



Lycoris radiata

PMDA Updates

September, 2012

News

1. PMDA's operating performance for Pharmaceutical Affairs Consultation on R&D Strategy (August 18)

PMDA announced its operating performance for the Pharmaceutical Affairs Consultation on R&D Strategy for a period of one year from July 2011 through June 2012. This consultation service started in July 2011 and is mainly intended to support universities, research institutions and ventures in their drug development. In this service, PMDA provides guidance and advice on design, etc. of studies which should be conducted during the period from the final phase of drug candidate selection to the early phase of clinical development.

Among 215 pre-consultation meetings conducted in the past one year, the most frequently addressed area was drug-related one (40% of all the topics), and the highest number of consultation meetings were requested by universities (40% of all the users). In the review categories, pre-consultations for antineoplastic drugs were the most commonly requested for drugs and the Category 8 medical devices (multicategory medical devices, advanced electronic medical devices, and other uncategorized medical devices) were the most common for devices. Besides those pre-consultations, 37 cases advanced to the full consultation on R&D strategy. PMDA also conducted 143 individual orientations to the consultation.

Please click on the [link for more details](#). (Japanese only)

2. International Liaison Officer dispatched to US (September 4)

PMDA sent Dr. Eriko Fukuda to the US as PMDA's third International Liaison Officer stationed in the US Pharmacopeia (USP) on September 4, 2012. She is the successor of Dr. Tetsuya Kusakabe, a former International Liaison Officer. Dr. Fukuda will act as the point of contact for PMDA in the US to reinforce the cooperative relationship between the US Food and Drug Administration (FDA) & USP and PMDA & the Ministry of Health, Labour and Welfare for the next one year.

Dr. Kusakabe's report during his term of office is available [here](#). (Japanese only)

3. Call for application to PMDA 3rd Training Seminar will start soon

PMDA will hold its 3rd Training Seminar for officials of foreign regulatory agencies from January 21 to 25, 2013. This seminar will address post-marketing safety measures and relief services for adverse health effects, and PMDA experts will present the outline of the PMDA's operations and the current status. Also, group work on case studies is scheduled in the program. The deadline for application is October 31, 2012.

The more detailed information will be posted on PMDA website in near future.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.293, August 29, 2012

1. Serious Adverse Reactions Associated with Over-the-counter Drugs
2. Important Safety Information
Pregabalin, Methotrexate (tablet 2 mg, capsule), Influenza HA Vaccine
3. Revision of Precautions (No. 238)
Metformin Hydrochloride, (and 9 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of Aug 2012)

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

Events

Conferences/Meetings PMDA participates in

Date	Title	Location
September 4-7	China International Medical Device Regulatory Forum	Beijing, China
September 13-14	IMDRF MDSAP WG	Ottawa, Canada
September 20-21	Swissmedic International Regulatory Symposium	Interlaken, Switzerland
September 25-27	IMDRF	Sidney, Australia
October 21-26	ICDRA	Tallinn, Estonia

