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PMDA Updates

December, 2018

News

1. ICH meeting in Charlotte

The 7th International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met in Charlotte, the USA from November 10 to 15. The attendees included 29 PMDA staff members including Dr. Nobumasa Nakashima, Senior Director for International Programs, and Mr. Naoyuki Yasuda, Office Director, Office of International Regulatory Affairs, MHLW and other officers from MHLW.

At the meeting, due to a retirement or an expired term of previous appointees, the appointment of ICH Assembly Vice Chair and the election of MC Chair and Vice Chair were conducted. Dr. Nakashima was re-elected as MC Vice Chair for another term. Also, the Assembly approved NRA, Iran as a new Observer, and ICH is now constituted by 16 Members and 28 Observers.

Main outcomes from the meeting included reaching a basic consensus on the 2 draft guidelines of M10 (Bioanalytical Method Validation) and E19 (Optimization of Safety Data Collection), which is aimed for endorsement by February 2019 based on the confirmation of consensus, to proceed to the public comment procedure. Also, as reflection papers outlining a strategic plan to future development of ICH guidelines, 2 documents on Generic Drug and on Pharmacoepidemiological Studies were basically supported, which will be discussed from a technical perspective by the Discussion Group.

The next ICH meeting will be held on June 1-6, 2019 in Amsterdam, the Netherlands.

2. 15th DIA Japan Annual Meeting and ICMRA Innovation Project Face to Face Meeting

The DIA Japan Annual Meeting was held for three days from November 11th to 13th at Tokyo Big Sight. At the DIAmond session, the progress of the ICMRA（International Coalition of Medicines Regulatory Authorities）Innovation Project was presented, and Dr. Kondo presented findings on one of its activities, horizon scanning methodology analysis. Dr. Kondo, Chief Executive emphasized that the key to horizon scanning was multi-dimensional analysis and objective evaluation based on regulatory science, and stressed the need for regulators to strengthen their regulatory science activities to prevent new technologies from being buried under noise (lost discoveries)—such issues are common across nations and regions.

The ICMRA Innovation Project DIAmond Session

In addition, a face to face meeting of the ICMRA Innovation Project was also held at the same time, and 10 participants from 6 overseas regulators (DKMA, EMA, FDA, HC, HPRA, Medsafe) participated in the meeting. From PMDA, Dr. Kondo and 7 other staff, and from MHLW, Councilor Mori and one other staff also participated in discussions on how to prepare the outputs of the Innovation Project, and how to progress international collaboration in horizon scanning within ICMRA. In the future, ICMRA intends to actively cooperate in horizon scanning activities and developing and securing the necessary expertise for novel innovations.

3. PMDA-ATC Medical Devices Seminar 2018

From November 12 to 16, PMDA held PMDA-ATC Medical Devices Seminar 2018. This seminar was designed for medical devices and in vitro diagnostic products reviewers from overseas regulatory authorities, and participated by a total of 25 regulators from 17 countries/regions (i.e. Argentina, Azerbaijan, Bangladesh, Brazil, Cameroon, Ecuador,

Hong Kong, India, Indonesia, Malaysia, Philippines, South Africa, Sri Lanka, Taiwan, Tanzania, Thailand and Uganda). Lectures in the seminar delivered topics including medical device regulations, medical device and in vitro diagnostic product reviews, consultations, Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Quality Management System (QMS), post-marketing safety measures, registration system, standards for medical device (utilization of international standards, etc.), third party certification process. Group works in case studies using examples of the new medical device review are also provided. In addition, special lectures by medical device industries and site visit to manufacturing facilities recommended by The Japan Federation of Medical Devices Associations were provided. The participants and PMDA staff members actively engaged in discussions throughout the seminar.

Front row from left to right, Dr. Eriko Fukuda, Office Director of Office of International Cooperation (2nd), Mr. Katsumi Kinoshita, Associate Center Director for Product Evaluation of Medical Devices and IVD (3rd), Dr. Kensuke Ishii, International Senior Training Coordinator/Office Director of Office of Medical Devices II (4th)

On the final day of the seminar, the course completion certificates were handed to each participant by Dr. Kensuke Ishii, International Senior Training Coordinator/Office Director of Office of Medical Devices II.

Please refer to the following web site for the details of PMDA-ATC Medical Devices Seminar 2018.
http://www.pmda.go.jp/english/symposia/0136.html

4. PMDA-ATC GMP Inspection Seminar 2018

From November 26 to 30, PMDA held a seminar entitled "PMDA-ATC GMP Inspection Seminar 2018" in Utsunomiya city, Tochigi prefecture with the support of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). This seminar focusing on GMP inspection was designed for GMP inspectors from oversea regulatory authorities, and participated by 14 regulators from Bangladesh, Brazil, Hong Kong, India, Indonesia, Malaysia, Mexico, Myanmar, Philippines, Russia, Sri Lanka, Taiwan, Thailand and Vietnam. A WHO officer also joined the seminar as a facilitator.

Lecture scene

In the seminar, lectures were delivered by PMDA staff on the topics including risk-based inspection and data integrity. And, group discussions and a mock inspection were provided with the cooperation of an actual manufacturing site recommended by Japan Pharmaceutical Manufacturers Association (JPMA). The participants had active discussions throughout the seminar.

On the final day of the seminar, the course completion certificates were handed to each participant by Dr. Shingo Sakurai, Senior Director.

Please refer to the following web site for the details of PMDA-ATC GMP Inspection Seminar 2017.
http://www.pmda.go.jp/english/symposia/0129.html

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	Non-proprietary Name	Posting date

Mundesine	forodesine hydrochloride	November 21
Keytruda [Partial Change Approval]	pembrolizumab (genetical recombination)	November 22
Epoprostenol ACT [Partial Change Approval]	epoprostenol sodium	December 3

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS, November 27, 2018

- Aluminum potassium sulfate hydrate/tannic acid (with saline)
- Aluminum potassium sulfate hydrate/tannic acid (with analgesic agents)
- Calcitriol (injectable dosage form)
- Freeze-dried live attenuated varicella vaccine

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0006.html

Risk Information which some safety measures might be taken, December 7, 2018

- Nusinersen sodium
- Daclatasvir hydrochloride
- Asunaprevir
- Daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride
- Moxifloxacin hydrochloride (oral dosage form)
- Tosufloxacin tosilate hydrate (oral dosage form)
- Levofloxacin hydrate (oral and injectable dosage forms)
- Sitafloxacin hydrate
- Ciprofloxacin hydrochloride hydrate
- Ciprofloxacin
- Garenoxacin mesilate hydrate
- Prulifloxacin
- Ofloxacin (oral dosage form)
- Norfloxacin (oral dosage form)
- Lomefloxacin hydrochloride (oral dosage form)
- Pazufloxacin mesilate
- Lenalidomide hydrate
- Axitinib

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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
January 21-24	PMDA-ATC MRCT Seminar 2019	Tokyo
January 21-24	PMDA-ATC Pharmaceuticals Review Seminar 2019 in Jakarta, Indonesia	Jakarta
February 5-7	31st DIA EuroMeeting	Vienna

Reports from overseas

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

Coming application of Clinical Trial Regulation in EU

Clinical Trial Regulation EU No. 536/2014, replacing the current EU Clinical Trial Directive (EC) No. 2001/20/EC, is to be applied to clinical trials related to investigational medicinal products. The timing of the application depends on that of implementation of EU portal and database whose development is being led by the EMA. The development of the auditable release of the portal and database is complete. The release is now in an intensive phase of pre-testing before formal user acceptance testing can start in early 2019.

It is expected that Clinical Trial Regulation will bring improvement for efficiency and consistency of implementation of clinical trial regulations among EU national competent authorities. In addition, ensuring transparency on clinical trial information will be promoted with more information disclosure.

The introduction of EU portal and database is one of key changes. With this system, in addition to digitization of assessment procedures to start clinical trials, the assessment process itself will be revamped (collaborative assessment among relevant national competent authorities, incorporation of opinions form Ethics Committees during the assessment process etc.). Many Japanese pharmaceutical companies with London offices have clinical development function, and exchange opinions actively, such as sharing their status of preparation, in order to handle these changes well.

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

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Science Day

The United States Pharmacopeial Convention (USP) held the internal event "Science Day" on Nov 13th. The purpose of this event was to learn about the exciting science happening at USP that helps to fulfill USP's public health mission. At the beginning of Science Day, the keynote speaker presented the view point of a USP's user and educator of pharmacopeia. In addition, there were two oral presentations, tabletop presentations and a large poster session in which USP staff were able to present on individual science topics. The event was open to all USP staff. Moreover, a discussion between presenters and participants was facilitated through a unique format, where questions on important topics were distributed among participants, and the participants drove the discussion. The Questions seemed to be good help for participants to visit presenters freely. I participated in the tabletop presenting on International cooperation and international exchange program. I supported the team's overview of the presentation and was able to discuss with participants on the PMDA Liaison's perspectives and to tell our appreciation for the program.

Such exhibition to introduce and discuss PMDA's regulatory science researches is also held in PMDA annually[1,2].

1) http://www.pmda.go.jp/rs-std-jp/symposia/0010.html (Japanese only)
2) http://www.pmda.go.jp/files/000226912.pdf

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