



*Traditional houses
in Shirakawa Village*

PMDA Updates

February, 2017

News

1. PMDA provides JICA training program “Strengthening the National Regulatory Authorities (NRA) for Vaccine's Quality and Safety”

From January 18 to 19, PMDA provided training to 10 officers from regulatory agencies of Philippines and Vietnam, on 1) outlines of PMDA's organization and the roles of PMDA in the vaccine regulation, 2) Good Clinical Practice (GCP) inspections, 3) Good Manufacturing Practice (GMP) inspections, 4) post-marketing safety measures (survey of adverse reactions after vaccination), and 5) Relief services for adverse health effects. This training was provided as a part of the specific training program, “Strengthening the National Regulatory Authorities (NRA) for Vaccine's Quality and Safety” by the Japan International Cooperation Agency (JICA), and the training was well appreciated by the participants for being very productive. The objective of this training is to enhance the NRA function through capacity development of officials for manufacturing and use of vaccines.

PMDA supports this training by providing relevant training contents to contribute to public health of the country/ region of the participants and the world.

2. PMDA-ATC MRCT Seminar 2017

From January 23 to 26, PMDA held a seminar entitled “PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2017”. This seminar, focusing on multi-regional clinical trials, was designed for pharmaceutical reviewers from overseas regulatory authorities, and was held as a Center of Excellence Pilot Workshop for the MRCT/GCP Inspection Priority Work Area, which is led by Japan with Thailand as a champion economy, in the APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Science Innovation Forum, Regulatory Harmonization Steering Committee).



Group Photo of Participants and PMDA staff members including Dr. Junko Sato, Office Director, Office of International Cooperation (right end), Dr. Tatsuya Kondo, Chief Executive (4th), Mr. Haruo Akagawa, Director of PMDA-ATC (5th) and Dr. Yoshiaki Uyama, Office of Medical Informatics and Epidemiology (6th) in the front line.

The seminar was participated by 32 regulators from Brazil, China, Indonesia, Malaysia, Mexico, Myanmar, Nepal, Papua New Guinea, Peru, Philippines, Sri Lanka, Taiwan, Tanzania and Thailand. The program of the seminar included lectures by staff members from PMDA as well as regulatory authorities overseas, Japan Pharmaceutical Manufacturers Association (JPMA), and academic institutions such as universities on the topics including efficacy and safety evaluation, and quality assurance of clinical data. Besides the lectures, group work with case studies were provided as well, and the participants had active discussions throughout the seminar.

Please refer to the following web site for the details of PMDA-ATC MRCT Seminar 2017.

<https://www.pmda.go.jp/english/symposia/0095.html>

3. The APEC-LSIF-RHSC MRCT/GCP Inspection Workshop

On January 26, PMDA held a workshop entitled "APEC-LSIF-RHSC MRCT/GCP Inspection Workshop" under the auspices of Ministry of Health, Labour and Welfare.

Japan is leading the MRCT/GCP Inspection Priority Work Area (PWA) in the APEC-LSIF-RHSC with Thailand as a champion economy.

To date, Duke-NUS Medical School (Singapore), Peking University (China) and PMDA have had seminars with an aim to be certified as APEC Training Centers of Excellence for Regulatory Science.

This workshop had an audience of about 190 people. In the workshop, the summaries of each seminar conducted by the three organizations were reported, and the future direction in the MRCT/GCP Inspection PWA was discussed among the speakers including regulators overseas, industry representatives experienced in global development, etc.

Please refer to the following web site for the details of APEC-LSIF-RHSC MRCT/GCP Inspection Workshop.

<http://www.pmda.go.jp/english/symposia/ooq8.html>



Dr. Tatsuya Kondo, Chief Executive gave closing remark.



Dr. Yoshiaki Uyama, Director of Office of Medical Informatics and Epidemiology (2nd right) at panel discussion.

4. Workshop on “Utilization of pharmacometrics in clinical development including pediatric drugs and unmet medical needs”

On January 27, PMDA held a workshop on the theme of pharmacometrics entitled “Utilization of pharmacometrics in clinical development including pediatric drugs and unmet medical needs”.

Dr. Takao Yamori, Executive Director of PMDA made opening remarks, Dr. Mayumi Shikano, Associate Center Director (for Advanced Review with Electronic Data Promotion and Science Board) chaired the panel discussion and Dr. Naomi Nagai, Principal Senior Scientist (Pharmacokinetics) participated as a panelist, and also staff from Advanced Review with Electronic Data Promotion Group delivered a presentation.

In the workshop, lectures were delivered on the topics including updates on the preparation of the "Guideline on Population Pharmacokinetic and Pharmacodynamic Analysis (Draft)", which Japan has been working on in pharmacometrics, and the policy toward the preparation of future relevant guidelines, as well as the use of pharmacometrics for development of drugs for pediatric or intractable diseases and appropriate use in a clinical setting in the U.S. In the panel discussion, the importance of capacity building and collaboration among industry, academia, and government including medical institutions in Japan were discussed to facilitate the use of pharmacometrics for drug development and appropriate use in a clinical setting. Through this workshop, it is expected to raise the importance of pharmacometrics in Japan in the future and to promote practical application of pharmacometrics for drug development and appropriate use in a clinical setting.



Dr. Yamori



Dr. Shikano

5. The 4th Thailand-Japan Symposium

The 4th Thailand-Japan Symposium was held in Bangkok on February 2, co-hosted by Thai Food and Drug Administration (Thai FDA) and PMDA, and was attended by 260 people (including 93 regulators and 88 industry representatives in Thailand).

The participants from PMDA included Mr. Haruo Akagawa (Senior Executive Director), Mr. Shinobu Uzu (Chief Safety Officer) and Dr. Junko Sato (Office Director, Office of International Cooperation), as well as staff from Office of Standards and Guidelines Development, Office of Manufacturing/Quality and Compliance and Office of International Cooperation, who made presentations. From Thai FDA, Dr. Wanchai Sattayawuthipong (Secretary-General) and many other staffs participated in the symposium.

This 4th symposium included opening remarks from Dr. Wanchai, Mr. Akagawa and Mr. Akihiro Uchikawa (Minister of Economics, Embassy of Japan in Thailand) followed by sessions on pharmaceuticals as well as those on medical devices, where presentations and discussions were held by the participants from both countries to share regulatory updates on pharmaceuticals and medical devices.

The details of the symposium are available at the following link.

<http://www.pmda.go.jp/english/symposia/oog9.html>



Group photo of Participants. From the 6th left, Mr. Uchikawa, Mr. Akagawa, Dr. Wanchai, Mr. Uzu and Dr. Sato

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
Spiolto	tiotropium bromide hydrate/ olodaterol hydrochloride	January 24
Synflorix	pneumococcal 10-valent conjugate vaccine adsorbed	January 27
Iribow	ramosetron hydrochloride	February 6
Opdivo [Partial Change Approval]	nivolumab (genetical recombination)	February 16
Yondelis	trabectedin	February 16

Medical Devices

<http://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html>

Brand Name	Generic Name	Posting date
SATAKE-HotBalloon Catheter	cardiac ablation catheter	February 16

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 340, February 7, 2017

1. Precautions Concerning Recurrent and Similar Medical Accidents
2. Revision of Precautions (No. 281)
Iguratomod (and 2 others)
3. List of Products Subject to Early Post-marketing Phase Vigilance
(Reference)
Precautions Regarding Handling of Fire During Long-Term Oxygen Therapy (LOT)

<http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0014.html>

Pharmaceuticals Revisions of PRECAUTIONS, February 14, 2017

- Hydroxyzine Hydrochloride (Injection)
- Hydroxyzine Hydrochloride (Tablets)
- Hydroxyzine Pamoate (Powders)
- Hydroxyzine Pamoate (Capsules/Dry Syrup)
- Hydroxyzine Pamoate (Syrup)
- Hydroxyzine Pamoate (Tablets)
- Vemurafenib

<http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0004.html>

Notification (medical device)

PSEHB/ELD/OMDE Notification No. 1227-1, PSEHB/SD Notification No. 1227-1

Notification: "Handling of Powdered Medical Gloves"

(Posted on February 1, 2017, Originally Posted in Japanese on December 27, 2016)

<http://www.pmda.go.jp/english/safety/regulatory-info/0001.html>

PMDA/OSI Notification No. 1031002, PMDA/OSII Notification No. 1031002

Notification: "Points to Consider for Consultations Related to Revisions of Package Insert Language"

(Posted on February 8, 2017, Originally Posted in Japanese on October 31, 2014)

<http://www.pmda.go.jp/english/safety/regulatory-info/0001.html>

PMDA/OSI Notification No. 1031001, PMDA/OSII Notification No. 1031001

Notification: "Points to Consider regarding the Notification and Publication of Package Insert Language"

(Posted on February 8, 2017, Originally Posted in Japanese on October 31, 2014)

<http://www.pmda.go.jp/english/safety/regulatory-info/0001.html>

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
March 14-16	11th IMDRF Management Committee Meeting	Vancouver
March 29-31	29th Annual DIA Euro Meeting 2017	Glasgow
April 5	5th Asia Partnership Conference of Pharmaceutical Associations	Tokyo

April 6-7	9th Asian Regulatory Conference	Tokyo
April 17-18	11th DIA Annual Conference in Japan for Asian New Drug Development	Tokyo
April 24	2nd India-Japan Medical Products Regulation Symposium	Tokyo

Reports from overseas

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

Consideration how to utilize “big data” in drug development/regulations

While I introduced discussions in EU and Japan for patient registries in the last PMDA Update, EMA is also promoting discussions of “big data” in drug development/regulations, a broader topic including areas such as patient registries.

As part of this, EMA hosted a workshop for big data in November 2016. Various topics, including the landscape of big data and the introduction of specific examples like use of gene information in cancer field, were shown, and further discussion points for utilization of big data were shared among stakeholders.

In Japan, big data related activities such as MID-NET project, where information in medical institutes such as medical records and medical expense claims is used for drug safety, and a project to utilize study data electronically provided in consultations at drug development phases as well as pre-market reviews have been conducted. The use of big data in drug regulation is a new challenge for regulators around the globe and there are growing expectations; discussion and collaboration between Japan and the EU on the best way to apply big data are essential.

Mr. Hideyuki Kondo

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

General Chapters Early Input Process

The United States Pharmacopeial Convention (USP) has convened Stakeholder Forums through annual face-to-face meetings and tri-monthly webinars. Implementation status of a pilot process^{1),2)}, which was proposed in a webinar last year, for early input on general chapters was reported in a webinar held on January 19³⁾. General chapters are often identified as high-impact standards because they may be applied to numerous articles and their scope can sometimes overlap with other guidance for industry and practitioners. Also, stakeholders’ input on general chapters early in their development has a potential to save time and effort required for development and revision. In this process, soon to be fully implemented, USP staff and expert volunteers try to collect input from any interested stakeholder in the early stage of development by publishing a brief prospectus for new general chapters or major general chapter revisions on the USP website before they publish the drafts in Pharmacopeial Forum (PF). It was reported in this webinar that USP has posted prospectuses of 8 general chapters and has received 14 comments. USP also showed challenges experienced during piloting of the process, which USP should address with stakeholders so that this process can work more effectively, and discuss them with stakeholders.

Such kind of improvement for standard setting process will enable me to gather information regarding USP’s standard setting activities earlier than before. In addition, I believe this improvement will also be helpful for promoting our global harmonization activity with USP and the Pharmacopeial Discussion Group (PDG). Therefore, I will keep watching where this pilot process will go.

- 1) General Chapters Early Input Process Proposal
http://www.usp.org/sites/default/files/events/stakeholder_forums/2015/webinar-registration-now-open/general-chapters-early-input-process-proposal-2016-01-28.pdf
- 2) USP to Pilot Process for Early Input on General Chapters
<http://www.usp.org/usp-nf/notices/usp-pilot-process-early-input-general-chapters>
- 3) General Chapters Prospectus Process Update
http://www.usp.org/sites/default/files/events/stakeholder_forums/2016/webinar/general-chapter-prospectus-process-update-2017-01-19.pdf

Dr. Yujiro Kameyama

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

Guidances to be published by CDER in 2017

Recently, Center for Drug Evaluation and Research (CDER) released a new list of about 100 guidance documents it plans to publish in 2017. (Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2017).¹⁾ This latest Guidance Agenda includes a wide variety of fields such as Advertising, Clinical/Medical, Clinical Pharmacology, Clinical/Statistical. In clinical pharmacology area, 8 revised guidances (Clinical Drug Interactions Studies, Clinical Lactation Trials, Exposure-Response Relationships, *in vitro* Metabolism-and-Transporter-Mediated Drug-Drug Interaction Studies, Pharmacokinetics in Patients with Impaired Hepatic Function, Pharmacokinetics in Patients with Impaired Renal Function, Pharmacokinetics During Pregnancy and the Postpartum Period, and Population Pharmacokinetics) are in process to be published within 2017.

In Japan, a draft guideline on drug interaction study was published in 2014²⁾, and the work is proceeding toward finalization. Also, we had closed the public comment recruitment for a population pharmacokinetic guideline in 2016³⁾. In addition, a guideline on exposure-response relationships is being developed⁴⁾.

In order to contribute to efficient drug development, publishing guidelines is one of the important roles of a regulatory agency. It is important to promote international harmonization on guidelines or guidance created at the same time by different agencies. I hope to contribute to such international harmonization activities.

- 1) <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm417290.pdf>
- 2) <http://www.nihs.go.jp/mss/T140710-jimu.pdf> (in Japanese)
- 3) <http://search.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=495150257&Mode=0> (in Japanese)
- 4) <http://www.pmda.go.jp/files/000215965.pdf> (in Japanese)

Mr. Shin-ichi Kijima

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



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PMDA Website: <http://www.pmda.go.jp/english/index.html>

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