PMDA Updates

December 2010

< NEWS >

1. **PMDA's 30th Anniversary Symposium on Relief System for Adverse Drug Reactions held: December 6, 2010**

   PMDA hosted a symposium to mark the 30th anniversary of its relief system for adverse drug reactions on December 6, 2010. Under the relief system PMDA provides relief benefits to compensate for health damages such as disease and disabilities requiring hospitalization that were caused by adverse reactions to drugs prescribed at hospitals or clinics as well as drugs purchased at pharmacies. Dr. Tatsuya Kondo, the Chief Executive of PMDA delivered the opening remark. Among the speakers were representatives from academia and from an organization of adverse drug reaction sufferers. In the panel discussion titled" Publicity Service on Relief System- how to launch a public relations campaign-", the panelists conducted candid discussion from various standpoints.

2. **5th Taiwan and Japan Joint Seminar held in Tokyo : December 10, 2010**

   The 5th Taiwan and Japan Joint Seminar was hosted by the Japan Pharmaceutical Manufacturers Association (JPMA) in Tokyo on December 10. Representatives from the regulatory authorities and industry of both countries participated in this seminar. The present situation of clinical trials in the two countries was discussed. The attendees also exchanged their views on the latest topics of pharmacovigilance. Dr. Akira Kawahara, Senior Executive Director of PMDA, delivered a speech titled "Challenges and Initiatives of the PMDA", followed by a lively Q&A session, which dealt with a broad range of topics on drug regulation in Taiwan and Japan.

3. **Training of Korea Food and Drug Administration (KFDA) Reviewers/Experts on New drugs, Generics and Pharmacovigilance : from November 24 to December 21, 2010**

   PMDA accepted three technical trainees from the Korean agency, who are reviewers or analysts dealing with review of new drugs as well as generics, and pharmacovigilance, from November 24 to December 21, 2010. PMDA provided specialized technical training programs by assigning the trainees to its related offices. The trainees reported their achievements to the whole PMDA in their reporting session on December 21, 2010.

4. **Second Session of PMDA Review and Safety Measures Operations Committee for FY 2010 / Second Session of PMDA Relief Service Operations Committee for FY 2010 held: December 22, 24, 2010**

PMDA sought recommendations and opinions on operations from its Review and Safety Measures Operations Committee (held on December 22) and Relief Service Operations Committee (held on December 24). The review results of PMDA's operating performance for FY 2009 by MHLW's Incorporated Administrative Agencies Evaluating Committee and its actual achievements from April 2010 to October 2010 were deliberated and acknowledged in the respective PMDA Committees.

5. Reporting Session "the latest trend of EMA and its current status on International collaboration" held at PMDA Office: December 24, 2010

PMDA held its first public Reporting Session by its Liaison Officer stationed abroad. Dr. Toshiyoshi Tominaga, the Office Director of Office of International Programs, PMDA, delivered a presentation titled "EMA and Japan; a view of Liaison Office" on behalf of Mr Yoshikazu Hayashi, PMDA International Liaison Officer at EMA. Mr. Hayashi was stranded in London due to the heavy snow storm. Mr. Shinobu Uzu, International Planning Director, MHLW presented "International cooperation by MHLW/PMDA", as the second speaker. The Session enjoyed an audience of more than 100, mostly from the pharmaceutical industry. The presentations were followed by Q&A sessions, which fielded numerous questions from those participants.

< Safety Information >

●Pharmaceuticals and Medical Devices Safety Information No.274, November 2010

The articles in this issue describe the following information.

- Important Safety Information [Adalimumab (Genetical Recombination), Erlotinib Hydrochloride, Gefitinib, Goserelin Acetate, Solifenacin Succinate, Bicalutamide, Flutamide, Pemetrexed Sodium Hydrate, Leuprorelin Acetate]
- Revision of Precautions section of package inserts [Alglucosidase Alfa (Genetical Recombination) and 22 others)
- List of Products Subject to Early Post-marketing Phase Vigilance

For more details: http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-274.pdf

< Events >

1. Conferences/meetings PMDA participates in

Date	Title	Location
February 1-2	HTA Workshop	London
March 16-17	HBD East 2011 Think Tank Meeting	Tokyo