



*Diospyros kaki*

# PMDA Updates

October, 2012

## News

### 1. PMDA participated in the 3rd China International Medical Device Regulators Forum (September 4 to 7)

The 3rd China International Medical Device Regulatory Forum (CIMDR) was held in Beijing, from September 4 to September 7, 2012, and five experts from PMDA participated. In its plenary meeting, Dr. Tamura, International Coordination Officer for Medical Devices and the PMDA experts made presentations on the Japanese medical device regulations, outline of regulatory review of medical devices, PMDA's Pharmaceutical Affairs Consultation on R&D Strategy and updates of QMS inspection, etc. In addition, they also delivered presentations in its UDI (Unique Device Identification) session on the 3rd day. The 4th CIMDR is scheduled to be held in September, 2013 in Xian.

### 2. Provision of Dear Healthcare Professional Letters of Rapid Safety Communications (September 11)

On September 11, 2012, PMDA posted the safety information on "Alert for the risk of severe hypocalcaemia in patients who take RANMARK® (denosumab)" on its Safety Information announced by MHLW web page, as Dear Healthcare Professional Letters of Rapid Safety Communications (blue letter). Simultaneously PMDA distributed the information via the Pharmaceuticals and Medical Devices Information E-mail Alert Service, which is known as the PMDA Medi-Navi, to its subscribers. Regarding the RANMARK® (Non-proprietary name: denosumab), the therapeutic product for preventing the progress of bone lesion, 32 cases of adverse drug reactions of serious hypocalcaemia were reported in the period between April, 2012, when its sales began, and August, 2012. Among the 32 cases, 2 fatal cases were included where the connection with use of the product can not be denied. Based on the reports, the Ministry of Health, Labour and Welfare (MHLW) required the marketing authorization holder of RANMARK® (denosumab) to add "WARNING" to the section of "PRECAUTIONS" in its package insert to call attention and to provide healthcare professionals with necessary information in a promptly by releasing a Rapid Safety Communication.

Click the link for more details "[Healthcare Professional Letters of Emergent Safety Communications](#)" and Dear "[Healthcare Professional Letters of Rapid Safety Communications](#)".

### 3. Subcommittee meetings of the Science Board held (September 24)

PMDA held the subcommittee meetings of the Science Board for specialized areas of pharmaceuticals, medical devices, biotechnological products, and cellular and tissue-based products, on September 24, 2012. After roles of the subcommittees were explained in the joint subcommittee meeting, each of the subcommittees discussed the proposed agenda for each specialized area and its review methods in the future plan for the discussion.

Click [here](#) for the materials and minutes of the subcommittees. (Japanese only)

#### **4. PMDA's Participation in the 2nd International Medical Device Regulators Forum (September 25 to 27)**

The 2nd International Medical Device Regulators Forum (IMDRF) was held on September 25-27, 2012 in Sydney, Australia, and PMDA sent its members to the Management. The forum was a closed meeting only for administrative officials on the first day and the last day, and the open session was held on the second day to which stakeholders were invited. In the forum, the outcomes of ongoing working groups were reported and the stakeholders had an opportunity to express their opinions. Based on the requests from the open session in the previous meeting, representatives of the industry were invited as observers to the limited part of agenda in the Management Committee, and they delivered their views. In addition, the prototype of IMDRF website developed by the secretariat was discussed. The next meeting will be held in France in March, 2013.

#### **5. Dr. Kondo, the Chief Executive of PMDA, delivered a speech in the Swissmedic International Regulatory Symposium (September 19)**

Dr. Kondo, Chief Executive of PMDA made a presentation at the Swissmedic International Regulatory Symposium which celebrates the tenth anniversary of the establishment of Swissmedic. The symposium was held for 2 days, on September 19 and 20, in Interlaken, Switzerland, and the participants discussed the wide-ranging topics such as roles of the regulatory agencies, and response to the emerging global issues under the main theme of "Approving & monitoring therapeutic products." Dr. Kondo introduced PMDA's efforts to control benefit-risk balance of drugs through the life cycle of drugs in Japan highlighting the Risk Manager System and the Risk Management Plan which were adopted recently in Japan.



#### **6. Dr. Tzou, Director of Division of Drugs and New Biotechnology Products, the Taiwan Food and Drug Administration visited PMDA (September 27)**

Dr. Meir-Chyun Tzou, Director of Division of Drugs and New Biotechnology Products of the Taiwan Food and Drug Administration (TFDA) visited PMDA on September 27, 2012. After making courtesy calls to Dr. Kondo, Chief Executive of PMDA and other executives, she had briefings on PMDA's service of review consultation, review system for generic drugs and over-the-counter (OTC) drugs and risk management plan, etc. In addition, views on the direction of future cooperative relationship were exchanged. Dr. Tzou and other officials stayed in Japan for 6 days as a part of the invitation programs by the Interchange Association, Japan.

#### **7. Reorganizaion of Center for Product Evaluation (October 1)**

As of October 1, PMDA made organizational changes: the scope of administration of Office of Biologics I and Office of Biologics II were reorganized. At the same time, names of the two offices were changed to the Office of Cellular and Tissue-based Products (mainly review cellular and tissue-based products, biologics) and the Office of Vaccines and Blood Products (mainly review of vaccines, blood products) respectively. It is expected that this organizational change reinforces the consultations and review systems on cellular and tissue-based products using the latest technologies and vaccines and promotes further cooperation with Pharmaceutical Affairs Consultation on R&D Strategy, the Science Board and various personnel exchange projects.

More details are available in [News Release](#).

## 8. Human Resource Exchange with universities and research institutions (October 1)

PMDA has started to implement human resource exchange with universities and research institutions based on the "Initiative for Accelerating Regulatory Science in Innovative Drug, Medical Device, and Regenerative Medicine" by the Ministry of Health Labour and Welfare (MHLW), on October 1. This initiative is intended to a) develop guidelines for evaluation of innovative products by establishing assessment methods of safety and efficacy of such products based on regulatory science at universities and research institutions which conduct researches of the latest technologies, and b) promote exchanges of personnel and nurture human resources with knowledge of the latest technologies.

Click [here](#) for more details

## 9. GHTF 13th Conference will be held (October 31 to November 1)

The 13th and the last Global Harmonization Task Force (GHTF) Conference will be held from October 31 to November 1, 2012 in Tokyo. The activities of GHTF will be terminated at the end of December 2012, and this conference will be a compilation of the past activities. In this final conference, past GHTF activities will be summarized, and presentations on broad-ranging topics such as regulatory update from member countries / regions, Unique Device Identification (UDI), software for medical device are scheduled to be made.

Click [here](#) for more details.

## 10. Call for application to PMDA 3rd Training Seminar has started

PMDA started to receive the application to the 3rd PMDA Training Seminar for foreign regulatory officers. It will cover post-marketing safety measures and relief services for adverse health effects, and PMDA experts will give lectures on the outline and the current status of the PMDA's operations. Also, group work on case studies is scheduled in the program.

The seminar will be held from January 21 to 25, 2013.

Click [here](#) for more details.

# Safety Information

## Pharmaceuticals and Medical Devices Safety Information No.294, September 26, 2012

1. Proper Use of Contact Lenses and Prevention of Eye Disorders
2. Summary of Report on Adverse Reactions to the Influenza Vaccine in the 2011 Season
3. Important Safety Information  
Oxaliplatin
4. Revision of Precautions (No. 238)  
Suxamethonium Chloride Hydrate (and 6 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance (as of Sep 2012)

[http://www.pmda.go.jp/english/service/precautions\\_2012.html](http://www.pmda.go.jp/english/service/precautions_2012.html)

## Events

### Conferences/Meetings PMDA participates in

Date	Title	Location
October 21-26	International Conference on Drug Regulatory authorities (ICDRA)	Tallinn, Estonia
October 31 to November 1	Global Harmonization Task force (GHTF) 13th Conference	Tokyo, Japan
November 10-15	ICH meeting	San Diego, US

## Letters from the liaison officers

New section starts to deliver the local reports from PMDA's International Liaison Officers.

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Six months have already passed since I started to work as PMDA's new liaison officer stationed in European Medicines Agency (EMA) on May 1.

Along with taking over predecessor's works, I would like to work hard to strengthen further cooperative relationship between EMA/EC and MHLW/PMDA, while relying on my past background. I strongly feel more than ever that the contents of the discussion made in EMA have many affinities with the contents discussed in PMDA. We have exchanged our views on the drugs in various phases such as development, under review and post-marketing, over the past year but I realized that exchange of our views more promptly than before. I hope that the information exchange on each item is not only for mutual understanding on each item but also it will lead to mutual constant thinking. I would like to continuously push forward with the promotion of further mutual understanding and the enhancement of cooperative system between both agencies. I kindly ask for continued cooperation.

Dr. Junko Sato  
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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I was dispatched as PMDA's new liaison officer stationed in United States Pharmacopeia (USP) from September 4, 2012.

I would like to work hard to take over the coordination and collaborative alliance between UPS/FDA and MHLW/PMDA which were established by successive liaison officers and also further reinforce them. Three months have passed since I was assigned to UPS, I feel grateful for the kindly accepting me in every related organization. Now I am making efforts to understand the structure of the organization and contents of the works in USP such as the affairs related to coordination with Japanese Pharmacopoeia.

Also, with respect to Food and Drug Administration (FDA), I have just started to exchange information with the officers responsible for FDA's international affairs. The trainees from administrative agencies and laboratories and the visitors all around the world have visited FDA. The international information has been lively exchanged on a daily basis here.

I realize the position of FDA in the world every day.

Dr. Eriko Fukuda  
PMDA's International Liaison Officers stationed at USP in the United States

