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PMDA Updates

November, 2018

News

1. Regulatory Affairs Professionals Society (RAPS) 2018

The Regulatory Affairs Professionals Society (RAPS) 2018 annual conference was held in Vancouver, Canada, from October 1 to 4. Dr. Nobumasa Nakashima, Associate Center Director for International Programs, 6 staff members from Office of International Programs, Office of Manufacturing/Quality and Compliance, and Office of Research Promotion of PMDA, and a staff member from MHLW, participated in the conference.

On October 3, in the session entitled "AI and How It Can Be Used to Change Health Products", a staff member of Office of Research Promotion delivered a presentation on a summary of discussion on AI in PMDA Scientific Board and the key points in reviewing. On October 4, the session entitled "Japan Forum" was held, chaired by Dr. Nakashima. In this session, PMDA and MHLW delivered presentations on the Japanese regulation of pharmaceuticals, medical devices and regenerative products, and the usage of the Medical Device Single Audit Program (MDSAP) so far in Japan. On the same day, in the session entitled "Interaction with Health Authorities", where the panelists from regulatory agencies of various countries answer questions from audience, PMDA corresponded to the questions on cybersecurity and how to improve medical device for pediatric patient. Vigorous discussion took place in each of the sessions, indicating a high level of interest in the Japanese regulations and the ongoing efforts.

PMDA also ran an exhibition booth in this year, where interaction with the visitors was actively promoted for disseminating information on the current regulations in Japan, enhancing recognition of PMDA, and providing information on the Japanese pharmaceuticals and medical device, as well as PMDA's efforts for enhanced visibility of review and safety measures. There were more than 280 visitors conclusively.

The next RAPS annual conference will be held in Philadelphia, the U.S. from September 21 to 24 in 2019.

2. Pharmacopoeial Discussion Group (PDG) Meeting

From October 2 to 3, Pharmacopoeial Discussion Group (PDG) Meeting was held at the European Directorate for the Quality of Medicines & HealthCare (EDQM) headquarters (Strasbourg, France), where staff members of Office of Standards and Guidelines Development, PMDA participated as the secretariat of Japanese Pharmacopoeia (JP). PDG is an international council comprised of the representatives of the European Pharmacopoeia (Ph. Eur.), U.S. Pharmacopeia (USP), and JP.

In this meeting, the excipient monograph for Copovidone was newly harmonized. In addition, monograph for Microcrystalline Cellulose, Wheat Starch, and Gelatin were revised. Thus, to date, 28 of the 31 General Chapters and 46 of the 60 excipient monographs on the current work program have been agreed for harmonization.

The next face-to-face PDG meetings will be held in Tokyo, hosted by the JP (PMDA) on October 1-2, 2019.

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

http://www.pmda.go.jp/files/000226450.pdf

3. The 6th Joint Conference of Taiwan and Japan on Medical Products Regulation

On October 11, the 6th Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Tokyo, hosted by the Japan-Taiwan Exchange Association and the Taiwan-Japan Relations Association. This conference was attended by more than 200 people from regulatory agencies and industry from Taiwan and Japan. Japanese participants included Dr. Tatsuya Kondo, Chief Executive; Dr. Yoshikazu Hayashi, Senior Executive Director; Dr. Junko Sato, Office Director, Office of International Programs; and 12 staff from PMDA as well as Mr. Kazuhiko Mori, Minister's Secretariat; Mr. Naoyuki Yasuda, Office Director and Mr. Katsuaki Ura, Deputy Director, Office of International regulatory Affairs; and 9 officers from Ministry of Health, Labour and Welfare (MHLW). Taiwanese participants included Dr. Shou-Mei Wu, Director-General with about 10 staff from Taiwan Food and Drug Administration (TFDA) as well as Dr. Churn-Shiouh Gau, Executive Director with 2 staff from Center for Drug Evaluation (CDE).

In this conference, regulatory updates in Japan and Taiwan were provided by PMDA's Dr. Sato and TFDA's Dr. Wu, and the past Japan-Taiwan cooperative activities were introduced. This conference covered a range of topics for

presentations including Reports on information related to adverse drug reactions (ICH E2B), Utilization of Real World Data, Health Insurance and Drug pricing system, and Patient access to OTC drugs in the pharmaceutical sessions and Regulatory information of Innovative products such as AI and 3D printing and Regulatory strategies in Asian regions in the medical devices sessions, which held active discussion concerning Questions and Answers during each session. As the result of Product Registration working group activity, the collection of Q&A for product registration (registration application) was finalized and published on TFDA and PMDA websites. The next conference is scheduled to be held in Taiwan in 2019.

Group Photo of participants

Materials including the program and presentations of the 6th Joint Conference of Taiwan and Japan on Medical Products Regulation are available at the website listed below.

http://www.pmda.go.jp/int-activities/symposia/0075.htm

4. PMDA-ATC Pharmaceuticals Review Seminar 2018 in Nay Pyi Taw, Myanmar

From October 15 to 16, PMDA held a seminar entitled "PMDA-ATC Pharmaceuticals Review Seminar 2018 in Nay Pyi Taw, Myanmar". This seminar is one of the basic course on pharmaceuticals for regulatory agencies, which Myanmar FDA would like to have. 32 regulators from Myanmar FDA participated in the seminar.


Group photo of participants and PMDA directors
Second row from right to left,
Dr.Nobumasa Nakashima, Associate Center Director Asia Training Center (5th)
Second row from left to right,
Dr. Eriko Fukuda, Office Director, Office of International Cooperation (4th)

The seminar started with outline of PMDA, activities from clinical trial application to approval, product reviews for new drugs and generic drugs. And then Myanmar FDA presented on outline of Myanmar FDA, regulation of drug and medical device, post-marketing activity in Myanmar. In addition, a speaker from National Cancer Center Hospital delivered a lecture on the phase I center network in the accelerating novel oncology drug development. The program included the group discussions on clinical review using an example of anti-tuberculosis, and the participants actively engaged in discussions.

At the end of the seminar, the course completion certificates were handed to each participant by Dr. Nobumasa Nakashima, Associate Center Director for Asia Training Center.

Please refer to the following web site for the details of PMDA-ATC Pharmaceuticals Review Seminar 2018 in Nay Pyi Taw, Myanmar.

http://www.pmda.go.jp/english/symposia/0132.html

5. PMDA-ATC Quality Control (Herbal Medicine) Seminar 2018

From October 22 to 24, PMDA held a seminar entitled "PMDA-ATC Quality Control (Herbal Medicine) Seminar 2018" in Toyama. This seminar was designed for officials of regulatory agencies overseas engaged in drug reviews, and participated by 15 regulators from Azerbaijan, Brazil, India, Malaysia, Nepal, Nigeria, Papua New Guinea, Singapore, South Africa, Sri Lanka, Taiwan, Tanzania, Thailand and Uganda.

In the seminar, lectures were delivered by PMDA staff, representatives from Toyama prefecture, Institute of Natural Medicine of Toyama University, National Institute of Health Sciences, and The Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ). The lectures covered outline of PMDA, drugs approved in prefectural government, current state of Japanese traditional medicine, forefront of herbal medicine

in modern medical care, quality evaluation, JP and non-JP standard for crude drugs, guidelines for marketing approval for crude drugs/Kampo, quality/manufacturing management of herbal medicine.

Besides these lectures, the program included the on-site tour to visit a manufacturing facility of herbal medicine and a practice on dissolution test at Toyama prefectural Institute for Pharmaceutical Research.

At the end of the seminar, the course completion certificates were handed to each participant by Ms. Akiko Ogata, Deputy Director of Office of International Cooperation.

Please refer to the following web site for the details of PMDA-ATC Quality Control (Herbal Medicine) Seminar 2018.

http://www.pmda.go.jp/english/symposia/0133.html

Group photo of participants and PMDA directors
Front row from right to left,
Ms. Akiko Ogata, Deputy Director, Office of International Cooperation ,
Dr. Yoshikazu Hayashi, Director, Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

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	Non-proprietary Name	Posting date
Kevzara	sarilumab (genetical recombination)	October 24
Parmodia	pemafibrate	November 9

Safety Information

Risk Information which some safety measures might be taken (November 2, 2018)

- Calcitriol (injectable dosage form)
- Aluminum potassium sulfate hydrate/tannic acid
- Freeze-dried live attenuated varicella vaccine

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

Medical Devices Revisions of PRECAUTIONS

Revision of Precautions to the Package Inserts of Ultrasonic Surgical Aspirator Devices

(Posted on November 13, 2018, Originally Posted in Japanese on August 8, 2018)

http://www.pmda.go.jp/english/safety/info-services/devices/0002.html

Pharmaceuticals and Medical Devices Safety Information No. 358, November 20, 2018

1. Safety Measures for Influenza Antiviral Drugs
2. Results of a Survey Investigating Access, Communication, and Utilization of Drug Safety Information at Hospitals and Pharmacies and Desirable Directions
3. Important Safety Information
   (1). Secukinumab (genetical recombination)
   (2). Lamotrigine

(3). Lenvatinib mesilate
4. Revision of Precautions (No. 298)
(1) Atorvastatin calcium hydrate
(2) Ezetimibe/atorvastatin calcium hydrate
(3) Pravastatin sodium
(4) Amlodipine basilate/atorvastatin calcium hydrate (and 11 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0016.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
December 3	3rd Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices	Tokyo
January 21-24	PMDA-ATC MRCT Seminar 2019	Tokyo
January 21-24	PMDA-ATC Pharmaceuticals Review Seminar 2019 in Jakarta, Indonesia	Jakarta

Reports from overseas

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

Workshop for establishment of Regulatory Science Strategy to 2025

Based on recent trends in science and technology such as utilization of real world data, emergence of ATMPs, complexities of clinical trial design, the EMA is working towards the establishment of Regulatory Science Strategy to 2025.

The EMA organized a workshop related to Regulatory Science to 2025 on 24 October 2018 to get together with stakeholders such as patient groups, academia, funders, HTA bodies and industries to hear their opinions on this topic. In the workshop, the following five strategic goals were proposed by the EMA, and Specific recommendations on each goal were discussed.

Goal 1	Catalysing the integration of science & technology in drug development
Goal 2	Driving collaborative evidence generation – Improving the scientific quality of evaluations
Goal 3	Advancing patient-centred access to medicines in partnership with healthcare systems
Goal 4	Addressing emerging health threats and availability/therapeutic challenges
Goal 5	Enabling and leveraging research and innovation in regulatory science

After taking into account the opinions expressed at this workshop, the EMA will start a public consultation for Regulatory Science Strategy to 2025 in December 2018, and intends to finalize it within 2019. The strategy is also expected to play an important role for developing the EU Medicines Agencies Network Strategy to 2025 which is a common strategy between EMA and EU medicines agencies.

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

Excipient Monographs 2 Expert Committee (EM2-EC) Meeting

The United States Pharmacopeial (USP) Convention held the face-to-face meeting on Excipient Monographs 2 Expert Committee (EM2-EC) on Oct 17th and 18th 1).

In USP, there are 2 Expert Committees related to Excipients; Excipient Monographs 1 Expert Committee (EM1-EC) and EM2-EC, and their face-to-face meetings are held annually. EM2-EC is mainly responsible for monographs which are/will be globally harmonized under the Pharmacopeial Discussion Group (PDG), and EM1-EC is responsible for all other excipient monographs in USP-NF. In the meeting in which I participated, the annual progress and focus of each monograph, strategy on control of elemental impurities in excipient monographs, and other topics were reported and discussed by the respective experts. At the end of the meeting, I had a chance to introduce JP Updates including a publication of the English version of Japanese Pharmacopoeia (JP) 17th edition supplement, major planed contents of JP 17th edition supplement 2, and a revision of Japanese Pharmaceutical Excipients (JPE).

In JP, Committee on Excipients is responsible for monographs of excipients. An introduction of control on elemental impurities based on International Council for Harmonisation (ICH)-Q3D guideline4) into JP has been discussed also in Japan.

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

