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PMDA Updates

November, 2017

News

1. Pharmacopoeial Discussion Group (PDG) Meeting

From September 12 to 13, Pharmacopoeial Discussion Group (PDG) Meeting was held at the U.S. Pharmacopeial Convention (USP) headquarters (Rockville, Maryland, U.S.A.), where staff members of Office of Standards and Guidelines Development, PMDA participated as a part of representatives of Japanese Pharmacopoeia (JP). PDG is an international council comprised of the representatives of the European Pharmacopoeia (EP), U.S. Pharmacopeia (USP), and Japanese Pharmacopoeia (JP).

In this meeting, a revision of the framework was discussed to facilitate more effective and efficient discussions for pharmacopoeial harmonization. Also, the new text for General Chapter "Conductivity" as well as 4 revised excipient monographs including "Microcrystalline Cellulose" were signed off. Thus, to date, 28 of the 31 General Chapters and 45 of the 62 excipient monographs on the current work program have been agreed for harmonization.

The next PDG meetings are scheduled for April 2018 (meeting via video conference) and around October 2-3, 2018 (face-to-face meeting).

Please see the following URL for the details of the press release.

http://www.pmda.go.jp/files/000220886.pdf

2. The 12th International Summit of Heads of Medicines Regulatory Agencies (and related events)

From October 24 to 25, the 12th International Summit of Heads of Medicines Regulatory Agencies was held in Kyoto, hosted by MHLW/PMDA. This summit was hosted by Japan for the first time, and attended by 86 participants in total, including representatives from regulatory authorities from 29 countries and regions around the world. Discussion topics in the summit included, as topics on innovation, "regulatory convergence on regenerative medicines" and "use of real world data (RWD)", and as topics on current regulatory issues in global public health, "Fight against antimicrobial resistance (AMR)" and "Countermeasure against Substandard/Falsified medical products".

The summit was followed by International Coalition of Medicines Regulatory Authorities (ICMRA) Meeting, which was held from October 25 to 26. In this meeting, the "innovation project" was agreed to be initiated based on the concept note made by Japan. Also, basic agreement on the papers of "supply chain integrity" as well as "use of big data for pharmacovigilance purposes" was reached, which will be published on the ICMRA web site. In addition, amended Terms of Reference (ToR) for the summit and ICMRA were agreed, to merge into the "ICMRA Summit".

During the summit period, bilateral meetings with regulatory authorities from different regions and an Asian network meeting were held, in which promoting information exchange and regulatory convergence was discussed.

Also, the first public symposium, "Heads of Medicines Regulatory Agencies Symposium" was held on October 27, in conjunction of Summit of Heads of Medicines Regulatory Agencies, and attended by an audience of around 1,500 people. In the symposium, outcomes of the summit and the ICMRA meeting were reported, and efforts and challenges by key regulatory agecies were outlined. This symposium also provided a valuable opportunity for attending presentations under the theme of technological developments and practical applications, delivered by representatives from regulatory authorities and industries, and also a Nobel laureate, Professor Shinya Yamanaka.

The first ICMRA Summit will be held in Washington, D.C. in September, 2018.

MHLW's press release on the outcomes of International Summit of Heads of Medicines Regulatory Agencies is available at the following link. (in Japanese)
http://www.mhlw.go.jp/stf/houdou/0000182876.html
Presentations from Heads of Medicines Regulatory Agencies Symposium are available at the following link.
http://www.pmda.go.jp/english/symposia/0121.html

Dr. Kondo giving comments at the Summit (Left) and Dr. Tominaga (Right)


Group photo of participants

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
Tagrisso	osimertinib mesilate	October 19

Safety Information

Risk Information which some safety measures might be taken (November 6, 2017)

- Selexipag
- Clopidogrel sulfate
- Clopidogrel sulfate/aspirin
- Clozapine
- Gadodiamide hydrate
- Meglumine gadopentetate
- Gadoxetate sodium
- Gadoteridol
- Meglumine gadoterate
- Gadobutrol

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

Pharmaceuticals and Medical Devices Safety Information No. 348, November 14, 2017

1. Initiative of Revision of the Manuals for Management of Individual Serious Adverse Drug Reactions
2. Prevention of Accidents with Electric Massagers for Household Use
3. Important Safety Information
   (1) Levetiracetam
   (2) Linagliptin
4. Revision of Precautions (No. 289)
   Levetiracetam (and 8 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

(Posted on November 14, 2017)
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0015.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
November 30-December 2	5th Joint Conference of Taiwan and Japan on Medical Products Regulation	Taipei
December 7	HBD East 2017 Think Tank Meeting in Tokyo	Tokyo
December 12-15	PMDA-ATC Pharmaceuticals Review Seminar 2017 in Bangkok, Thailand	Bangkok
January 15-18	PMDA-ATC Multi-Regional Clinical Trials Seminar 2018	Tokyo

Reports from overseas

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

First Public Hearing for pharmacovigilance held by EMA

The first public hearing for pharmacovigilance was held at the EMA on 26 September 2017 on the topic of safety of using valproate-containing medicines in women and girls who are pregnant or of childbearing age.

There was high interest from public, including media, and there were many participants. A variety of speakers, including those from patient groups and medical professional associations, made presentation within a tight schedule. A public summary report from the meeting is available on the EMA website[1)]. Rules of procedure for public hearings were finalised in April 2016 and ensured improved involvement by civil society, including patients, in the pharmacovigilance field. To make sure that any future hearing would go well, the Agency conducted a 'dry-run' of a public hearing with a fictional product in July 2016.

At this hearing, the chair and secretariat managed this first real hearing very well, which resulted in opinions and discussions that focused on the questions specified in advance. The experience from the 'dry-run' helped ensure successful management.

According to discussions at this time, the importance to hear opinions from a wide range of stakeholders will increase more and more, and such opportunities will bring significant insights for consideration of regulatory measures.

1) Summary report of Public Hearing for pharmacovigilance
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/10/WC500236051.pdf

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

USP Prescription/Nonprescription Stakeholder Forum

The USP (United States Pharmacopeial Convention) held a face to face Stakeholder Forum on October 19 to discuss compendial issues related to prescription/non-prescription drugs[1)]. In this stakeholder forum, USP staff

gave presentations on USP's brand identity[2] which promotes better communication with stakeholders, such as users and sponsors, by reflecting who USP is today and the dynamic future ahead, the posting frequency of accelerated revisions to the USP-NF (United States Pharmacopeia – National Formulary) which address safety or immediate compliance needs, USP's standard setting activities of non-US essential medicines for improved public health outcomes (Global Health Standards Program[3]), overview on revisions of high-impact standards, and others. Also, USP and stakeholders exchanged opinions concerning these activities vigorously. Among them, stakeholders gave many opinions on the revisions of the general chapters for organic impurities control and packaging materials/components because these standards influence many monographs and drug products. In addition, they discussed practical ways to revise and to implement these standards.

In this forum, USP tried to take stakeholder's opinions in a timely manner. Also, stakeholder worked with USP to enhance standards. I felt this kind of a face to face forum is important especially in a high-impact standard setting to ensure transparency and to heighten efficiency.

1) Prescription/Non-prescription (PNP) Stakeholder Forum
http://www.usp.org/get-involved/stakeholder-forums/pnp/face-to-face-meeting-october-2017
2) USP Identity
http://www.usp.org/identity
3) Global Health Standards Program
http://www.usp.org/sites/default/files/usp/document/our-work/global-health/Global_Health_Standards_FactSheet.pdf

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

