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# PMDA Updates

March, 2012

## News

### 1. The inaugural meeting of International Medical Device Regulators Forum (February 28 to March 1)

The inaugural meeting of the International Medical Device Regulators Forum (IMDRF) was held in Singapore from February 28 to March 1, 2012. The activity framework and future work plans of IMDRF were discussed in the meeting.

The regulatory authorities from Australia (the Chair), Brazil, Canada, EU, US and Japan participated in the meeting, while China, Russia and the World Health Organization joined as observers.

Its open session held on the 2nd day gathered approximately 100 participants including those from the industry. The participants exchanged their views on the transparency of IMDRF management and the effective utilization of the deliverables of GHTF. The industry stakeholders strongly requested their representatives' observer status to participate in the Management Committee.

### 2. A new partner university for PMDA's joint graduate school program (March 2)

As part of the efforts to advance regulatory science, PMDA has been maintaining its joint graduate school program. In this program, PMDA accepts students from, and sends PMDA employees to. The participating graduate schools, aiming at encouraging regulatory science research based on the experience at PMDA and developing human resources. Following the joint graduate school agreement signed with the United Graduate School of Drug Discovery and Medical Information Sciences, Gifu University in January 2012, PMDA concluded the same agreement with Teikyo University Graduate School of Medicine/Graduate School of Pharmaceutical Sciences on March 2, 2012. The latter is the ninth university participating in the program.

## Safety Information

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

1. Systemic Allergy Associated with the Use of Quasi-drugs/Cosmetics
2. Important Safety Information
  - 1) Daikenchuto
3. Revision of Precautions (No. 233)
 

Galsulfase (Genetical Recombination), Aripiprazole, Haloperidol (injectable dosage form), Chloramphenicol (vaginal dosage form), Enoxaparin Sodium, Acarbose, Voglibose, Mitiglinide Calcium Hydrate/Voglibose, Miglitol, Tacrolimus Hydrate (oral and injectable dosage forms), Lenalidomide Hydrate, Saireito, Sitafloxacin Hydrate, Lopinavir/Ritonavir, Daikenchuto (Over-the-counter drug)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of February 2012)

[http://www.pmda.go.jp/english/service/precautions\\_2011.html](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
March 26-28	DIA 24 <sup>th</sup> Annual EuroMeeting	Copenhagen, Denmark
March 28-30	APEC LSIF RHSC Meeting	Singapore