



# PMDA Updates

December, 2011

## News

### 1. ICH meeting held in Seville (Steering Committee/Expert Working Groups) (November 5–10)

PMDA sent their experts to the ICH Steering Committee and Working Group meetings held in Seville, Spain. During this ICH meeting, the S<sub>2</sub> (R<sub>1</sub>) guideline (revision: Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use), which a Japanese expert plays as a rapporteur in its formulation development, reached Step 4 of the ICH process, and three documents on points to consider on the implementation of Q<sub>8</sub>, Q<sub>9</sub> and Q<sub>10</sub> Guidelines were finalized. In addition, the Working Groups discussed other 13 topics including E<sub>2</sub>B (R<sub>3</sub>) (revision: Electronic Transmission of Individual Case Safety Reports Implementation Guide—Data Elements and Message Specification), E<sub>2</sub>C (R<sub>2</sub>) (revision: Periodic Safety Update Reports for Marketed Drugs), and Q<sub>11</sub> (Development and Manufacture of Drug Substances).

The next ICH meeting will be held in Fukuoka, Japan from June 2 to 7, 2012.

### 2. Pharmacopoeial Discussion Group meeting held (November 8-9)

The meeting of the Pharmacopoeial Discussion Group (PDG), consisting of the European Directorate for the Quality of Medicines and HealthCare (EDQM), the United States Pharmacopoeial Convention, Inc (USP) and the Ministry of Health, Labour and Welfare/PMDA of Japan, was held at the EDQM headquarters in Strasbourg, France. PMDA's representatives were sent to the PDG meeting to discuss harmonization of General Chapters and excipient monographs among the three pharmacopoeias. In this meeting, four revised excipient monographs were harmonized, and as a result, 28 of the 35 General Chapters and 41 of the 61 excipient monographs of the current work programme have been harmonized so far. PDG keeps showing a meaningful, steady progress. The next PDG meeting will be held in Tokyo, Japan in 2012.

### 3. PMDA's vision in the international arena (November 17)

PMDA is striving to carry out its international activities in line with the PMDA International Strategic Plan, aiming to be one of the leading regulatory agencies in the world, which is stated in the Second Mid-term Plan over the period from fiscal years 2009 to 2014. Recently, PMDA has formulated a vision statement to provide a clear picture of how PMDA should be over the next 5-10 years in the international arena of pharmaceutical and medical device regulation (hereinafter, "the Vision") and released it on its website. (The Vision statement is currently available in Japanese only, but the English version will be posted shortly.)

The Vision mainly focuses on the following points: (1) Securing the world's top-level Excellence in Performance, (2) Maintaining close partnership with the Orient, and (3) Actively contributing to international harmonization activities.

Taking the Vision to heart, every PMDA staff member will pursue their individual international activities in line with the overall purpose of the Agency.

#### 4. Indonesian government delegation visited PMDA (November 29)

The Indonesian government delegation including the officials of the National Agency of Drug and Food Control (NADFC) visited PMDA on November 29. The delegation intended to do research on Japanese regulations on pharmaceuticals and food towards formulation of new legislation to regulate pharmaceuticals and food in Indonesia.

To facilitate their research, PMDA explained the outline of Japan's regulatory system under the Pharmaceutical Affairs Act and PMDA's activities. Also, PMDA's reviewers and inspectors answered the questions which PMDA had received from the Indonesian officials in advance, followed by an additional Q&A session.

## *Safety Information*

### Pharmaceuticals and Medical Devices Safety Information No.285, November 30

1. Safety Measures against Nephrogenic Systemic Fibrosis Associated with Gadolinium Contrast Media
2. Carbamazepine-induced Serious Drug Eruption and Genetic Polymorphism
3. Important Safety Information
  - 1) Anastrozole
  - 2) Temozolomide
  - 3) Ritodrine
4. Revision of Precautions (No. 231)  
Atomoxetine Hydrochloride, Dasatinib Hydrate, Varenicline Tartrate, Zoledronic Acid Hydrate, Pamidronate Disodium Hydrate, Alendronate Sodium Hydrate (oral dosage form), Etidronate, Disodium, Sodium Risedronate Hydrate, Alendronate Sodium Hydrate (injectable dosage form), Minodronic Acid Hydrate
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of November 2011)

[http://www.pmda.go.jp/english/service/precautions\\_2011.html](http://www.pmda.go.jp/english/service/precautions_2011.html)