, bilateral cooperation, and other issues.

5. The 3rd Pilot Program Regarding Medical Device Collaborative Consultation and Review of Premarketing Applications（Collaborative Scheme）(June 16)

On June 16, 2011, MHLW issued a notification to solicit application for the *3rd Program Regarding Medical Device Collaborative Consultation and Review of Premarketing Applications*. In this pilot program, MHLW/PMDA and FDA collaborate in consultation and reviewing of specific products in order to improve the speed and quality of their services. Following the 1st and the 2nd programs in 2009 and 2010, MHLW/PMDA and FDA decided to continue this pilot program in 2011.

6. 47th DIA Annual Meeting (June 19 to 23)

Dr. Tatsuya Kondo, Chief Executive of PMDA, and 15 other members from PMDA participated in the Meeting. Dr. Kondo delivered a speech titled “Future Directions and Challenges of PMDA” at PMDA Town Hall Meeting (June 22). PMDA also chaired a session “China-Japan-Korea Joint Research on Ethnic Factors in Clinical Data” (June 23). PMDA had a booth throughout the Meeting to provide its up-to-date information.

7. Committee on Relief Service Operations (June 27)

PMDA held the first meeting of its Committee on Relief Services Operations for FY 2011. The committee discussed and approved Relief Services Report for FY 2010, and Annual Business Plan for FY2011

8. Advisory Council and Committee on Review and Safety Measures Operations (June 28)

PMDA held the first joint meeting of its Advisory Council and Committee on Review and Safety Measures Operations for FY 2011. The meeting discussed and approved Operation Report for FY2010, Accounting Report for FY2010, and New Business Plan for FY 2011.

Safety information

Pharmaceuticals and Medical Devices Safety Information No. 280 (June 29, 2011）
http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-280-d.pdf

Events

1. Conferences hosted by PMDA (incl. co-host)

Date	Title	Venue
October 31	China-Japan-Korea Director-General Meeting/Working Group	Tokyo, Japan
November 1-2	APEC Multi-Regional Clinical Trials Tokyo Workshop	Tokyo, Japan