



PMDA Updates

January, 2012

News

1. PMDA Chief Executive's New Year message (January 5)

Dr. Kondo, Chief Executive of PMDA delivered a New Year message to executives and employees of PMDA at the all-employees meeting held in early January 2012. The message is summarized as follows;

In 2011, Japan experienced the Great East Japan Earthquake. There was no foreseeing the calamitous event. The same holds true for this year: no one knows what will happen. This is not limited to natural disasters. In this era of uncertainty, the most important thing for us is to pursue fairness in the regulatory process in order to ensure public understanding of our services.

People always seek out new medical products. As a regulatory agency, recognizing their demands well, we must be humble and open to learning cutting-edge technologies developed by companies. This attitude forms the basis of regulatory science as we understand. I expect all the staff members of PMDA to be committed to their work with self-confidence and self-awareness as the leading regulatory scientists in Japan.

I believe PMDA must engage in global conversations more actively, which requires each individual at PMDA to be internationally minded, and carry out its mission based on regulatory science. To achieve the goal, it is essential for us to develop excellent communication skills along with a good command of English. Please try to actively interact with others and have lively discussions on a daily basis, either in English or in Japanese.

2. PMDA provided a training program to KFDA officials (December 1 to 22)

As with the previous year, PMDA accepted three trainees from the Korea Food and Drug Administration (KFDA) from December 1 to 22, 2011 and provided them with the three-week training program on regulatory review of drugs and medical devices and product safety measures. On the final day of the program, the trainees gave presentations on their outcomes from the training program in the internal reporting session.

3. WHO assessment of national regulatory system for vaccine quality (December 5 to 7)

From December 5 to 7, the World Health Organization (WHO) inspected the Ministry of Health, Labour and Welfare (MHLW), PMDA, the National Institute of Infection Diseases, and Kanagawa Prefectural Government with the aim of assessing the national regulatory system for vaccines. The WHO conducts on-site inspections to assess the functions of the national regulatory authorities (NRA) of the nations from which the United Nations International Children's Funds (UNICEF) purchases vaccines, as to the NRA's capacity to properly assure the quality and safety of vaccines. This periodic assessment takes place every five years.

4. The 2nd PMDA Training Seminar held (December 5 to 12)

The 2nd PMDA Training Seminar was held from December 5 to 12, mainly targeting at pharmaceutical Good Manufacturing Practice (GMP) inspectors of Asian regulatory authorities. On the 1st day of the seminar, PMDA's experts gave lectures on the Japanese pharmaceutical regulatory system and the services of PMDA. From the 2nd day onwards, the seminar focused on pharmaceutical GMP inspection and PMDA's inspection system, and its concepts were explained by the inspectors from the Office of GMP/QMS Inspections. Also, a mock inspection was conducted at a manufacturing plant of a pharmaceutical company. The main participants of the seminar were 10 health officials from Indonesia, Korea, and India. In addition, trainees under the programs organized by the Japan International Cooperation Agency (JICA) joined part of the PMDA seminar: nine participants from the "Study Program on Pharmaceutical Affairs" on December 5 and eight participants from the "Study Program on Manufacturing Control of Essential Drugs" from December 5 to 7.

5. The Committee on Review and Safety Operations convened for its 2nd meeting for FY 2011 (December 20)

The meeting of the Committee on Review and Safety Operations was held on December 20, 2011. In the meeting, PMDA reported to the Committee on the results of its FY 2010 operating performance which had been evaluated by the Evaluation Committee for Incorporated Administrative Agencies of MHLW. The operating performance for FY 2011 up to the end of October 2011 was also reported and the proposed future plans were discussed. All the reports and the proposals were approved.

6. The Committee on Relief Services convened for its 2nd meeting for FY 2011 (December 21)

The meeting of the Committee on Relief Services was held on December 21, 2011. In the meeting, PMDA reported to the Committee on the results of its FY2010 operating performance evaluated by the Evaluation Committee for Incorporated Administrative Agencies of MHLW. The operating performance for FY 2011 up to the end of October 2011 and the results of the questionnaire survey conducted in the Advanced Treatment Hospitals were also reported and discussed. The Committee approved all the reports made. In addition, two medical institutions reported on their efforts made for disseminating information on the relief services for adverse health effects, followed by a question-and-answer session, which helped the Committee members to become better aware of how the relief services is perceived in clinical practice.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.285, December 27, 2011

1. Cases of Non-payment under the Relief System for Sufferers from Adverse Drug Reactions and Proper Use of Drugs
2. Important Safety Information
 - 1) Epoprostenol Sodium
3. Revision of Precautions (No. 232)
 - Solifenacin Succinate, Nitrazepam, Fluticasone Furoate, Fluticasone Propionate (nasal solution), Acetazolamide, Acetazolamide Sodium, Isoniazid, Isoniazid Sodium Methanesulfonate Hydrate, Remifentanil Hydrochloride
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of December 2011)

http://www.pmda.go.jp/english/service/precautions_2011.html

Events

Conferences/Meetings PMDA (co-)hosted

Date	Title	Location
February 4-6	ICORD 2012 Conference	Tokyo, Japan
March 22	3rd China-Japan Symposium on Drug Development	Beijing, China