



PMDA Updates

September and October, 2011

News

1. International Liaison Officer dispatched to US (July 16)

Dr. Tetsuya Kusakabe was sent to US as PMDA's second liaison officer stationed in US Pharmacopeia (USP). Dr. Kusakabe will act as the point of contact for PMDA in the US to facilitate communication between Food and Drug Administration (FDA) & USP and PMDA & Ministry of Health, Labour and Welfare (MHLW) for the coming year.

The placement of liaison is in accordance with one of the vital pillars of the PMDA International Strategic Plan, "Strengthening of cooperation and building of collaborative relations with the United States (US), the European Union (EU), Asian countries, and relevant international organizations."

2. MHLW Evaluation Committee awards "S" to PMDA's operating performance for FY 2010 (August 22)

PMDA, as an incorporated administrative agency, undergoes strict annual performance review by the Japanese government. The Medical Care and Welfare Group of the Evaluation Committee for Incorporated Administrative Agencies in MHLW published its evaluation of PMDA's performance for FY2010. Out of 18 evaluation items, PMDA received the highest grade "S" for the following 2 evaluation items: "cost control efforts" and "expeditious operation and improvement of the system [drugs]." Highly recognized were PMDA's review times that were remarkably shorter than the target times, both for new drugs and for generic drugs. For the rest 16 evaluation items, PMDA received "A", indicating that the performance surpassed the target. Thus PMDA was judged to have outperformed the set targets in all of the 18 evaluation items.

3. PMDA appointed new Executive Directors (August 23).

Mr. Masatoshi Narita replaced Dr. Akira Kawahara as Senior Executive Director and Mr. Nobuyoshi Ishii succeeded Mr. Yoshio Kawajiri, as Executive Director on August 23, 2011. Mr. Ishii also serves as Chief Management Officer.

4. 2nd China-Japan Bilateral Meeting held (August 23)

The 2nd Bilateral Meeting was held between SFDA and MHLW/PMDA in Beijing according to the agreement in the MOU established between the agencies in January 2009. The participants reconfirmed the importance of cooperation between the two countries and agreed to establish 6 working groups according to the MOU. For more details, please see [News Release \(English\)](#).

5. Training of Chinese officials on vaccines in JICA project (August 23)

PMDA trained seven officials from the Chinese authorities on Japan's vaccine regulation, focusing on pre-market review, safety measures, and relief system for adverse health effects. The training was part of "Project for Surveillance and Control for Vaccine-preventable Diseases" organized by the Japan International Cooperation Agency (JICA).

The training was continued at the National Institute of Infectious Diseases and the National Center for Global Health Medicine, with intention to give the trainees practical knowledge to be used for infection control in China.

6. Chief Executive presented PMDA's efforts in regulatory science in 1st Annual Meeting of Society for Regulatory Science of Medical Products (September 2 to 3)

Dr. Tatsuya Kondo, Chief Executive of PMDA, discussed a case where application review of an anti-influenza virus agent was completed in less than 3 months through active utilization of prior assessment consultations, and illustrated the vital relationship between regulatory science and drug review in his presentation delivered on September 3 for the 1st Annual Meeting of Society for Regulatory Science of Medical Products held in Tokyo.

As another speaker of the Meeting, a PMDA reviewer introduced cases of drugs approved based on global clinical data, and indicated PMDA's policy of encouraging global clinical trials for drug development.

7. MHLW/PMDA and TGA exchanged letters on information sharing with confidentiality (September 7)

Dr. Rohan Hammett, National Manager of the Therapeutic Goods Administration (TGA), Department of Health and Aging of Australian Government, visited PMDA to exchange letters on sharing confidential information on September 7. Dr. Hammett, Mr. Noriyuki Kikura, Director-General of the Pharmaceutical and Food Safety Bureau, MHLW, and Dr. Tatsuya Kondo, Chief Executive of PMDA signed the letters to facilitate exchange of the type of information between the regulatory authorities of Australia and Japan. The conclusion of this arrangement is expected to strengthen mutual trust in confidentiality and to promote the collaborative relationship in various areas including product review and safety measures.

Mr. Kikura commented, "The timing of this meeting is very appropriate. The Australia-Japan relationship has so far been developed only on multilateral basis such as in GHTF and ICH. But now is the time to initiate cooperation on bilateral basis for our mutual good." Dr. Kondo expressed his expectation as follows: "Asia-Oceania has a potential to become one of the largest bases of drug development. If the two countries collaboratively tackle common challenges they are confronted with, it will greatly advance their public health." Dr. Hammett illustrated the planned merger of TGA (Australia) with MedSafe (New Zealand), announced in June.

8. The 3rd meeting of study group on reinforcement of GMP inspection system (September 9)

To prepare for the accession to Pharmaceutical Inspection Co-operation Scheme (PIC/S), Study Group on Reinforcement of GMP Inspection System met for the third time on September 9. Discussed topics include inspector training and inspection skill sharing to ensure inspection quality, implementation of the quality management system in testing facilities, and consistency between PIC/S guidelines and the Japanese guidelines.

9. HBD session held at AdvaMed 2011 (September 26)

AdvaMed MedTech Conference 2011 held HBD* Session, where HBD's recent activities, current and future directions, and newly emerging challenges were discussed. AdvaMed, or Advanced Medical Technology Association, is an association of US medical device industry. The session was open to general audience.

The Session compensated for US-Japan HBD East 2011 Think Tank Meeting, which was scheduled for March 2011 in Tokyo but canceled due to the Great East Japan Earthquake.

*HBD (Harmonization By Doing): HBD was established in December 2003 with the aim of bringing regulatory harmonization between the US and Japan into review of medical devices especially in the cardiovascular area. The regulatory authorities, industries, and academia in the US and Japan collaboratively engage in HBD activities.

Official website of AdvaMed 2011: <http://advamed2011.com/>
Brief information on the HBD session titled "Japan-USA Harmonization by Doing":
<http://advamed2011.com/go.cfm?do=Page.View&pid=97#japan>

Safety Information

1. Pharmaceuticals and Medical Devices Safety Information No.282, August 30

1. Revision of Contraindications for the Use of Coronary Stent
2. Revision of Contraindications for the Use of Intraocular Lens
3. Important Safety Information
 - 1) Oxaliplatin
 - 2) Recombinant Adsorbed Hepatitis B Vaccine (yeast-derived) (Bimmugen)
 - 3) Sunitinib Malate
 - 4) Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed)
 - 5) Varenicline Tartrate
 - 6) Lenalidomide Hydrate
4. Revision of Precautions (No. 228)
Pioglitazone Hydrochloride, Pioglitazone Hydrochloride/Glimepiride, Pioglitazone Hydrochloride/Metformin Hydrochloride, Ergotamine Tartrate/Anhydrous, Caffeine/Isopropylantipyrine, Gabapentin, Terbutaline Sulfate, Bevacizumab (Genetical Recombination), Fexofenadine Hydrochloride, Recombinant Adsorbed Hepatitis B Vaccine (yeast-derived) (HEPTAVAX), Tocilizumab (Genetical Recombination)
5. List of Products Subject to Early Post-marketing Phase Vigilance

<http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-282-d.pdf>

2. Pharmaceuticals and Medical Devices Safety Information No.283, September 28

1. Safety Measures against Bladder Cancer Associated with Diabetes Medication "Pioglitazone Hydrochloride-Containing Products"
2. Important Safety Information
 - 1) Influenza HA Vaccine
 - 2) Thalidomide
 - 3) Doxorubicin Hydrochloride
 - 4) Dabigatran Etxilate Methanesulfonate
3. Revision of Precautions (No. 229)
Modafinil, Shakuyakukanzoto, Esmolol Hydrochloride, Bosentan Hydrate, Clomifene Citrate, Methotrexate, Azithromycin Hydrate (tablet 250 mg, 600 mg, capsule for pediatrics, fine granule for pediatrics, injectable dosage form), Azithromycin Hydrate (dry syrup for adults), Clarithromycin, Lansoprazole/Amoxicillin Hydrate/Clarithromycin, Ofloxacin (oral dosage form), Levofloxacin Hydrate (oral dosage form) (low-dose), Levofloxacin Hydrate (oral dosageform) (high-dose), Levofloxacin Hydrate (injectable dosage form), Maraviroc, Sulfamethoxazole/Trimethoprim, Eptacog Alfa (Activated) (Genetical Recombination), Shakuyakukanzoto (OTC-drug)
4. List of Products Subject to Early Post-marketing Phase Vigilance

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Events

1. Conferences/Meetings PMDA (co-)hosted

Date	Title	Location
October 31	China-Japan -Korea Director-General Meeting	Tokyo, Japan
November 1-2	2011 APEC Multi-Regional Clinical Trials TOKYO Workshop – highlighting Korea, China and Japan Tripartite Symposium	Tokyo, Japan
December 5-12	2nd PMDA Training Seminar	Tokyo, Japan

2. Conferences/Meetings PMDA participates in

Date	Title	Location
October 23-28	Heads of Medicines Regulatory Agencies Summit 2011	Sydney, Australia
November 5-10	ICH meeting	Seville, Spain