Abies firma

PMDA Updates

January, 2013

News

PMDA Chief Executive's New Year message for 2013

A Happy New Year to all of you.

The current situation in the international community still remains unstable. It is important for us to accomplish our mission, having a lofty spirit in such difficult circumstances. We need to broaden our perspective and firmly maintain our stances to establish mutual relationship with other regulatory authorities from a global point of view.

This year, PMDA intends to take drastic measures to meet two objectives. The first objective is to accomplish high quality performances for medical products as one of world's leading regulatory agencies. We would like to more closely interact with foreign regulatory agencies. The second objective is to globally promote "regulatory science". Regulatory science that has originated in Japan is already becoming essential for regulatory authorities to regulate medical products. We strive to achieve the progress of our services, research, and education in an integrated manner, by focusing on the scientific aspects of such activities while recognizing the importance of regulatory science, which forms the basis of the activities at PMDA.

1. CMC Strategy Forum Japan 2012 (December 3 to 4)

The CMC Strategy Forum was held in Tokyo on December 3 and 4, 2012 for the first time in Asian. This Forum was started in 2002 and 2007, respectively, in the US and in Europe. The CMC Strategy Forum series are annually held to provide an open forum for regulators, industries and academia to present and discuss emerging issues and findings on analytical procedures and methods for assessment and regulation of biologics. Representatives from the US Food and Drug Administration, the European Medicines Agency, and other regulatory agencies, and pharmaceutical companies attended the Forum. PMDA supported the launch of the Forum in Tokyo and sent Dr. Kondo, Chief Executive; Mr. Jun Sakamoto, Director of the Office of Cellular and Tissue-based Products; and Dr. Mayumi Shikano, Director of the Office of Standards and Guidelines Development as a speaker or panelist. The next CMC Strategy Forum will take place in Japan next year as well.

2. The meeting of IGDRP held (December 3 to 4)

Dr. Nobumasa Nakashima, Director of the Office of International Programs, participated in the meeting of International Generic Drug Regulators Pilot (IGDRP) held in Nanchang, China, on December 3 and 4, 2012. The mission of IGDRP is to promote collaboration and convergence between health authorities in the area of generic drug regulation. In this meeting,

potential areas of collaboration among regulators were discussed by representatives from regulatory authorities of 11 countries/regions including Japan, the World Health Organization (WHO), and the European Directorate for the Quality of Medicines (EDQM). The next meeting of IGDRP is tentatively scheduled for Spring 2013 in Australia.

3. The 15th IGPA Annual Conference (December 4 to 6)

The 15th Annual Conference of International Generic Pharmaceutical Alliance (IGPA) was held in Kyoto for the first time in Japan. Dr. Kazuyuki Saito, Director of the Office of OTC/Generic Drugs from PMDA joined a pre-conference workshop as a speaker. He presented key points for the review of generic drugs in Japan, including the studies necessary for the assessment of bioequivalence, and the importance of GLP/GCP compliance. He also attended the panel discussion together with other regulators invited from Asia.

4. The 27th ICH Public Meeting held (December 14)

On December 14, the 27th ICH Public Meeting co-hosted by the Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ) and the Japan Pharmaceutical Manufacturers Association (JPMA) was held in Tokyo. This meeting was intended to report to the public about the discussion and progress made at the ICH meeting held in San Diego in November 2012, which would increase the transparency of the ICH meeting. PMDA sent Ms. Ayumi Endo who has served as the rapporteur of E2B (R3) guideline (Revision of the Electronic Submission in Individual Case Safety Reports) that was approved as Step 4 of the ICH process during this meeting. She reported the updates and responded to questions from the floor, thereby contributing to an increase in the transparency.

5. The Committee on Review and Safety Operations convened for its 2nd meeting for FY 2012 (December 26)

The meeting of the Committee on Review and Safety Operations was held on December 26, 2012. In the meeting, PMDA reported to the Committee on the status of new drug review and the update of safety measures as of October 31, 2012. The median total review time of new drugs was 6.1 months for priority review products and 10.0 months for standard review products. These results showed that both review times for new drugs were reduced from the previous year and successfully achieved their targets of 9 months and 12 months, respectively. Also, PMDA received over 180 thousand adverse drug reaction reports from healthcare professionals and both Japanese and foreign pharmaceutical companies.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.297, December 26, 2012

1. Surveillance on Dissemination and Utilization of Safety Information in Medical Institutions
2. Precautions for Using Gastrointestinal Stents
3. List of Products Subject to Early Post-marketing Phase Vigilance (as of December 2012)

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

Events

Conferences/Meetings PMDA hoseted or participates in:

Date	Title	Location
January 21-25	3rd PMDA Training Seminar	Tokyo, Japan
February 5-7	IMDRF RPS Table of Contents （ToC） Meeting	Brasilia, Brasil
February 14	Japan-Indonesia Symposium	Jakarta, Indonesia
March 4-6	DIA 25th Annual EuroMeeting	Amsterdam, Netherlands

Letters from the liaison officers

In January 2007, "Paediatric Regulation" was entered into force in EU to facilitate the development and accessibility of medicinal products for use in paediatric population etc. The experience with the regulation after 5 years was published in September 2012[1]. It reported the regulation has contributed to increase paediatric development, and so on. As result of the increase, paediatric specific pharmaceutical problems became evident. To resolve these problems, EMA prepared "Guideline on Pharmaceutical development of medicines for paediatric use (Draft)[2] " and started second public consultation in January 2013. Most of problems which are described in the draft guideline are common to us too. To facilitate multi-regional paediatric development, I suggest to review it and submit your comments to EMA.

1) 5-year Report to the European Commission General report on the experience acquired as a result of the application of the Paediatric Regulation http://ec.europa.eu/health/files/paediatrics/2012-09_pediatric_report-annex1-2_en.pdf

2) Guideline on Pharmaceutical development of medicines for paediatric use（Draft） http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/01/WC500137023.pdf

Dr. Junko Sato
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

---

FDA commented on drugs that treat serious or life-threatening diseases and that may fill an unmet medical need. According to the comments from Commissioner of the FDA and Director of CDER, FDA has approved 35 innovative drugs for devastating diseases, and most of them were approved before they were approved in other countries in FY 2012. And they also commented that after enforcement of the law, FDASIA, on July 2012, FDA has a new program to help expedite the development of new drugs that could potentially offer a substantial

improvement over existing therapies for patients with serious or life-threatening diseases. FDA issued a draft guidance for new drug applications and biologics license application, Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products, in December 2012. Appropriate use of enrichment could result in smaller studies, shortened drug development times, and lower development costs.

Through activities such as developing laws, guidance and putting out information and comments from key people, we can know FDA's current thinking on this topic. FDA also emphasizes that FDA always decides whether to approve a drug after evaluating whether its benefits outweigh its risks, and regardless of which development or review program, FDA never compromises its safety or efficacy standards in exchange for rapid approval. In addition to these strategies, the stance to provide information and current thinking of regulatory authority in various ways would be informative for affairs of PMDA.

Dr. Eriko Fukuda
PMDA's International Liaison Officers stationed at USP in the United States

---

