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PMDA Updates

May, 2019

News

1. ICH Management Committee Interim Meeting

From April 1 to 2, ICH Management Committee Interim Meeting was held at the Albert Borschette Congress Centre in Brussels, Belgium.

The purpose of this meeting is to efficiently implement the process of adopting new topic proposals by the ICH Assembly, which will be held in Amsterdam, Netherland in June this year. Taking this opportunity, we also discussed some issues regarding the process for future ICH reflection paper, development of a plan for the future use of ICH surplus funds, and provision of training consultant in the training subcommittee. Active discussion was held for each issue and contributed significantly to the efficiency of discussion in the ICH Assembly/Management Committee in June 2019, and it was a very meaningful meeting.

The picture of the meeting
(Dr. Nakashima, Associate Executive Director, PMDA, seated in the middle, Vice-chairman of ICH Management Committee)

2. PIC/S Committee Meeting

PIC/S Committee Meeting was held from April 9 to 10 in Geneva, Switzerland. This meeting was attended by 49 out of 52 PIC/S Participating Authorities as well as by Applicants, Pre-Applicants, and Associated Partner Organizations including WHO, under the chairmanship of Mr. Boon Meow Hoe (Singapore / HSA). The participants from Japan were 2 staff members from Office of Manufacturing Quality for Drugs, PMDA and 1 staff member from Ministry of Health, Labour and Welfare (MHLW).

In the meeting, we introduced contents of the PIC/S seminar which will be held in Toyama Prefecture, Japan from November 13 to 15 by using video and received with keen interest from the participants.

Also, we reported the result of PMDA-ATC (PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs) training, facilitated with the support from PIC/S, which was held from November 26 to 30 last year in Tochigi Prefecture. The participants commented that they would expect us to continue with the training.

The next PIC/S Committee Meeting will be held in Toyama, Japan from November 11 to 12, 2019.

3. The 2nd Asian Network Meeting and Bi-lateral Meeting with Asian Economies

MHLW and PMDA held the 2nd Asian Network Meeting in Tokyo on April 10. The Meeting was co-chaired by Japan, China, India, and Singapore. Top-level executives of regulatory agencies from ten countries including Indonesia, Malaysia, Myanmar, Philippines, Thailand, and Vietnam joined in the meeting. The participants confirmed the importance of the opinion exchange from a high-level perspective on the common issues across Asian region, fostering trusting relationships, and sharing best practices through the meeting. They also agreed to hold this meeting periodically in the future.

In conjunction with the Asian Network Meeting, MHLW and PMDA held bi-lateral meetings on April 8 and 10 with each country. In order to enhance healthcare service in the Asian region, we confirmed to have continuous discussion on the future cooperative relationship with each country, based on the respective needs, in these meetings.

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (May 9, 2019)

- Dulaglutide (genetical recombination)
- Ipragliflozin L-proline
- Tofogliflozin hydrate
- Empagliflozin
- Empagliflozin/linagliptin
- Canagliflozin hydrate
- Sitagliptin phosphate hydrate/ipragliflozin L-proline
- Dapagliflozin propylene glycolate hydrate
- Teneligliptin hydrobromide hydrate/canagliflozin hydrate
- Luseogliflozin hydrate
- Nivolumab (genetical recombination)
- Lenvatinib mesilate
- Influenza HA vaccine

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0007.html

Risk Information which some safety measures might be taken (May 10, 2019)

- Baloxavir marboxil
- Nivolumab (genetical recombination)
- Pembrolizumab (genetical recombination)
- Avelumab (genetical recombination)

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

Dear Healthcare Professionals Letter of Rapid Safety Communication (BLUE LETTER) (May 17, 2019)

- Serious Interstitial lung disease by Verzenio Tablets 50mg, 100mg, 150mg

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

Pharmaceuticals Revisions of PRECAUTIONS (May 20, 2019)

- Abemaciclib

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0007.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
June 1-6	ICH Week	Amsterdam
June 23	International Coalition of Medicines Regulatory Authorities (ICMRA) Meeting	San Diego
June 23-27	DIA 54th Annual Meeting 2019	San Diego
July 8-11	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2019	Tokyo
July 16	4th Korea-Japan Joint Symposium on Medical Products	Seoul

July 22-26 PMDA-ATC & WHO Pharmaceuticals Review Seminar 2019 Tokyo

Reports from overseas

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

USP's Activity on Nanomedicines

Development program and guidance publication[1)] of nanomedicines, such as liposomes and block copolymer micelles, are proceeded in including, but not limited to the U.S., Europe, and Japan. In Japanese Pharmacopoeia (JP), "Measurement of the Diameter of Particles Dispersed in Liquid by Dynamic Light Scattering" is published as General Information. Moreover, JP will introduce characteristics of "Liposome Injections" into "Monographs for Preparations" section in JP17 Supplement II[2)], which will be noted that liposome injections have an appropriate function of controlled release and an appropriate particle size.

The United Sates Pharmacopeia (USP) also discusses to introduce the standard on nanomedicines. USP formed the Joint Subcommittee with Experts from Committees on Dosage Forms, Physical Analysis, Chemical Analysis, and Excipients. A workshop on nanomedicines was held at USP in March 2017[3)]. USP also published and made public consultation on 2 stimuli articles and draft general chapter as follows;

- Stimuli article "Drug Products Containing Nanomaterials" (USP PF 43(3), May 2017), which discussed and specified testing methods useful for characterization of physicochemical properties,
- Stimuli article "In Vitro Release Test Methods for Drug Formulations for Parenteral Applications" (USP PF 44(6), Nov 2018), which discussed about release testing method of liposomes and so on,
- Draft general chapter "<432> DETERMINATION OF ZETA POTENTIAL BY ELECTROPHORETIC LIGHT SCATTERING" (USP PF 44(6), Nov 2018).

Considering USP's active endeavor described above, I will continue to follow USP's discussion on nanomedicines.

1) https://www.pmda.go.jp/english/rs-sb-std/rs/0010.html
https://www.pmda.go.jp/files/000213460.pdf
https://www.pmda.go.jp/files/000213462.pdf
https://www.fda.gov/media/70837/download
https://www.fda.gov/science-research/nanotechnology-programs-fda/nanotechnology-guidance-documents
https://www.ema.europa.eu/en/data-requirements-intravenous-liposomal-products-developed-reference-innovator-liposomal-product
2) https://www.pmda.go.jp/files/000226979.pdf (Japanese Only)
http://search.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000184069 (Japanese Only)
3) https://www.usp.org/sites/default/files/usp/document/workshops/agenda-2017-03-20.pdf
4) https://www.pmda.go.jp/files/000206528.pdf

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