Chimonanthus praecox

PMDA Updates

February, 2012

News

1. Mexico to recognize equivalence to Japanese regulatory requirements for medical devices (January 25)

The Department of Health of Mexico published an ordinance in Official Gazette of the Federation on January 25, 2012 confirming that the Japanese medical device regulatory requirements to be equivalent to its own. The impelemtation of the ordinance allows applicants to reduce the amount of documantation of applications for their medical device registration in Mexico, if the products have already been approved/certified in Japan, thereby minimizing regulatory review timein the Mexican registration process. Japan is the third country to receive the preferential status from the Mexican government, following the US and Canada.

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), in cooporation with Japanese manufacturers (their local subsidiaries) and the Japanese Embassy in Mexico, had held briefing sessions in Mexico to explain the Japanese regulatory system for medical devices, upon the requests from the Federal Commission for Protection against Sanitary Risks (COFEPRIS). This arrangement will facilitate smooth introduction of the latest Japanese medical devices into the Mexican market. The ordinance comes into effect on February 24, 2012.

2. PMDA provides a training program for TFDA employees (February 1 to March 2)

On February 1, a one-month training program was commenced for two health officials from the Taiwan Food and Drug Administration (TFDA). The two trainees are both engaged in review of medical device applications and monitoring of adverse event reports at TFDA. PMDA provides the trainees with lectures on the regulatory system, review for marketing approval, and safety measures for medical devices in Japan. At the end of the training program, an internal reporting session is scheduled for the trainees to report the outcomes of the training.

3. Confidential arrangement extended between Japan and EU (February 2)

MHLW/PMDA and the European Commission/ the European Medicines Agency have extended the period of their confidential arrangement to exchange regulatory information for one year. The original confidential arrangement was to expire on February 1, 2012. Both parties recognize the importance of sharing information based on this arrangement. This extension allows continuous exchange of regulatory information, which will benefit both regulatory authorities.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.287, January 27, 2012

1. Lamotrigine-induced Severe Drug Eruption and Compliance with Dosage and Administration
2. Fatal Fire Accidents Involving Patients during Use of Long-term Oxygen Therapy
3. List of Products Subject to Early Postmarketing Phase Vigilance (as of January 2012)

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

Events

Conferences/Meetings PMDA (co-)hosted

Date	Title	Location
March 22	3rd China-Japan Symposium on Drug Development	Beijing, China

Conferences/Meetings PMDA participates in

Date	Title	Location
February 28 – March 1	International Medical Device Regulators Forum (IMDRF) Meeting	Singapore
March 26-28	DIA 24th Annual EuroMeeting	Copenhagen, Denmark
March 28-30	APEC LSIF RHSC Meeting	Singapore