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PMDA Updates

August, 2012

News

1. ICH Japan symposium 2012 held (July 25)

On July 25,PMDA representatives attended the ICH Japan Symposium 2012 co-hosted by the Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ) and the Japan Pharmaceutical Manufacturers Association (JPMA). This Symposium was intended to report to the public about the discussion and progress made at the ICH meeting held in Fukuoka in June 2012, which should increase the transparency of the ICH meeting.

Six experts from PMDA participated as a session chair or speaker in the Symposium that addressed 14 ICH topics. Of those topics, 5 were explained by the five PMDA speakers, such as E2B guideline (Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports) and E3 guideline (Structure and Content of Clinical Study Reports). After the presentations, the speakers answered questions from the floor, thereby contributing to the enhanced transparency of the ICH process.

2. The second Science Board meeting held (July 31)

The second meeting of the PMDA Science Board was held on July 31, 2012. In the meeting, the Board members discussed the set-up of subcommittees, the appointment of the subcommittee members, respective roles of the Science Board and its four subcommittees, and their future plans. For more details, see Press Release.

The Science Board was established by PMDA on May 14, 2012 as the high-level body that provides scientific advice to the Agency. The Board is expected to help PMDA to handle scientific and regulatory aspects of state-of-the-art technology products more appropriately, through close collaboration with academia where front-line research programs are conducted.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.292, July 25, 2012

1. Launch of a pilot program of "Direct Patient Reporting System for Adverse Drug Reactions"
2. Important Safety Information
   Ivermectin, Telaprevir, Garenoxacin Mesilate Hydrate
3. Revision of Precautions (No. 237)
   Escitalopram Oxalate, (and 6 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of July 2012)

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

Events

Conferences/Meetings PMDA participates in

Date	Title	Location
August 21-24	APEC RHSC	Singapore
September 4-7	China International Medical Device Regulatory Forum	Beijing, China
September 13-14	IMDRF MDSAP WG	Ottawa, Canada
September 20-21	Swissmedic International Regulatory Symposium	Interlaken, Switzerland
September 25-27	IMDRF	Sidney, Australia