



Chimonanthus praecox

PMDA Updates

January, 2014

News

1. PMDA Chief Executive Dr.Kondo's New Year message for 2014



I wish you all a Happy New Year.

In the midst of remarkable advances in medicines and medical devices, needs are growing for prompt and universal provision of more effective and safe products to society, thereby increasing expectations for PMDA from Japanese citizens. To respond to the societal demands, PMDA has enhanced its performances focusing on product reviews, safety measures and relief services through the First and Second Mid-term Plans. The total number of employees was only 250 when PMDA was established, and it is scheduled to become over 750 in April, 2014 and is planned to be increased more. Such development of PMDA has been recognized not only in Japan but also in the rest of the world. PMDA has been establishing its presence as the regulatory agency with superior quality and speedy services. PMDA will be committed to promoting regulatory science further, providing services based on patients' viewpoint and the ethical aspects of science through the Third Mid-term Plan which will be implemented from April this year. Moreover, PMDA will work hard to build a stable presence as one of the world's top regulatory agencies by deepening exchanges with foreign regulatory agencies. We will band together and strive to make the year of 2014 the happiest and the best for everyone and PMDA.

2. 1st Japan-Taiwan Medical Device Exchange Seminar (December 10) and 2013 TFDA EP/STED Medical Device Reviewer Training Course (December 11)

A PMDA expert participated in the 1st Japan-Taiwan Medical Device Exchange Seminar held in Taipei on December 10, 2013, along with Ministry of Health, Labour and Welfare (MHLW) staff, and gave a presentation on the outline of the Japanese medical device regulations. The seminar drew about 100 audiences from medical device industry of Taiwan and Japan, with vigorous Q&A session ensued. On the next day (December 11), the PMDA staff attended in 2013 TFDA EP/STED Medical Device Reviewer Training Course as the instructor, and introduced the concept of Essential Principles (EP) and Summary Technical Documentation (STED), in line with Global Harmonization Task Force Guidance, through case study based on the actual review, which was favorably received by about 20 staff members of Taiwan Food and Drug Administration (TFDA).

3. PMDA provides a training program to CDE officials, Taiwan (December 11 to 13)

PMDA accepted two officials from the Center for Drug Evaluation (CDE), Taiwan, from December 11 to 13, 2013, and provided them with a training program on regulatory review of drug applications focusing on the review of biological products. During the program, PMDA reviewers explained the Japanese drug review system on drugs, while the trainees from CDE made a presentation on an overview of its drug regulation systems, organization, major tasks, current status and future prospects to PMDA staff members. Throughout the training period, lively discussions were held and mutual understanding was enhanced.



From left, Dr. Nakashima (Office Director of the Office of International Program), Dr. Li (CDE), Dr. Kondo (Chief Executive), Dr. Chen (CDE)

4. Ambassador of the Kingdom of Belgium and Representative for Japan at AWEX Pay Calls on Dr. Kondo (December 16)

His Excellency Mr. Luc Liebaut, Ambassador Extraordinary and Plenipotentiary of the Kingdom of Belgium in Japan, paid a courtesy call on Dr. Tatsuya Kondo, Chief Executive, PMDA on December 16, 2013. In the meeting, Dr. Kondo introduced current PMDA's efforts and received the various questions, especially on Japanese safety measures from H.E. Mr. Liebaut. In addition, on December 25, Ms. Claire Ghyselen, Representative for Japan at Belgium Wallonia Foreign Trade and Investment Agency visited Dr. Kondo to exchange the views on regulations of regenerative medicine and biological products in both countries. The need to establish further cooperative relationship between Japan and Belgium have been affirmed in either of the meetings.



Left: From the left, Dr. Takamatsu (Director of the Office of Safety II), Mr. Yamamoto, (Chief Safety Officer), Mr. Branders (First Secretary of Embassy of the Kingdom of Belgium in Japan), H.E. Mr. Liebaut (Ambassador Extraordinary and Plenipotentiary of the Kingdom of Belgium in Japan), Dr. Kondo (Chief Executive), Dr. Nakashima (Director of the Office of International Programs)
 Right: From the left, Dr. Nakashima, Ms. Ghyselen, Dr. Kondo

5. The 1st Joint Conference of Taiwan and Japan on Medical Products Regulation (December 23 to 24)

The 1st Joint Conference of Taiwan and Japan on Medical Products Regulation was held on December 23 to 24, 2013 in Taipei, Taiwan, hosted by East Asia Relations Commission and Interchange Association, Japan, and co-hosted by PMDA, Japan Pharmaceutical Manufacturers Association (JPMA), etc. From PMDA, Dr. Nobumasa Nakashima, Director of the Office of International Programs, Dr. Daisaku Sato, Director of the Office of New Drug V, Dr. Kazuyuki Saito, Director of the Office of OTC/Generic Drugs, and Mr. Ichiro Tsunoi, Inspection Director of the Office of GMP/QMS Inspection participated as speakers of the conference and delivered presentations on PMDA's recent trends, regulatory reviews of new

drugs and generic drugs, Good Manufacturing Practice (GMP) inspection, etc. in its sessions. Mr. Katsufumi Jo, Director of the Economic Affairs Division, MHLW, Mr. Naoyuki Yasuda, International Planning Director, MHLW, Prof. Ming-Kung Yeh, Director General, TFDA, and many officials from regulatory authorities in Taiwan participated in this 1st Joint Conference. The conference achieved significant results by exchanging opinions on the pharmaceutical regulatory systems and future collaborative relationship between Japan and Taiwan. The 2nd Joint Conference is scheduled to be held in autumn 2014 in Japan.



6. PMDA provides training for officials from Asian regulatory agencies (January 16)

As a part of the training course titled "Strengthening the Administrative Function for Vaccine's Quality and Safe Security" hosted by the Japan International Cooperation Agency, ten officials from five Asian regulatory agencies visited PMDA. During the training, PMDA reviewers gave lectures on securing quality and safety of vaccines, Good Clinical Practice, post-marketing safety measures and GMP in Japan and active discussions were made.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.308, December 26, 2013

1. Review of Driving Precautions in Package Inserts of Ethical Drugs
2. Important Safety Information
 - (1) Bosentan Hydrate
3. Revision of Precautions (No. 252)
 - (1) Donepezil Hydrochloride (and 5 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of December 2013)

http://www.pmda.go.jp/english/service/precautions_2013.html

English translations of review reports

The followings are current information about English version of review reports on PMDA web site.

Pharmaceuticals <http://www.pmda.go.jp/english/service/drugs.html>

Brand Name	Generic Name	Posting date
Acofide	acotiamide hydrochloride hydrate	December 26

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
February 3-7	4th PMDA Training Seminar –Reviewing of Generic Drugs-	Tokyo
February 8	PMDA Forum	Tokyo
February 9	DIA Special Symposium	Tokyo
February 18-21	APEC LSIF RHSC Meeting	Ningbo
March 3-7	1st PMDA Medical Devices Training Seminar	Tokyo
March 10	EMA/FDA/MHLW-PMDA Orphan Product Designation Workshop	London
March 25-27	26th Annual EuroMeeting Vienna 2014	Vienna

Letters from the liaison officers

Our liaison officers deliver lively reports for their activities at their stationed overseas authorities.

Collaboration between the EMA and the MHLW-PMDA in the field of orphan medicines was initiated in 2012 to accelerate the development of orphan products. The agencies currently exchange information on the legal grounds, regulatory systems and operational aspects of orphan medicine development. You might have read the details posted in each agency's website. Based on the collaboration, EMA-FDA-MHLW/PMDA joint orphan medicinal product workshop¹⁾ will be held on Monday 10 March 2014 at the EMA.

The aim of workshop is to provide information to industries as well as academics on EU, US and Japanese systems for orphan medicine designation. The workshop will be also dedicated to one-to-one meetings with EMA, FDA and MHLW-PMDA staff. It means the participants will have the opportunity to present a draft application for orphan designation and discuss issues with the three agencies. I would like to suggest the industries and academics are planning to develop orphan products.

1) http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2013/12/event_detail_000810.jsp&mid=WCob01ac058004d5c3

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PMDA's International Liaison Officers stationed at EMA in the United Kingdom



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