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PMDA Updates

August, 2018

News

1. 3rd Korea-Japan Joint Symposium on Medical Products

On July 3, the 3rd Korea-Japan Joint Symposium on Medical Products was held in Tokyo, which was attended by about 200 people from PMDA, Ministry of Health, Labour and Welfare (MHLW), Ministry of Food and Drug Safety (MFDS), National Institute of Food and Drug Safety Evaluation and industries. This symposium was held as part of the cooperation activities which was set out in the "Memorandum of Cooperation on Medical Products Regulatory Dialogue and Cooperation Framework" signed between MFDS and MHLW in August 2015. Those who participated in the symposium from PMDA included Dr. Tatsuya Kondo, Chief Executive; Mr. Seiichi Inoue, Executive Director (at that time); Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs (at that time); and 5 other staff, and from MHLW included Mr. Kazuhiko Mori, Councilor for Pharmaceutical Affairs; Dr. Nobumasa Nakashima, Director, Division of General Affairs, Office of International Regulatory Affairs (at that time) and other staff. In the symposium, presentations were provided by the regulators from both countries on a regulatory overview and updates, and by the industries on recent trends in the pharmaceutical and medical device industries. Each presentation was followed by active discussion among the participants.

On the following day, July 4, a bilateral meeting was held where regulators of Korea and Japan exchanged views on regulatory harmonization and cooperation. The working groups which were established last year will be reorganaised to make both side's cooperation more efficiently by using the outcomes of bilatereal meeting at international conferences.

MHLW's press release is available at the following link.
http://www.mhlw.go.jp/stf/houdou/0000164935.html (in Japanese)

2. AMDC-PMDA Standard Workshop 2018

PMDA has been conducting "Innovative medical device promotion project to achieve international standardization" (formerly known as "Medical device international standardization strategy promotion project") since FY2014. As part of this project, the agency has been holding workshops for regulators in ASEAN countries on use of standards for medical devices since FY2017.

Group photo of the participants of the workshop in the Philippines
Mr. Shunsuke Tamaki, Office of Standards and Guidelines Development (6th from left, first row)
Mr. Hiroshi Ishikawa, Technical Expert, Office of Standards and Guidelines Development (8th from left, first row)

The implementation plan for FY2018 workshops was discussed at the 6th ASEAN Medical Device Committee (AMDC) Meeting (in April 2018), and it was agreed to conduct the workshops under the theme "Essential Principles of Safety and Performance of Medical Devices and the Appropriate Use of Medical Device Standards". The workshop was held on July 11-12 in the Philippines (successfully completed), and scheduled on August 20-21 in Thailand, and TBD in Myanmar. These workshops aim to identify common agenda toward the implementation of ASEAN Medical Device Directive (AMDD), and to explore concrete cooperation possibilities. The outcomes and issues of the workshops will be fed back to the next AMDC meeting for discussion of future activities.

3. 20th Foundation Anniversary Meeting of Center for Drug Evaluation, Taiwan and International Symposium on the 20th Anniversary of Dug Injury Relief System in Taiwan

The 20th Foundation Anniversary Meeting of Center for Drug Evaluation (CDE) and the Taiwan and International Symposium on the 20th Anniversary of Drug Injury Relief System in Taiwan were held on July 13 and 18, respectively.

Mr. Seiichi Inoue, Executive Director and one staff member from Office of International Programs attended the 20th Foundation Anniversary Meeting of CDE. A presentation entitled "Innovation and Regulatory Science" was delivered focusing on review processes including conditional approvals, regulatory science-based approach to review and pharmacovigilance, horizon scanning, and international collaboration.

At the International Symposium on the 20th Anniversary of Drug Injury Relief System, Mr. Shinichi Okamura, Office Director of Relief Funds, and one staff member from Office of International Programs attended. A presentation was delivered by Mr. Okamura on the history, impacts and challenges of relief services for adverse drug reactions in Japan. Also, prospects of the relief service for adverse health reaction were discussed with the relief funds in Taiwan and Korea.

Participating these meetings was a good opportunity for continued Taiwan-Japan cooperation on future initiatives.

4. Call for application to PMDA-ATC GMP Inspection Seminar 2018 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold a seminar entitled "PMDA-ATC GMP Inspection Seminar 2018" from November 26 to 30, 2018. This seminar is designed for GMP inspectors from overseas regulatory authorities.

The seminar theme is biologics and includes lectures, group discussions and a mock inspection at an actual manufacturing site with the objective of acquainting the participants with Risk-based GMP Inspection. The seminar is supported by Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Please refer to the following web site for the details of PMDA-ATC GMP Inspection Seminar 2018.
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	Generic Name	Posting date
Rapalimus (topical gel)	sirolimus	August 10
Xofluza	baloxavir marboxil	August 14

Medical Devices

http://www.pmda.go.jp/english/reviewservices/reviews/approved-information/devices/0003.html

Brand Name	Term Name	Posting date
Suncon Kyoto-CS	Limbal-supported contact lens for abnormal corneal shape	July 17

Safety Information

PMDA Alert for Proper Use of Medical Devices (July 2018)

Adverse Events involving the Use of Bioprostheses for Transcatheter Aortic Valve Implantation
(Posted on July 31, 2018)http://www.pmda.go.jp/english/safety/info-services/devices/0005.html

Pharmaceuticals Revisions of PRECAUTIONS, August 2, 2018

- Apremilast
- Ceftriaxone sodium hydrate

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

PMDA Medical Safety Information No. 55 (August 2018)

Introduction of Connectors to Prevent Misconnection (Neuraxial Anesthesia)
http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Pharmaceuticals and Medical Devices Safety Information No. 355, August 7, 2018

1. Review of Contraindications for Immunosuppressants in Pregnant Women, etc.
2. List of Products Subject to Early Post-marketing Phase Vigilance

(Reference)
Revision of the Ministerial Ordinance on Good Post-marketing Study Practice (GPSP Ordinance)
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0016.html

Pharmaceuticals Revisions of PRECAUTIONS, August 21, 2018

- Amantadine hydrochloride
- Oseltamivir phosphate
- Zanamivir hydrate
- Laninamivir octanoate hydrate
- Baloxavir marboxil
- Favipiravir
- Peramivir hydrate

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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
September 3-7	ICDRA meeting	Dublin
September 10-12	ICMRA Summit	Washington D.C
September 25-27	GCRSR・GSRS18	Beijing
October 1-4	RAPS (Regulatory Affairs Professional Society) Annual Conference	Vancouver
October 11-12	6th Joint Conference of Taiwan and Japan on Medical Products Regulation	Tokyo
October 15-16	PMDA-ATC Pharmaceuticals Review Seminar 2018 in Nay Pyi Taw, Myanmar	Nay Pyi Taw

Reports from overseas

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

Product scope of GMP MRA between Japan and EU expanded

The product scope of the GMP MRA between Japan and EU was expanded by a decision that entered into force on 17 July 2018. The original scope of the GMP MRA was limited to non-sterile chemical products like tablets with a low-molecular compound, but now it includes most products such as sterilized products like injections, biologics, drug substances and vaccines.

The expansion will lead to greater efficiencies. For example, EU competent authorities issued more than 90 GMP certificates for manufacturers in Japan, as of June 2018. PMDA conducted more than 50 on-site inspections of manufacturers in EU in the past 5 years. For these GMP inspections, both sides can accept the inspection results from the other side based on the expanded GMP MRA, which will allow both sides to implement GMP regulations more effectively and efficiently.

To reach this decision of the scope expansion, GMP representatives between Japan and EU had technical discussions and have confirmed that regulations and implementation of GMP in both regions are reliable. The stronger relationship between Japan and EU through this activity would promote further cooperation in the GMP field.

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

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Dispatch to USP

I'm Hiroshi Takeda, a new USP (the United States Pharmacopeia) liaison from PMDA. I work in Office of Standards and Guidelines Development. My dispatch to the United States Pharmacopeial Convention[1)] (Rockville, Maryland) will be about 18 months from July 14th, 2018. This summer, we have extreme hot weather in Japan. On the other hand, there is a lot of rain in Rockville compared to usual years, and I experienced short-term electric outage by lightning and flood alert.

USP is a non-profit organization with the mission to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP–NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF. USP creates and continuously revises USP–NF standards through a unique public–private collaborative process, which involves pharmaceutical scientists in industry, academia, and government as well as other interested parties from anywhere in the world. In Japan, we also have Japanese Pharmacopoeia (JP) as a compendium for pharmaceuticals. The draft of JP is edited on the basis of Expert Committees' discussion, which PMDA, Office of Standards and Guidelines Development serves as secretariats. After the discussion in Pharmaceutical Affairs and Food Sanitation Council, JP is published by Minister of Health, Labuor, and Welfare in Japan. USP and JP cooperatively progress international harmonization on pharmacopeial standards including excipients monographs and general testing methods, aiming for common goals concerning contribution to health and welfare by assuring quality of pharmaceuticals. I'm the 6th exchange visitor from PMDA/MHLW (Ministry of Health, Labour, and Welfare) to USP.

I think the role of pharmacopoeia is changing, with progression of internationalization of pharmaceutical supply chain, development of manufacturing technology, permeation of Quality by Design2). Under these circumstances, I want to further develop the cooperation between USP and JP, utilizing my experience as a quality reviewer of new drugs.

1) http://www.usp.org/about
2) A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management. (http://www.pmda.go.jp/files/000156835.pdf)

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