Wisteria floribunda

PMDA Updates

May, 2014

News

1. PMDA Expert Dispatched to CDER, U.S.FDA (April 16)

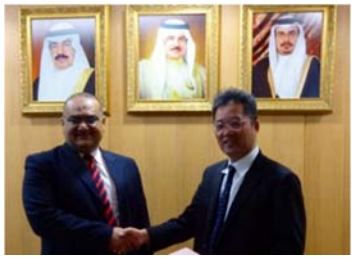
On April 16, PMDA sent Ms. Mami Yabuki, inspector, Office of GMP/QMS Inspection (concurrently assigned to Office of International Programs), to the Center for Drug Evaluation and Research (CDER), U.S.FDA. She is expected to engage in exchanging information and opinions on the system and methodology of Good Manufacturing Practice (GMP) inspection. The term of the dispatch is for three months.

2. Representatives of PMDA visit to NHRA and Ministry of Health of the Kingdom of Bahrain (April 20, 21)

On April 20, Dr. Nobumasa Nakashima, Director, Office of International Programs, PMDA, and a staff member of the Office of International Programs, visited the National Health Regulatory Authority (NHRA) and held a bilateral meeting with Mr. Ahmed Abdelsalam Hafez, Legal Affairs Advisor, NHRA, and other executives. In the meeting, the following two points were clarified. 1) Approved products in Japan are subject to abbreviated review in Bahrain. 2) Japanese Pharmacopoeia is the reference standard in Bahrain. These clarifications will be released on NHRA web site. In addition, PMDA Training Seminar and medium term training for officials from overseas regulatory agencies hosted by PMDA were introduced during the talks, and the future participation from Bahrain was called for.

On April 21, Dr. Nakashima and the staff member made a courtesy call on Mr. Sadiq Abdulkarim Al Shehabi, Minister of Health, Ministry of Health of the Kingdom of Bahrain, and Dr. Aysha Mubarak Buaneq, Undersecretary of the Ministry. Dr. Nakashima introduced pharmaceutical regulations in Japan and opinions were exchanged on the cooperative relationship between Japan and Bahrain in the meeting.

PMDA's meetings with NHAR and the Ministry of Health of the Kingdom of Bahrain attracted attention such as being reported in the leading three Bahrain's newspapers.



Left: from left, Mr. Hafez, Dr. Nakashima
Right: forth from left to right, Dr. Buaneq, Dr. Nakashima, Mr. Shehabi, Mr. Daisuke Yamamoto (Counsellor, Deputy Chief of Mission, Embassy of Japan, Kingdom of Bahrain)

3. APEC MRCT / GCP Inspection Workshop (May 8 to 10)

APEC Multi-Regional Clinical Trials (MRCT) / Good Clinical Practice (GCP) Inspection Workshop was held from May 8 to 10 in Qingdao. In this workshop, PMDA staff members made six presentations including the outcome of MRCT Gap Analysis elaborated by Japanese working group. The speakers were not only from Asia-Pacific area but also from EMA. The participants could share the current situations of MRCT and GCP inspection and discussed toward the future progress in these areas.

4. Bilateral meeting with NA-DFC and the 2nd Indonesia-Japan Symposium (May 20, 21)

On May 21, the 2nd Indonesia-Japan Symposium was held in Jakarta, co-hosted by PMDA, National Agency of Drug and Food Control (NA-DFC), Japan Pharmaceutical Manufacturers Association, and Gabungan Perusahaan Farmasi Indonesia (GPFI). From PMDA, Dr. Taisuke Hojo, Senior Executive Director, Mr. Shinobu Uzu, Director, Office of New Drug I, and three other staff members participated in the symposium. From NA-DFC, many staff members headed by Ms. Antonia Rento Tyas Utami, Deputy-I, participated in the symposium. The presentations and discussions took place under the theme of "Ensuring and Enhancing Quality Assurance of Medical Products", and the participants from both regulatory agencies and from pharmaceutical industries deepened the understanding of each other's regulatory systems in the symposium. The discussions lively took place with approximately 150 participants and a great expectation was risen for sharing information based on Japan's experiences and regular holding of the symposium in the future.

On May 20, a bilateral meeting between PMDA and NA-DFC was held. In the meeting, expectations for PMDA were presented by NA-DFC and further cooperation in the future was agreed.

The details of the symposium are available at following PDF file.

http://www.pmda.go.jp/english/events/pdf/symposium20140513_e.pdf

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.312, April 30, 2014

1. Use of Dermatologic Ketoprofen during Pregnancy
2. Important Safety Information
3. Revision of Precautions (No. 255)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of April 2014)

http://www.pmda.go.jp/english/service/precautions_2014.html

Events

Conferences / Meetings PMDA hosts or participates in:

Date	Title	Location
May 31-June 5	ICH US meeting	Minneapolis
June 15-19	The 50th DIA Annual Meeting	San Diego
June 16-17	The 4th ASEAN-USP Scientific Symposium	Da Nang
June 25-26	Pharmacopoeial Discussion Group Meeting	Rockville
July 24-26	CVIT2014 HBD Session	Nagoya

Reports from overseas

Our officers deliver lively reports for their activities at their stationed overseas authorities.

The meeting entitled "2nd Periodic Safety Update Report Information Day" was held in EMA on April 29. The representatives from regulatory authorities in EU, Canada, and Japan, and pharmaceutical industries, participated in the meeting. They reported on the status of the introductions and implementations of periodic safety report system and ICH E2C (R2) guideline (the Periodic Benefit-Risk Evaluation Report). It was an honor for me to have an opportunity to make a presentation to explain the situation in Japan during the meeting, even though I am new to the current post. In particular, I mainly introduced an overview of Japan's periodic safety report system, and enforcement of the new system based on E2C (R2) on October 1 this year and setting a new reporting deadline within 70 days (90 days in case the report written in non-Japanese languages)[1)].

In the meeting, I keenly felt the significance of international cooperation through a very active question and answer, and opinion exchanges between speakers and participants. I expect that explanation on Japan's system and its implementation status may be required at various future opportunities and therefore I would like to proactively provide information on Japan's situation including PMDA's to EMA colleagues and other concerned parties.

Please refer to the following PDF file for the details of the meeting.
http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/04/WC500164978.pdf

1) Notifications for reference:
"Enforcement of the Ministerial Ordinance on partial amendment of Pharmaceutical Affairs Law and its Enforcement Regulation, and Periodic Safety Update Reports system for new medicines" (PFSB Notification No. 0517-2, of the Food Safety Bureau, MHLW)
"On Periodic Benefit and Risk Evaluation Report (PBRER)" (PFSB/SD Notification No. 0517-1, of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW)

Mr. Yoshihiko Sano
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

---

"Contribution to Master's degree program"

Swissmedic contributes to master's degree program in Medicinal and Industrial Pharmaceutical Sciences (MIPS) at ETH Zürich and sends its staff members as lecturers several times a year. Among them, there was a lecture to introduce international cooperation of Swissmedic. I attended MIPS for 2 days as a lecturer as well as the "Living example" of international collaboration. Approximately 20 students from Switzerland, other European countries (most of them have dual nationality in Switzerland and the other European country), Middle East, and China, attended the program. The language used in the lecture is English (English is not an official language in Switzerland), although most of the students understand German. In addition to the international relationship of Swissmedic, we also had a lecture on "Requirement for European submission" on the days I attended. I explained Japanese situation in the course of comparing differences in submission requirements between EMA and Swissmedic. I found similarity between the students here and in Japan since they were not so actively participated during the lectures but suddenly became active when they did group work.

PMDA also contributes to lectures at master's degree courses through our joint graduate school program. I am interested in how other regulators are doing.

Dr. Jun Kitahara
PMDA's International Liaison Officer stationed at Swissmedic in the Switzerland

---

I am Kosuke Haneda who have been stationed at Health Canada since April. For the past one month, I have learned about the system of safety measures for drugs and medical devices in Canada. I truly appreciate a warm welcome I have received from staff members in the department of post-marketing safety measures and I also thank them for having shown me their daily duties including detection of safety signals, evaluations of risk management plan, periodic safety update reports for marketed drugs, and periodic benefit-risk evaluation reports. I would like to gain a further understanding of the differences in evaluation processes of safety information between Health Canada and PMDA, and to make use of the knowledge I obtained for the collaboration with Health Canada in the future.

As a Federal department, Health Canada treats English and French equally because they are official languages in Canada, and signs, posters on notice boards, and so on are displayed in both languages. Moreover, management staff are required to be English-French bilingual. The bilingual proficiency exam is performed periodically and the language training programs are also provided when necessary.

The opportunities that PMDA accepts officials from overseas regulatory agencies are increasing, and I believe the above mentioned measures may be a good reference for us when accepting non-Japanese native officials.

Mr. Kosuke Haneda
PMDA's International Liaison Officer stationed at Health Canada in the Canada

---

I am Mami Yabuki, Inspector, Office of GMP/QMS Inspection (concurrently assigned to Office of International Programs), stationed at Center for Drug Evaluation and Research (CDER), U.S.FDA. The dispatch period will be for 3 months from April 16 to July 10. Throughout my stay in CDER, I will be assigned to work at Office of Strategic Programs (OSP). This office is responsible for establishing various strategic plans and implementing them, closely collaborating with other offices in CDER and with offices outside of CDER, such as the Office of Regulatory Affairs (ORA). I have started joining several workgroups on topics that are related to Good Manufacturing Practice (GMP) inspections, and participated in the exchange of opinions on the various regulatory subjects. Through my involvement in these workgroups, I would like to learn about current thinking on key issues at CDER, and CDER's ways including its model for the risk-based site selection for inspections, systems for management of manufacturers' data, and GMP inspection procedures at ORA, which enable me to suggest improvements in the PMDA's GMP inspections. At the same time, through these workgroups and other meetings, I am sharing information of PMDA's experience in inspections and regulatory practices with colleagues in CDER who are eager to learn about practices at PMDA. I would like to make the best use of this opportunity to establish close relationships with U.S.FDA staff and to deliver information for PMDA and subscribers.

Ms. Mami Yabuki
PMDA's International Officer stationed at CDER, U.S.FDA in the U.S.A.
