



Rosa

PMDA Updates

August, 2015

News

1. PMDA training to the exchange group from Henan Food and Drug Administration, China visiting Japan (July 30)

PMDA provided a training to 5 officials from Henan Food and Drug Administration and Henan Provincial Institute of Food and Drug Control in China on reviews of pharmaceuticals, post-marketing safety measures and relief for adverse health effects, etc. at PMDA's Tokyo office on July 30. This training was provided for the first time as requested by Henan Food and Drug Administration through Japan China Economic Cultural Exchange Center.



2. CVIT 2015 HBD Town Hall Meeting (August 1)

Six PMDA members, including Dr. Yuka Suzuki, Director, Office of Medical Devices II, participated in the Harmonization By Doing (HBD) Town Hall Meeting held in Fukuoka on August 1, in conjunction with the 24th Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics Meeting (CVIT 2015). In this session entitled "Change and Harmonize", presentations were given on PMDA's efforts towards accelerated medical device development, regulatory framework, medical device development by universities and venture companies in the US and Japan, and consolidated efforts to promote global clinical trials, followed by active discussions.

HBD Steering Committee is planning to hold HBD East 2015 Think Tank Meeting on September 18th in Kyoto, after the International Medical Device Regulators Forum (IMDRF) 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
Daklinza and Sunvepra (as dual therapy)	daclatasvir (Daklinza) and asunaprevir (Sunvepra)	August 10
Suglat	ipragliflozin L-proline	August 21

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 325, August 6, 2015

1. Surveillance on Access to, Dissemination, and Utilization of Drug Safety Information in Medical Institutions
2. Important Safety Information
 - (1) asunaprevir and daclatasvir hydrochloride
 - (2) abiraterone acetate
 - (3) indapamide
 - (4) influenza HA vaccine
 - (5) interferon beta-1a (genetical recombination)
3. Revision of Precautions (No. 266)

Tramadol hydrochloride (OD tablets, capsules, and injection) and tramadol hydrochloride/acetaminophen (and 2 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of June, 2015)

<http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0013.html>

Pharmaceuticals Revisions of PRECAUTIONS, August 6, 2015

- hydroxyzine hydrochloride (Tablets)
 - hydroxyzine hydrochloride (Injection)
 - hydroxyzine pamoate (Powder)
 - hydroxyzine pamoate (Tablets)
 - hydroxyzine pamoate (Capsules, Dry Syrup)
 - hydroxyzine pamoate (Syrup)
 - memantine hydrochloride
 - deferasirox
 - sterile talc
 - panitumumab (genetical recombination)
 - pomalidomide
 - laninamivir octanoate hydrate
 - zanamivir hydrate
- <http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0003.html>

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
September 3	Celebrating MHLW's and PMDA's new International Strategic Plans "Toward further promotion of regulatory science and global capacity building"	Tokyo
September 10	The 2nd Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices	Tokyo
September 14-18	IMDRF Management Committee (MC) Meeting, HBD Think Tank	Kyoto

October 11-13	Global Coalition for Regulatory Science Research (GCRSR)	Milan
October 19-23	6th PMDA Training Seminar	Tokyo
October 24-28	RAPS' Regulatory Convergence 2015	Baltimore

Reports from overseas

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

Encouragement of use of scientific advice for non-imposed post-authorisation safety studies (PASS)

EMA published the launch of a 12-month pilot to encourage companies to use scientific advice for non-imposed PASS on July 28. A formal PASS scheme was started in 2012 aiming to identify or quantify a safety hazard, confirm the safety profile of a medicine, and measure the effectiveness of risk-management measures. A PASS is currently obligatory only for those products where this is a specific condition as part of the approval. This pilot aims to encourage companies to use scientific advice for non-imposed safety studies to help foster a more integrated approach to planning of safety, quality and efficacy studies during the lifecycle of a medicine in the interests of the patients. This pilot will be implemented in collaboration with Pharmacovigilance Risk Assessment Committee (PRAC) and Scientific Advice Working Party (SAWP).

Safety studies of pharmacovigilance are important not only in EU but in Japan. I consider we need to continue to pay attention to implementation and result of this pilot.

(Reference)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/07/news_detail_002382.jsp&mid=WCob01ac058004d5c1

Mr. Yoshihiko Sano

PMDA's International Liaison Officer stationed at EMA in the United Kingdom

New cycle (2015-2020 cycle) of the USP

The USP started its new Council of Experts 2015-2020 cycle on July 1, 2015. At the beginning of this new cycle, the USP held training for members of Expert Committees on July 20-21 at the USP headquarters and Bethesda North Marriott Hotel. Expert Committees consist of volunteers and roughly half of their members are newly elected for this new cycle, while the other half are returning experts from the 2010-2015 cycle. The training included an overview of the USP and its standards-setting process. The Expert Committee structure was reorganized for this cycle to optimize its ability to set and update USP standards. For example, the Excipient monographs Expert Committee which was one Expert Committee in the previous cycle was divided into two Expert Committees. One Expert committee (The Excipient Monographs 1 Expert Committee) is mainly responsible for developing new and revising existing monographs and their associated reference standards for pharmaceutical excipients. The other Expert Committee (The Excipient Monograph 2 Expert Committee) is mainly responsible for global harmonization activities including the Pharmacopoeial Discussion Group (PDG), bilateral harmonization and prospective harmonization of API, DP and excipients. This shows the USP is expanding its commitment to global harmonization in this cycle, in support of USP Resolution III on Globally Harmonized Standards. The Japanese pharmacopoeia also places high importance on promoting global harmonization. Therefore I expect further progress on harmonization among the EP, JP and USP at the next PDG meeting hosted by the USP on November 3-4, 2015.

Dr. Chie Mizumaru

PMDA's International Liaison Officer stationed at USP in the U.S.A.

Regulatory Science Staff

The Regulatory Science Staff (RSS) is a unique group within the Office of Surveillance and Epidemiology (OSE). It proactively develops new tools and approaches to assess post-marketing drug safety data through managing regulatory science research activities. OSE conducts a variety of scientific research, mostly epidemiological research, in collaboration with other organizations outside the U.S. FDA. RSS is responsible for assuring that those projects answer questions that could improve the field of pharmacovigilance. For example, the U.S. FDA, through the RSS, recently entered into a research collaborative agreement with PatientsLikeMe ¹⁾, a company that provides a social media platform for patients with a wide range of diseases to describe their disease experience with other patients. Together RSS and PatientsLikeMe will explore if and how social media can be used to assess drug safety. To ensure that these external partnerships provide maximum value to the U.S. FDA, RSS works closely with other OSE staff and contract specialists. Having those specialists could be valuable to strengthen regulatory science at PMDA.

1) www.patientslikeme.com

Ms. Shohko Sekine

PMDA's Officer at CDER, U.S. FDA in the U.S.A.

The Brookings/FDA conference on "Improving Productivity in Pharmaceutical Research and Development"

On July 28, the Center for Health Policy at Brookings (American think tank), in collaboration with the International Consortium for Innovation & Quality in Pharmaceutical Development (consortium of pharmaceutical and biotechnology companies) and the U.S. FDA, hosted a public meeting on "Improving Productivity in Pharmaceutical Research and Development". In this meeting, leading experts from FDA, industry, and academia in clinical pharmacology introduced recent scientific thinking and case studies on drug discovery, drug development and new drug review utilizing exposure-response analysis and biomarker. Expected roles and current issues on application of clinical pharmacology tools to identification of target and compound selection, improving dose optimization, biomarker science and supports for demonstration of efficacy were discussed. It was agreed in this meeting that greater collaboration among stakeholders needs to accomplish the efficient drug development utilizing emerging clinical pharmacology tools. The video and slides can be published on the website of Brookings Institution¹⁾.

I realized again that advanced clinical pharmacology tools indeed have been already applied to current drug development to reduce the amount of time and resources necessary and to accomplish precision medicine. I think it is important that PMDA has continued to develop its policy about the application of clinical pharmacology tools to drug development and new drug review in Japan based on the review experiences to facilitate the international harmonization and strengthen collaboration among stakeholders.

1) Brookings Institution Event: Improving productivity in pharmaceutical research and development
<http://www.brookings.edu/events/2015/07/28-clinical-pharmacology-and-experimental-medicine>

Dr. Masanobu Sato

PMDA's Officer at CDER, U.S. FDA in the U.S.A.

The Dispatch to Center for Devices and Radiological Health, U.S. FDA

I am Nobuhiro Handa, a principal reviewer, Office of Medical Devices at PMDA. I am stationed at Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), U.S. FDA. The dispatch period will be for about three month from August 3 to October 25 I belong to the division of epidemiology and work on how to use registry data for post-marketing surveillance. I would like to learn how a registry is constructed in the U.S. as well as to share information regarding a currently existing registry in Japan. I also would like to collect information how to promote the linkage between registry data and claim data. I do hope to utilize this opportunity to make close relationship between U.S.FDA and PMDA.

Dr. Nobuhiro Handa

Visiting scientist, Division of Epidemiology, Office of Surveillance and Biometrics at CDRH, U.S. FDA in the U.S.A.



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Contact: <http://www.pmda.go.jp/english/contact/0001.html>