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(with hanging frame for snow)*

PMDA Updates

December, 2015

News

1. Pharmacopoeial Discussion Group (PDG) Meeting (November 3 to 4)

From November 3 to 4, Pharmacopoeial Discussion Group (PDG) Meeting was held at the U.S. Pharmacopoeial Convention (USP) headquarters (Rockville, Maryland, U.S.A.), where staff members of Office of Standards and Guidelines Development, PMDA attended as representatives of the Japanese Pharmacopoeia (JP). PDG is an international council comprised of the representatives of the European Pharmacopoeia (EP), USP, and JP.

In this meeting, 1 item in the general tests (Uniformity of Dosage Units) was agreed for revision, and 4 items (povidone, wheat starch, glucose (glucose anhydrous and glucose monohydrate) and isomalt) were agreed for correction. By these agreements, 29 items in 36 general tests, 48 items in 62 excipient monographs have been agreed for harmonization to date. Also, the initiatives for implementation of the ICH Q3D Guideline for Elemental Impurities were shared, and the aim to achieve harmonization for general tests for elemental impurities was reaffirmed in the meeting.

The next PDG meeting will be held in Strasbourg, France on May 25-26, 2016.

2. The 10th International Summit of Heads of Medicines Regulatory Agencies and International Coalition of Medicines Regulatory Authorities (ICMRA) (November 10 to 13)

The 10th International Summit of Heads of Medicines Regulatory Agencies was held in Mexico City, Mexico, from November 10 to 13. From PMDA, Dr. Tatsuya Kondo, Chief Executive, and Dr. Toshiyoshi Tominaga, Associate Executive Director (for International Programs), and from Ministry of Health, Labour and Welfare, Mr. Kazuhiko Mori, Minister's Secretariat (for pharmaceutical affairs) and Dr. Nobumasa Nakashima, International Planning Director participated in the Summit. The Summit is held annually for the discussion of various topics related to the regulation of pharmaceuticals, among the heads of the regulatory agencies of pharmaceuticals. In this time, participants had a detailed opinion exchange on the four themes, i.e. supply chain issues, speeding innovation and increasing access to safe and effective medicines (one presentation made by Dr. Kondo), changing paradigm of clinical trials globally (moderator: Dr. Tominaga) and capacity building. International Coalition of Medicines Regulatory Authorities (ICMRA) was established for better public health by facilitating greater cooperation. Canada is the chairperson and Ireland and Japan serve as vice chairpersons. This time, future operation policy of ICMRA, which was the interim organization until this meeting, was discussed in detail. PMDA made presentations on the updates on its leading projects of ICMRA external website and capacity building. The next Summit will be held in Switzerland in autumn, 2016.

3. PMDA provides JICA training program “Roles of regulatory systems and pharmacists on ensuring proper access to quality assured medicines” (November 12 and 24)

PMDA accepted eleven officers from Brazil, China, Indonesia, Iraq, Malawi, Malaysia, Papua New Guinea, Sri Lanka, and Sudan, and gave lectures on outlines of PMDA's organization and international activities, quality management and Good Manufacturing Practice (GMP), post-marketing safety measures, and relief system for adverse health effects, etc. on November 12. PMDA also gave case studies on GMP and new drug review to seven officers on November 24. This training was provided upon the request from Japan International Corporation of Welfare Services



Group photo of participants

(JICWELS), based on the contract between JICWELS and Japan International Cooperation Agency (JICA), which organized "Roles of regulatory systems and pharmacists on ensuring proper access to quality assured medicines". PMDA has been contributing to the public health of partner countries/regions through this training program by sharing the accumulated knowledge and experience with the officers of those countries.

4. DIA Japan 2015: The 12th Annual Meeting (November 15 to 17)

From November 15 to 17, DIA Japan 2016, the 12th Annual Meeting was held in Tokyo under the theme of "A New Horizon of Innovation in Medicine Development." On November 16, Dr. Tatsuya Kondo, Chief Executive of PMDA delivered a presentation on PMDA's initiatives to contribute to the public health around the world. In this 3 day conference, a total of 28 staff members from PMDA participated as session chairs, speakers or panelists including Mr. Yoshikazu Hayashi, Associate Center Director (for New Drug Review), Mr. Kensuke Ishii, Office Director, Office of Medical Devices III, Dr. Junko Sato, Office Director, Office of International Cooperation, Dr. Yoshiaki Uyama, Office Director, Office of Medical Informatics and Epidemiology, Dr. Daisaku Sato, Office Director, Office of Cellular and Tissue-based Products, and a staff member of Office of New Drug II who chaired 8 sessions, as well as Dr. Mayumi Shikano, Associate Center Director, Dr. Wataru Asakura, Office Director, Office of New Drug IV, Dr. Daisaku Sato, Dr. Yuka Suzuki, Office Director, Office of Medical Devices II, Mr. Naoyuki Yasuda, Office Director, Office of International Programs, and a staff member each from Office of New Drug IV and Office of Safety II who served as panelists at PMDA Townhall and answered questions from the audience.

In addition, at the PMDA exhibition booth in the exhibition hall, staff members of the Office of International Programs actively communicated with the visitors on PMDA's recent activities. The DIA Japan 2016, 13th Annual Meeting, will be held from November 13 to 15, 2016, in Tokyo, Japan.

5. 5th China-Japan-Korea Director-General Meeting (November 19)

The 5th China-Japan-Korea Director-General Meeting was held in Qingdao, China on November 19, 2015, after an interval of 4 years. The following representatives participated in the conference: from PMDA, Dr. Tetsuo Nagano, Executive Director, Dr. Toshiyoshi Tominaga, Associate Executive Director (for International Programs), Dr. Yoshiaki Uyama, Office Director, Office of Medical Informatics and Epidemiology, Dr. Junko Sato, Office Director, Office of International Cooperation; from Ministry of Health, Labour and Welfare, Mr. Kazuhiko Mori, Minister's Secretariat (for pharmaceutical affairs) and Dr. Nobumasa Nakashima, International Planning Director.

In the meeting, regulatory updates of each country during the interval period were exchanged, and discussion on the previous themes including Multi-Regional Clinical Trials (MRCT) were held. The three parties agreed to hold the next China-Japan-Korea Director-General Meeting next year, around the same time.

6. The 3rd Joint Conference of Taiwan and Japan on Medical Products Regulation (November 26)

The 3rd Joint Conference of Taiwan and Japan on Medical Products Regulation was held co-hosted by East Asia Relations Commission and Interchange Association, supported by PMDA, Japan Pharmaceutical Manufacturers Association (JPMA), and others. The representatives from regulatory authorities of both countries who participated in the conference included: from PMDA, Dr. Kazuhiro Shigetoh, Executive Director, Dr. Toshiyoshi Tominaga, Associate Executive Director (for International Programs), Dr. Junko Sato, Office Director, Office of International Cooperation, and 7 staff members; from Ministry of Health, Labour and Welfare (MHLW), 3 officers; from Taiwan FDA (TFDA), Ms. Li-Ling Liu, Director, Division of Medical Products, Ms. Pei-weng Tu, Director, Division of Medical Devices and Cosmetics; from Center for Drug Evaluation (CDE), Prof. Churn-Shiuh Gau, Executive-Director.

In this meeting, presentations on of New Drug Review, Good Clinical Practice (GCP), Regenerative Products and Over-the-counter (OTC) Drugs were provided in Pharmaceutical session, and the presentations on Product Registration, Quality System Documentation (QSD)/Quality Management System (QMS) were provided in Medical Device session.



Group photo of participants (Dr. Shigetoh at 6th from the right and Dr. Tominaga at 5th from the right)

On November 27, the next day of the conference, a bilateral meeting was held between TFDA/CDE and MHLW/PMDA, and views on future collaboration were proactively exchanged. The 4th conference is scheduled to be held in Japan in 2016.

The details of the 3rd Joint Conference of Taiwan and Japan is available at following URL:
<http://www.pmda.go.jp/english/symposia/oo83.html#r=s&r=s>

7. The REACTA Forum 2015 (November 26)

On November 26 and 27, The REACTA Forum 2015 Regional Asian Clinical Trial Annual Forum was held at Chiba University, Japan, where Dr. Kazuhiro Shigetoh, Executive Director, Dr. Akihiro Umezawa, Deputy Center Director (for Cellular and Tissue-based Products), Dr. Daisaku Sato, Office Director, Office of Cellular and Tissue-based Products, and a staff member of Office of International Programs participated from PMDA. The participants included people from industry and academia from China, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, U.S.A. and Japan, and also PMDA as a regulatory authority. Lectures and panel discussions took place under the theme of "global clinical trials in Asia". Major initiatives to accelerate global clinical trials and achievements so far as well as issues were presented from the respective point of view of industry, government, or academia, and there were active discussions towards country/region and industry-government-academia collaboration in the future. Dr. Shigetoh and Dr. Umezawa delivered special lectures entitled "PMDA's challenge for promoting development of advanced medical devices" and "Science Board to the PMDA administration", respectively. Dr. Sato delivered the keynote lecture entitled "Japan's PMDA in Asia". Also, a staff member from Office of International Programs delivered a lecture entitled "Recent Activities of PMDA for International Collaboration". In the lectures, PMDA's recent initiatives, global clinical trial cases, and the current situation of global collaboration with a focus on Asia were presented.

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 |
|---------------|---|--------------|
| Revolade | eltrombopag olamine | November 30 |
| Samsca | tolvaptan | November 30 |
| Eliquis | apixaban | December 7 |
| Takelda | aspirin/lansoprazole | December 16 |
| Alecensa | alectinib hydrochloride | December 16 |
| Anoro Ellipta | umeclidinium bromide/ vilanterol trifenate | December 18 |

Medical Devices

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.htm>

| Brand Name | Generic Name | Posting date |
|-----------------------|-----------------------|--------------|
| Wingspan Stent System | cerebral artery stent | December 7 |

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 328, December 1, 2015

1. Hypermagnesaemia caused by magnesium oxide
2. Summary of the Relief System for Sufferers from Adverse Drug Reaction and Cases of Non-payment of Relief Benefits Due to Improper Use of Drugs
3. The Japan Drug Information Institute in Pregnancy
4. Important Safety Information
 - (1) asunaprevir and daclatasvir hydrochloride
5. Revision of Precautions (No. 269)
 - Galantamine hydrobromide (and 4 others)
6. List of Products Subject to Early Post-marketing Phase Vigilance (as of October 2015)

<http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0013.html>

Pharmaceuticals Revisions of PRECAUTIONS, November 24, 2015

- fomepizole
- nivolumab (genetical recombination)
- lenvatinib mesilate
- elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate

Pharmaceuticals Revisions of PRECAUTIONS, November 26, 2015

- ombitasvir hydrate/paritaprevir hydrate/ritonavir

<http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0003.html>

Events

Conferences/Meetings PMDA hosts or participates in:

| Date | Title | Location |
|----------------|---|-----------|
| February 15-19 | The 2nd PMDA Training Seminar (Medical Devices) | Tokyo |
| March 1-4 | APEC MRCT/GCP Regulatory Science Centre of Excellence Pilot Program | Singapore |
| March 8-10 | International Medical Device Regulators Forum (IMDRF) MC Meeting | Brasilia |

Reports from overseas

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

Training Session for representatives of patients' and consumers' organisations

EMA held a training session for representatives of patients' and consumers' organisation, "Training session for patients and consumers interested in European Medicines Agency activities"⁽¹⁾, with more than 30 participants, as a part of the activities of the patients' and consumers' working party (PCWP)⁽²⁾, at the EMA on 25th November 2015. This training session has continued since 2007 and this was the 9th training session. The session aimed at deepening the understanding of how patients' and consumers' organization can participate in the process of medicines evaluation by explanation and discussion of this process with PCWP members. First of all, in the meeting, all participants had explanation of EMA's centralized authorization procedure with the plenary session, then they were divided into 5 small groups to have a discussion with support of EMA officers. It was said it was the first attempt to hold this type of individual group discussion since 2007 when the PCWP meeting started. In

particular, it was discussed how to express the risk of adverse drug reactions of a medicine in a leaflet for the public and validity of using medical terminologies in a summary of product characteristics for the public. Then the discussion outcomes were explained in the following plenary session and the whole participants discussed further.

This time I participated in the training session as a liaison officer stationed at EMA. I found it interesting, especially in the small-group sessions, that EMA officers mentioned EMA was eager to adopt better medical communication styles in documents for the public. As a liaison officer stationed at EMA, I consider we need to continue to pay attention to the EMA activities for improving information provision to the public.

- 1) Detailed information on the training session
http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000318.jsp&mid=WCob01ac0580289efe
- 2) Activities of representatives of patients' and consumers' working party
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/10/event_detail_001234.jsp&mid=WCob01ac058004d5c3

Mr. Yoshihiko Sano

PMDA's International Liaison Officer stationed at EMA in the United Kingdom

2nd Excipient Workshop: Focus on Excipient Quality, Compendial Testing, and Regulatory Impact

The 2nd Excipient Workshop: Focus on Excipient Quality, Compendial Testing, and Regulatory Impact was held on November 17-18 at the USP headquarters¹⁾. This workshop was the second USP Excipient Workshop since July, 2009 and focused on the following sessions; "Strategy to bring USP-NF Excipient Monograph Specifications Up to Date", "Challenges and Opportunities in Excipient Monograph Development and Update Moderators" and "Challenges and Opportunities in Development and Update of Excipient Monographs Used for Biologics Drug Applications". Many stakeholders from industries, academia and regulatory agencies, participated in this workshop and Dr. Hiroshi Tokunaga, who is one of the members of Japanese Pharmacopoeia (JP) Expert Committee, made a presentation on behalf of JP. His presentation was about an overview of Pharmacopoeial Discussion Group (PDG) and the update of PDG Tokyo meeting held on June, 2015, entitled "Pharmacopoeial Discussion Group (PDG) Update on Harmonization Activities". On the second day of the workshop, main topic was excipient monographs used for biologics drug applications, which is one of the challenges that industries and pharmacopoeias facing currently. Industry, U.S. FDA and USP provided their perspectives, respectively. In addition, participants were divided into some groups of about fifteen people and had interactive discussion in Parallel Breakout Sessions. An international approach for harmonization of excipient monographs used for biologics drug applications is still at an early stage. I hope the discussion in this workshop expedites the international approach for excipient monographs used for biologics drug applications in the future.

- 1) 2nd Excipient Workshop: Focus on Excipient Quality, Compendial Testing, and Regulatory Impact
<http://www.usp.org/meetings-courses/workshops/2nd-excipient-workshop-focus-excipient-quality-compendial-testing-and-regulatory-impact>

Dr. Chie Mizumaru

PMDA's International Liaison Officer stationed at USP in the U.S.A.

