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PMDA Updates

February, 2018

News

1. IMDRF Registry Working Group Meeting

From December 4 to 8, a meeting of International Medical Device Regulators Forum (IMDRF) Patient Registry Working Group was held at PMDA. Since September 2014 when this working group's establishment was approved at the IMDRF Management Committee Meeting, two documents have been developed and published, "Principles of International System of Registries Linked to Other Data Sources and Tools"; and "Methodological Principles in the Use of International Medical Device Registry Data".

This meeting aimed to produce the final draft of the WG's third document "Tools for Assessing the Usability of Registry in Supporting Regulatory Decision-Making" to address the responses collected during the period of public consultation from October to December 2017. Those who attended the meeting included regulators from Japan, USA, Canada, Singapore and Russia, as well as industry and academia members from Japan and USA, and active discussions were held during the meeting. Also, during the period of the meeting, views were exchanged on regulatory uses of registries in each country as well as real world evidence.

2. PMDA-ATC MRCT Seminar 2018

From January 15 to 18, PMDA held a seminar entitled "PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2018". 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 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 Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

Front row from left to right, Dr. Junko Sato, Office Director, Office of International Cooperation (2nd), Mr. Haruo Akagawa, Director Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (3rd), Dr. Toshiyoshi Tominaga, Associate Executive Director (4th), Dr. Yoshiaki Uyama, International Senior Training Coordinator (5th)

The seminar was participated by 25 regulators from Azerbaijan, Brazil, Hong Kong, India, Indonesia, Malaysia, Philippines, Sri Lanka, Chinese Taipei, Thailand.

The program of the seminar included lectures by staff members from PMDA, Japan Pharmaceutical Manufacturers Association (JPMA) and academic institutions on the topics including protocol designing and planning of MRCT, clinical operation, clinical data evaluation, GCP inspections, post-marketing issues and safety measures for approved products based on MRCT. Besides the lectures, group work with case studies, introduction of review systems and regulations by participants and clinical site tour were provided as well, and the participants had active discussions throughout the seminar.

At the end of the seminar, the course completion certificates were handed to each participant by Dr. Tatsuya Kondo, Chief Executive of PMDA.

Please refer to the following URL for the details of PMDA-ATC MRCT Seminar 2018.
http://www.pmda.go.jp/english/symposia/0117.html

3. ISO TC194 WG4 Meeting

From January 23 to 24, ISO TC194 WG4 Meeting was held at the headquarters of the Association for the Advancement of Medical Instrumentation (AAMI) in Arlington, Virginia, USA, and was attended by one staff member from Office of International Programs, PMDA.

ISO TC194 WG4 is a working group for revising clinical investigation of medical devices for human subjects - Good Clinical Practices (ISO 14155), which is chaired by a Belgian industry member and convened since 2015 to develop a revised version of the current ISO 14155:2011. As ISO 14155:2011 is recognized as an equivalent standard to Japan's medical device GCP requirements as stated in Ministerial Ordinance, Japan has been actively participating in discussions to work to ensure revised standards remain acceptable.

Group photo of the participants

This meeting reviewed the comments collected by each domestic committee on the Committee Draft published last year, and discussed the policy on how to reflect those in the documents. The key points of the proposed changes include more informative description of principles on risk management in clinical trials, and statistical design in clinical trials as recommendation. Also, the wording "safety or performance" is to be changed to "performance, effectiveness or safety", which is more closely aligned with the assessment in Japan and the U.S.

A Draft International Standard (DIS) is to be circulated to each domestic committee for vote in this fiscal year.

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
Prizbind	idarucizumab (genetical recombination)	January 30
Genvoya	elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide fumarate	February 1
Vemlidy	tenofovir alafenamide fumarate	February 6
Symproic	naldemedine tosilate	February 8
Rebetol	ribavirin	February 8
Viekirax [Partial Change Approval]	ombitasvir hydrate/ paritaprevir hydrate/ritonavir	February 8

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 350, February 6, 2018

1. An Incident of Distribution of Counterfeit HARVONI Combination Tablets and Government Measures Against Counterfeit Drugs
2. Important Safety Information
   (1) [1] Teriparatide (genetical recombination), [2] Teriparatide acetate (subcutaneous injection)
   (2) Edoxaban tosilate hydrate
   (3) Lenvatinib mesilate
3. Revision of Precautions (No. 291)

(1) Aripiprazole
(2) Aripiprazole hydrate (and 5 others)

4. List of Products Subject to Early Post-marketing Phase Vigilance (Posted on February 9, 2018)
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0015.html

Pharmaceuticals Revisions of PRECAUTIONS, February 13, 2018

- Gardenia fruit
- Inchinkoto extract
- Orengedokuto extract
- Kamishoyosan extract
- Shiniseihaito extract
- Unseiin extract
- Kamikihito extract
- Keigairengyoto extract
- Gorinsan extract
- Saikoseikanto extract
- Shishihakuhito extract
- Seijobofuto extract
- Seihaito extract
- Bofutsushosan extract
- Ryutanshakanto extract
- Efavirenz
- Iohexol (for urinary tract, blood vessel)
- Iohexol (for urinary tract, blood vessel, CT)
- Iomeprol
- Products containing gardenia fruit (OTC drugs)

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0005.html

Risk Information which some safety measures might be taken (February 23, 2018)

- Tolvaptan
- Linagliptin
- Teneligliptin hydrobromide hydrate
- Teneligliptin hydrobromide hydrate/canagliflozin hydrate
- Anagliptin
- Sterile talc

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
March 19-22	The 4th Self-CARER meeting	Taipei
March 20-22	IMDRF Management Committee	Shanghai
March 26-27	ICH Interim Meeting	London
April 16-19	30th DIA Euro Meeting	Basel

April 16	ICMRA Plenary meeting	Basel

Reports from overseas

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

Addressing medicinal products quality defects through collaboration between EMA and EU regulatory authorities

The EMA and EU national regulators actively promote cooperation to harmonize measures for quality defects of medicinal products and falsified medicinal products among countries through regular meetings.

Discussions at these meetings include how to improve appropriate information-sharing of quality defects by standardizing templates, creation of helpful tools for determination and actions for a product recall and sharing of knowledge and experience on the detection of falsified medicinal products. These face-to-face discussions are complemented by pilot projects that recruit volunteers to verify that the templates and tools are actually useful.

These activities affect not only EU countries but also PIC/S where international regulators, including those from Japan, participate and aim to secure the quality of medicinal products. As the introduction of Good Distribution Practice (GDP) for medicinal products is under intensive discussions in Japan, they also provide valuable opportunities to learn about the European experiences and situation where GDP has been already implemented. Therefore, it is important to carefully follow the activities in EU and make the best use of them for measures in Japan and cooperation with EU countries.

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

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Reflection on 18 Months Stay at USP

On January 25, I had the honor of giving a presentation about Japanese Pharmacopoeia (JP) and my activities at the United States Pharmacopeial Convention (USP) to USP staff. In this presentation, I talked about overview of PMDA and JP, collaboration between USP and JP, and similarities or differences between the two pharmacopoeias, which I have felt through this dispatch, such as those in the origin, the legal status, the management of expert committees and the composition of pharmacopoeia. After my presentation, I received several questions including, but not limited to collaboration between the two pharmacopoeias. The USP staff expressed interest in the expansion of collaboration between USP and JP.

For these last 18 months, I have been doing my best efforts to reinforce the partnership between USP and JP by addressing our common challenges. These challenges include the following: (1) standard settings and revisions corresponding to growth of pharmaceutical manufacturing/analytical technologies and changes in environments surrounding pharmaceuticals, (2) optimization of standard setting processes including international harmonization in order to follow the rapid growth of technologies in the recent years, and (3) further global collaboration with the other pharmacopoeias in order to ensure pharmaceutical quality in the globalized supply chains. Although I finished my dispatch on January 31, I would like to further collaborate with USP by continuing to address the challenges while taking advantage of experience and personal relationship which I have obtained through this dispatch.

Finally, I would like to extend my deepest appreciation to Dr. Kevin Moore, the Science-Excipient team and all USP staffs who supported my activities and provided various opportunities. Also, I sincerely acknowledge PMDA staff who supported my dispatch.

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