PMDA Updates

July, 2020

News

1. 56th DIA Global Annual Meeting / 32th DIA Europe Meeting (Virtual)

The 56th DIA Global Annual Meeting was held from June 14 to 18, and the 32th DIA Europe Meeting was held from June 29 to July 3. These meetings were offered virtually. Participants from PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), Dr. ARAI Hiroyuki (Executive Director / Director of Center for Product Evaluation), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs) and Dr. SATO Junko (Director of Office of International Programs). In addition, from Ministry of Health, Labour and Welfare (MHLW), Mr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs) participated.

32th DIA Europe Meeting
"How to promote patient centricity?" Session
* on the top row: Dr. SATO Junko (left) and Dr. FUJIWARA Yasuhiro (center).

For this 56th DIA Global Annual Meeting, a session titled "PMDA Town Hall – The Path of a New Chief Executive Since His Appointment – " was chaired by Dr. NAKASHIMA. In this session, Mr. YASUDA gave regulatory updates such as revision of PMD Act. Dr. FUJIWARA delivered a presentation on PMDA's recent progress toward realization of 4F (Access First, Safety First, Asia First, Patient First). Dr. ARAI spoke on PMDA's further advancement for Early Patient Access to innovative medical products, focusing on product review. Throughout the session, the recent activities by MHLW/PMDA to address COVID-19 were also introduced.

In the 32th DIA Europe Meeting, PMDA mainly participated in the four sessions below.

In a session titled "ICMRA, The Hub of International Collaboration on COVID-19", Dr. FUJIWARA participated as a panelist and delivered a presentation on PMDA's prompt action for COVID-19. After presentations, discussion was also held on each authorities' Regulatory Flexibility to address regulatory challenges arising from the COVID-19.

A session titled "Comparing Accelerated Approval Pathways among EMA, FDA and PMDA" was chaired by Dr. NAKASHIMA. He introduced current status of Accelerated Approval Pathway including *SAKIGAKE Designation System* in Japan. In addition, the future prospects of each authorities' Accelerated Approval Pathway such as PRIME in EMA and Breakthrough Therapy Designation in FDA were discussed, with the industry perspective.

In a session titled "ICH at 30 - What Will Come the Next 30 Years?", Dr. NAKASHIMA participated as a speaker and delivered a presentation on patient engagement in ICH's activity.

On the last day, a session titled "How to Promote Patient Centricity? – Based on Experiences of Clinician and Head of Regulatory Agency –" was chaired by Dr. SATO. In this session, Dr. FUJIWARA spoke on current initiative of PPI (Patient and Public Involvement) in Japan.

Each session had a panel discussion based on questions from viewers and active exchange of opinions between speakers and panelists. Throughout the DIA Meeting, many attendees viewed our sessions.

The 33th DIA Europe Meeting will be held in Basel, Switzerland, from March 17 to 19 in 2021. The 56th DIA Global Annual Meeting will be held in Philadelphia, the U.S., from June 27 to July 1 in 2021.

2. Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC- LSIF-RHSC) Meeting

Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC- LSIF-RHSC) telephone conference was held on June 15, 2020, instead of the one planned in February, 2020, due to COVID-19 outbreak. Key participants from Japan included Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA) and staff of MHLW.

The APEC-LSIF-RHSC aims to "promote strategic framework for regulatory convergence of medical products regulation", and is co-chaired by Dr. NAKASHIMA along with Dr.Limoli from the U.S. FDA. Reguratory authoriteis of APEC economies, representatives from industry coalition (pharmaceuticals, bio-pharmaceuticals, medical devices) and academia participated in the meeting. APEC-LSIF-RHSC has established Centers of Excellence (CoEs) focusing on seven Priority Work Areas (PWAs) to offer workshops for regulatory capacity building to regulators and relevant personnel. At the meeting, PMDA reported the result of PMDA-ATC MRCT Seminar 2020, a CoE workshop on MRCT/GCP Inspection PWA held in January 2020, and PMDA-ATC Pharmacovigilance Seminar 2020, a CoE workshop on Pharmacovigilance PWA held in Febrary 2020.

Also, PMDA was endorsed to be a Formal CoE of Medical Device PWA by APEC-LSIF-RHSC at the meeting[1]. Since 2016, PMDA has been providing PMDA-ATC Medical Devices Seminar to share GHTF/IMDRF documets and to intoroduce implementation of the documents with the experiences of Japanese medical device regulation; PMDA held PMDA-ATC Medical Devices Seminar 2019 in November, 2019, as CoE Pilot workshop of Medical device PWA[2]). PMDA would like to contribute to accelerate international medical device regulatory convergence through sharing GHTF/IMDRF documents and introducing Japanese implementation of the documents worldwide as the agency of Japan, the founding member of GHTF and IMDRF.

1) https://www.pmda.go.jp/int-activities/int-harmony/apec-lsif-rhsc/0001.html
2) https://www.pmda.go.jp/english/symposia/0171.html

3. Call for Application to PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020 Starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020" from September 9 to 11 through web conference system. This webinar is designed for pharmaceuticals reviewers from regulatory authorities. The objective of the webinar is to provide the participants with opportunities to share the knowledge and experiences of approval review of OTC drug and quality control of crude drug and herbal medicine through self-learning by advance viewing of E-learning contents and pre-recorded lectures followed by Live Q&A sessions, as well as the video-taped tour of the medicinal plants center and manufacturing site, and consequently apply them to enhance the regulatory system in the participants' own countries or regions.

Please refer to the following website for details of the PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020.
https://www.pmda.go.jp/english/symposia/0175.html

4. Call for Application to PMDA-ATC & U.S. FDA Pediatric Review Webinar 2020 Starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC & U.S FDA Pediatric Review Webinar 2020" jointly with the Food and Drug Administration of the United States (U.S. FDA), from September 28 to October 1 through web conferencing system. This webinar is designed for pediatric drug application reviewers from overseas regulatory authorities. The objective of the webinar is to provide the participants with opportunities to acquire knowledge and perspectives on a wide range of topics including ICH E11(R1) and pediatric clinical trials, and consequently apply them to enhance the development of pediatric drug in the participants' own countries or regions. Participants will view pre-recorded lectures and E-learning contents in advance, which will be followed by Live Q&A sessions and group works using case studies.

Please refer to the following website for details of PMDA-ATC & U.S FDA Pediatric Review Webinar 2020.
https://www.pmda.go.jp/english/symposia/0176.html

5. PMDA-ATC Seminars This Fiscal Year Are Offered Online as "Webinars"

In consideration of the current situations of COVID-19 pandemic, PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the PMDA-ATC Training Seminars, scheduled for this fiscal year, primarily online as "Webinars". These webinars are designed for officers from regulatory authorities around the world, who are engaged in the review of pharmaceuticals, medical devices, etc. The webinars consist of self-learning by advance viewing of pre-recorded seminar lectures, followed by live Q&A sessions, live group discussions based on the case studies, etc. Thus, the webinars will be conducted with the aim of offering the online participants with opportunities to share the knowledge and the experience on the theme of each seminar, likewise those provided in the conventional face-to-face seminars, and to consequently apply them to enhance the regulatory system in the participants' own countries or regions.

PMDA-ATC Webinar Planned Trainings: FY2020 (April 2020 – March 2021)

No.	Contents	Date
1	Quality Control (Herbal Medicine)	September 9-11, 2020
2	Pediatric Review	September 28-October 1, 2020
3	Medical Devices Review	November 16-20, 2020
4	Pharmaceuticals Review	December 14-17, 2020
5	Multi-Regional Clinical Trial (MRCT)	January 18-21, 2021
6	Pharmacovigilance	February 1-4, 2021

No.2: Joint webinar with U.S.FDA, No.3, 5, 6: APEC-LSIF-RHSC CoE Workshop

Please refer to the following web site for the up-to-date webinar schedules.
https://www.pmda.go.jp/english/int-activities/training-center/0004.html

English Translations of Review Reports

The followings are current information about English version of review reports on PMDA website.

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Non-proprietary Name	Posting date
Dupixent [Initial Approval]	dupilumab (genetical recombination)	June 18
Revcovi [Initial Approval]	elapegademase (genetical recombination)	June 23
Veklury [Special Approval for Emergency]	remdesivir	June 29
Crysvita [Initial Approval]	burosumab (genetical recombination)	June 29
Poteligeo [Partial Change Approval]	mogamulizumab (genetical recombination)	July 10
Intuniv [Partial Change Approval]	guanfacine hydrochloride	July 10

English Translations of Notifications and Administrative Notices

The followings are English version of Notifications and Administrative Notices newly published on PMDA website.

https://www.pmda.go.jp/english/review-services/regulatory-info/0003.html

Issue Date	Document Type & No.	Title	Posting date
June 19, 2019	PSEHB/PED Administrative Notice	Guideline on Population Pharmacokinetic and Pharmacodynamic Analysis	July 3, 2020
July 9, 2019	PSEHB/MDED Notification No.0709-2	Guideline on Ensuring the Quality and Safety of Gene Therapy Products	July 3, 2020
June 8, 2020	PSEHB/PED Administrative Notice	Guideline for Exposure-Response Analysis of Drugs	July 3, 2020

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (June 25, 2020)

- Oxytocin
- Dinoprost
- Dinoprostone (oral dosage form)
- Calonary L, Calonary M, Calonary H Infusion Solution
- Hicaliq-1, Hicaliq-2, Hicaliq-3 Liquid
- Hicaliq NC-L, Hicaliq NC-N, Hicaliq NC-H Infusion Solution
- Rehabix-K1, Rehabix-K2 Infusion Solution
- Amicaliq Infusion Solution
- Paresafe Infusion Solution
- Pareplus Infusion Solution
- Amizet B Infusion Solution
- Aminic Infusion Solution

- Pleamin-P Injection, Hy-Pleamin Injection, Hy-Pleamin S Injection
- Proteamin 12 Injection
- Moriamin-S Injection
- Moripron-F Infusion Solution
- Amiparen Injection
- Plas-amino Injection
- Aminoleban Injection
- Terufis Intravenous Drip Infusions
- Hikarilevan Injection
- Elneopa-NF No.1 Injection, Elneopa-NF No.2 Injection
- Neoparen No.1 Injection, Neoparen No.2 Injection
- Mixid L Injection, Mixid H Injection
- Twinpal Infusion Solution
- Bfluid Injection
- Pntwin No.1, Pntwin No.2, Pntwin No.3 Infusion Solution
- Fulcaliq 1, Fulcaliq 2, Fulcaliq 3 Infusion Solution
- Onepal No.1, Onepal No.2 Infusion Solution
- Morihepamin Intravenous Drip Infusions

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0008.html

Pharmaceuticals and Medical Devices Safety Information No. 374 (July 14, 2020)

1. Revision of Package Inserts regarding Insulin Vial Preparations
2. Initiatives to Ensure Safety of Homecare Medical Devices against Radio Waves Emitted by Mobile Phones, etc.
3. Important Safety Information
   (1) Memantine hydrochloride
   (2) Bevacizumab (genetical recomnibation) including the biosimilars

4 Revision of Precautions (No. 314)
Memantine hydrochloride and 1 other

5. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0018.html

Pharmaceuticals Revisions of PRECAUTIONS (July 20, 2020)

- Iodixanol
- Iohexol (preparations with indications of cerebral angiography)
- Iopamidol
- Iopromide
- Iohexol [preparations with indications of cerebral angiography, angiocardiography (including pulmonary artery angiography), aortography, and angiocardiography of pediatrics (including pulmonary artery angiography)]
- Ioversol
- Iomeprol

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0008.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
September 13-16	RAPS (Regulatory Affairs Professionals Society) Regulatory Convergence	Virtual

Reports from Overseas

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

European medicines agencies network strategy to 2025

On 6th July 2020, EMA released the draft "European medicines agencies network strategy to 2025" on its website for a two-month public consultation [1]. It was developed by the EMA and HMA* to provide a five-year strategy to continue to enable the supply of safe and effective medicines that meet patients' needs in the face of challenges posed by ever-accelerating developments in science, medicine, digital technologies, globalization as well as emerging health threats, such as the COVID-19 pandemic.

In addition to this strategy, some other mid-/long-term measures in the field of health have been recently developed or are under discussion in the EU. EMA published "Regulatory Science Strategy 2025" [2] on 31th March 2020. Furthermore, the European Commission (EC) has opened a public consultation to launch a new strategy, called "Pharmaceutical strategy for Europe", to improve and accelerate patients' access to safe and affordable medicines and to support innovation in the EU pharmaceutical industry [3]. From a broader perspective, EC has also proposed a new health program for the 2021-2027 period, called "EU4Health Programme" [4]. Building on the lessons learned from the COVID-19 crisis, the EC will make significant investments to strengthen health systems in the EU under the EU4Health Programme.

The documents related to these measures show us the trends in the EU's health field over the next few years.

* Heads of Medicines Agencies; The network of the heads of the regulatory authorities responsible for the regulation of human and veterinary medicines in the European Economic Area.

1) https://www.ema.europa.eu/en/news/launch-public-consultation-joint-network-strategy-2025
2) https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy
3) https://ec.europa.eu/health/human-use/strategy_en
4) hhttps://ec.europa.eu/health/funding/eu4health_en

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