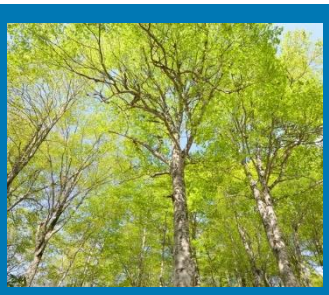

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PMDA Updates

May, 2017

News

1. The 6th Asia Partnership Conference of Pharmaceutical Associations

Dr. Kondo

On April 5, the 6th Asia Partnership Conference of Pharmaceutical Associations (APAC) was held in Tokyo, and was attended by Dr. Tatsuya Kondo, Chief Executive; Dr. Shingou Sakurai, Office Director, Office of Manufacturing/Quality and Compliance; and Dr. Junko Sato, Office Director, Office of International Cooperation, and other 6 staff members from PMDA. The conference held under the theme of "Accelerating Access To Innovative Medicines through advancing collaborative partnership in Asia" was also attended by participants including regulators from Indonesia, Korea, Singapore, Taiwan, and Thailand, and presentations and panel discussions were conducted. Dr. Sakurai chaired the session "Sharing Evaluation Process for GMP Compliance Assessment and Finding Opportunities to Improve Efficiency - Aiming early approvals of innovative medicines in Asia" and moderated active discussions toward more efficient evaluation process for GMP compliance assessment. Dr. Sato introduced and chaired the session "Toward Efficient & High-Quality Registration Process for Innovative Medicines -Campaign for Rolling out the Good Registration Management" where she outlined the activities of PMDA Asia Training Center (PMDA-ATC), and moderated active discussions toward the promotion of Good Registration Management.

The 7th APAC will be held in April 2018, in Tokyo.

2. The 9th Asia Regulatory Conference

Dr. Tominaga (left) at closing panel discussion

The 9th Asia Regulatory Conference (ARC) was held in Tokyo from April 6 to 7, attended by Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; Mr. Naoyuki Yasuda, Office Director, Office of International Programs; and Dr. Junko Sato, Office Director, Office of International Cooperation from PMDA as well as Mr. Kazuhiko Mori, Councilor for Pharmaceutical Affairs, Minister's Secretariat and Dr. Daisaku Sato, Director, Safety Division, Pharmaceutical Safety and Environmental Health Bureau from MHLW. ARC this year was cohosted by International Federation of Pharmaceutical Manufacturing & Associations (IFPMA) and Japan Pharmaceutical Manufacturers Association (JPMA) in collaboration with PMDA. The conference convened under the theme of "Optimizing Access to Medicines in Asia through Regulatory Excellence" included presentations from regulatory agencies on the updates on global regulatory harmonization initiatives (e.g. APEC-LSIF-RHSC, ICH, PIC/S), and from industry on expectations for collaboration between regulatory agencies, which led to active discussions among participants from regulatory agencies and industry.

Conference scene

3. 2nd India-Japan Medical Products Regulation Symposium

On April 24, the 2nd India-Japan Medical Products Regulation Symposium was held in Tokyo between Ministry of Health and Family Welfare (MoHFW)/Central Drugs Standard Control Organization (CDSCO) of India and MHLW/PMDA of Japan.

This symposium was initiated as part of the cooperation activities based on the "Memorandum of Cooperation on Medical Products Regulation Dialogue and Cooperation Framework" signed between CDSCO and MHLW in December 2015.

Those who participated in the symposium included Dr.Tatsuya Kondo, Chief Executive; Mr. Haruo Akagawa, Senior Executive Director; Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; and Mr. Naoyuki Yasuda, Office Director, Office of International Programs from PMDA; Mr. Toshihiko Takeda, Director General, Pharmaceutical Safety and Environmental Health Bureau; Mr. Kazuhiko Mori, Councilor for Pharmaceutical Affairs, Minister's Secretariat; and Dr. Nobumasa Nakashima, Office Director for International Regulatory Affairs; and Mr. Yasuhiro Sensho, former Secretary at Embassy of Japan in India from MHLW. Participants from India included Sh. K. L. Sharma, Joint Secretary from MoHFW; and Dr. G. N. Singh, Drugs Controller General and Dr. V. G. Somani, Joint Drugs Controller from CDSCO. In the symposium, presentations were provided by the regulators of both countries on the overview and updates on the regulations of pharmaceuticals and medical devices, and by the industries on their activities to address regulatory requirements, which was followed by discussion. On the following day, April 25, a bilateral meeting was held where regulators of India and Japan exchanged views on future regulatory harmonization and cooperation. The symposium was informative with a presentation of an overview of a new Medical Devices system in India (to be implemented in 2018). The bilateral meeting agreed on concrete areas of cooperation between India and Japan in terms of international conferences and GMP/GCP inspections.

MHLW's press release is available at the following link.

http://www.mhlw.go.jp/stf/houdou/0000163590.html (in Japanese)

4. Tripartite Meeting held between EMA, FDA and PMDA towards enhancing development for Antibacterial Agents

From April 26 to 27, a tripartite face-to-face meeting was held between the EMA, FDA and PMDA in Vienna, Austria which was the second meeting toward facilitating antimicrobial drug development, following the previous meeting in last September.

This meeting was held in response to the proposal by PMDA to EMA and FDA to explore tripartite collaboration in developing guidelines. From PMDA, Mr. Yoshikazu Hayashi (Associate Center Director), Dr. Junko Sato (Office Director, Office of International Cooperation) and a staff member attended the meeting. This meeting focused on discussion of study design for each disease, etc., aiming convergence of regulatory requirements.

A summary of the outcome of the meeting will be available at web sites of the three agencies in the same way as the previous meeting.

English translations of review reports

The followings are current information about English version of review reports on PMDA web site.

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Generic Name	Posting date	Brand Name
Proemend	fosaprepitant meglumine	April 26	Proemend
Repatha	evolocumab (genetical recombination)	April 26	Repatha

Safety Information

Risk Information which some safety measures might be taken (April 28, 2017)

- Treprostinil
- Dulaglutide (genetical recombination)
- Bosutinib hydrate
- Pneumococcal vaccine

http://www.pmda.go.jp/english/safety/info-services/drugs/risk-communications/0001.html

Pharmaceuticals and Medical Devices Safety Information No. 343, May 23, 2017

1. Project of the Japan Drug Information Institute in Pregnancy
2. Revision of Precautions (No. 284)
   Denosumab (and 2 others)
3. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0015.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
May 27- June 4	ICH Week	Montreal
June 5-8	5th International Generic Drug Regulators Programme (IGDRP) meeting	Ottawa
June 18-22	DIA 53rd Annual Meeting 2017	Chicago
June 19	International Coalition of Medicines Regulatory Authorities (ICMRA) meeting	Chicago
June 26-30	PMDA-ATC Pharmaceuticals Review Seminar 2017	Tokyo
July 6-8	CVIT 2017 HBD Town Hall Meeting	Kyoto

July 31-August 4	PMDA-ATC GMP Inspection Seminar* (*with the support of PIC/S)	Yamaguchi

Reports from overseas

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

Importance of exchanging opinions with representatives in Japanese pharmaceutical companies who are active in London

I have had some opportunities to exchange opinions with representatives from Japanese pharmaceutical companies who live and work in London, and everyone I met is very energetic. The functions of their London offices depend on the companies, but personally, I have an impression that there are relatively many persons in Development Department while seeing those in a wide range of departments such as Safety Department, Sales Department and Business Alliance Department.

In addition, there are some persons in Pharmaceutical Affairs Department. Though I often communicated with representatives from this kind of department during my work in Japan, those who are working in London seem even more strong-minded than those I met in Japan. This might be due to the necessity of higher vitality, as their business quite often covers the whole Europe as well as USA in some cases.

These people working actively in London actually perform businesses not only within companies and between companies but also with academia and even EMA. They provide me with significant opportunities to hear their insights/opinions based on the outside perspectives as well as experiences in Japan and Europe.

Furthermore, it is valuable that we can talk about cultural aspects and everyday life issues. I hope to make use of such opportunities for exchanging opinions in order to promote my liaison work smoothly.

Mr. Hideyuki Kondo
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

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ExcipientFest Americas 2017

ExcipientFest Americas 2017 was held in Rhode Island on April 24-26[1]. ExcipientFest Americas is a forum focusing on pharmaceutical excipients and has been held annually in the U. S. This forum is composed of an excipient industry's leading exposition and workshops/seminars for new technologies and regulatory issues on pharmaceutical excipients. In the current forum, a formulation technology using a 3D printing technique, regulatory trends on elemental impurities around the world, regional differences of regulations applied to pharmaceutical excipients and others were introduced. USP also hosted a workshop and displayed an exhibition booth. In addition, USP staff and expert volunteers gave several presentations in educational sessions and presented a poster. USP actively built a network with their stakeholders through the activities.

In the workshop hosted by USP, several important topics were discussed, including efforts for consistency of nomenclature between the U.S. FDA Inactive Ingredient Database and excipient monographs in the USP-NF, impact of excipient variability on drug products, influence of an excipient and its impurities on formation of insoluble particulate matters in protein preparations, as well as overview of the workshop[2] which was held at USP headquarters this February. These presentations included the background of standard developments and revisions currently conducted by USP.

I believe it is important to understand the standard setting activities as well as the recent trends and issues of the area in the counterpart country in order to make a progress in global harmonization. I will continuously gather and provide information regarding trends and issues including regulations for pharmaceutical quality in the U.S. through this PMDA Updates.

1) http://www.excipientfest.com
2) http://www.usp.org/sites/default/files/events/workshops/2016/fda-and-usp-workshop-standards-pharmaceutical-products-critical-importance-excipients-product-development-why-excipients-are-imp/e-program-2017-02-27.pdf

Dr. Yujiro Kameyama
PMDA's Liaison Officer stationed at USP in the U.S.A

