PMDA Updates

February, 2021

News

1. Saudi Food and Drug Authority and Ministry of Health, Labour and Welfare signed a Memorandum of Cooperation on medical products.

On December 14, 2020, the Saudi Food and Drug Authority (SFDA) and the Ministry of Health, Labour and Welfare (MHLW) signed a "Memorandum of Cooperation Between The Ministry of Health, Labour and Welfare of Japan And The Saudi Food and Drug Authority On Medical Products". Due to the impact of COVID-19, the signing ceremony was not held face-to-face, but the memorandum was signed by the two countries and exchanged by postal mail.

Areas of cooperation on the memorandum include "The priority review and licensing by SFDA for new pharmaceutical products approved by MHLW and marketed in Japan"; "Capacity building by training SFDA's technical staff in the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs of the Pharmaceuticals and Medical Devices Agency in Japan"; "Joint cooperation at international forum such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), International Medical Device Regulators Forum (IMDRF) and Pharmaceutical Inspection Co-operation Scheme (PIC/S)". This is expected to accelerate access to Japanese pharmaceutical products in Saudi Arabia, and contribute to strengthening pharmaceuticals and medical devices review based on the international harmonized guidelines etc.

MHLW and PMDA continuously promote collaboration with SFDA for the international regulatory convergence and make efforts to strengthen relationship between the two countries.

MHLW's press release is available at the following link.

https://www.mhlw.go.jp/stf/houdou/0000202344_00001.html (in Japanese)

2. The 7th Thailand-Japan Symposium and Thailand-Japan Bilateral meeting

The 7th Thailand-Japan Symposium was held on January 13 and 14, 2021, co-hosted by Thai Food and Drug Administration (Thai FDA) and PMDA via the internet.

The 7th symposium was planed to hold in April 2020 in-person at first, however, it was postponed to January 2021 due to the global pandemic of COVID-19.

The participants from PMDA included Dr. FUJIWARA Yasuhiro (Chief Excective), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs) as well as staffs from Office of Pharmacovigilance II, Office of In Vitro Diagnostics, Office of Medical Devices I, Office of Manufacturing Quality and Vigilance for Medical Devices and Office of International Programs. From Thai FDA, Dr. Paisarn Dunkum (Secretary-General), Dr. Surachoke Tangwiwat (Deputy Secretary-General) and other staffs participated in the symposium. And a total of 315 people from Thailand and Japan attended.

The symposium consisted of the pharmaceutcal session and the medical devices session. The pharmaceutcal session involvled good registration management, scientific consultarion and benefit-risk managemant. The medical devices session involved review of medical devices and in vitro diagnostics, and medical devices vigilance. The speakers from both countries gave presentations about the regulation in their country respectively, and answered questions from the participants.

The details of the symposium are available at the following link.

https://www.pmda.go.jp/english/symposia/0193.html

Following the symposium, Thai FDA and PMDA had a bilateral meeting on January 14 to discuss further cooperation in the area of pharmaceuticals and medical devices regulation, and international activities by both countries.

PMDA and Thai FDA decided to continue the cooperation and the planning of Thailand-Japan symposium.

Bilateral meeting
Left picture: Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA)
Right picture: Dr. Paisarn Dunkum (Secretary-General, Thai FDA), Dr. Surachoke Tangwiwat (Deputy Secretary-General, Thai FDA)

3. PMDA-ATC with National Cancer Center MRCT Webinar 2021

From January 18 to 21, PMDA held a webinar entitled "PMDA-ATC with National Cancer Center MRCT Webinar 2021" with the collaboration of the Clinical Research Support Office of the National Cancer Center (NCC) Japan. This webinar, focusing on multi-regional clinical trials, was designed for pharmaceutical reviewers from overseas regulatory authorities, and was held as a Center of Excellence Workshop for the MRCT/GCP Inspection Priority Work Area, which is led by Japan with Thailand as a champion economy, in the Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC).

The webinar was attended by total 25 participants including regulators from countries/regions such as Indonesia, Myanmar, Peru, Philippines, Taiwan, Tanzania and Uganda, and clinical investigators from Philippines and Viet Nam. Recorded lectures by PMDA staff members, Japan Pharmaceutical Manufacturers Association (JPMA) , NCC and academic institutions on the topics such as points to consider at protocol designing and planning of MRCT, clinical operation, clinical data evaluation, regulatory review based on results of GCP inspections, international cooperation and regulatory convergence among regulatory authorities were provided as preliminary training materials. During the live period of the webinar, participants took part in the Questions and Answer sessions on the 1st day. From the 2nd to the 4th (final) day, live case study sessions including group discussion on the topic of planning, evaluating and operating MRCT were provided. Participants had active discussions throughout the webinar.

From the top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA), Dr. NAKAGAMA Hitoshi (President, NCC), Dr. NAKAMURA Ryuta (Senior Coordinator for International Training, PMDA), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), Dr. SHIMADA Kazuaki (Director of the National Cancer Center Hospital), Dr. SATO Junko (Director of the Office of International Programs, PMDA)
At the bottom: Some of the participants at the webinar

Please refer to the following web site for the details of PMDA-ATC with National Cancer Center MRCT Webinar 2021.

https://www.pmda.go.jp/english/symposia/0184.html

4. Philippines-Japan Bilateral Meeting

PMDA held Philippines-Japan Bilateral Meeting together with Food and Drug Administration of the Philippines (FDA Philippines) via the internet on January 20. Key participants from PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), Dr. SATO Junko (Director of Office of International Programs). In addition, a staff from Ministry of Health, Labour and Welfare (MHLW) and Dr.OKADA Takeo from Embassy of Japan in the Philippines participated. Dr. Roland Enrique Domingo (Director General) attended with other 8 staff members from FDA Philippines.

Following opening remarks by Drs. Domingo and FUJIWARA, FDA Philippines shared information on the latest trends of pharmaceutical regulations in the Philippines. And both discussed actively several activities in the areas of review, pharmacovigilance and GMP to deepen cooperative relationship in this bilateral meeting, and concluded with an agreement to continue discussion for further cooperation.

On the top row: PMDA participants
On the bottom row: Participants from FDA Philippines and Japan
*Picture on the upper left: Dr. FUJIWARA Yasuhiro (Chief Executive), Picture on the upper right: Dr. OKADA Takeo (First Secretary of Embassy of Japan in the Philippines), Picture on the middle center: Dr. Roland Enrique Domingo (Director Genreral of FDA Philippines)

English Translations of Review Reports

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

Pharmaceuticals

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

Brand Name	Non-proprietary Name	Posting date
Biktarvy [Initial Approval]	bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate	January 22

Enhertu [Initial Approval]	trastuzumab deruxtecan (genetical recombination)	January 22
Enhertu [Partial Change Approval]	trastuzumab deruxtecan (genetical recombination)	January 22
Tabrecta [Initial Approval]	capmatinib hydrochloride hydrate	January 29

Medical Devices

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

Brand Name	Term Name	Posting date
CureApp SC Digital Therapeutic and CO Checker for Nicotine Dependence [Initial Approval]	smoking cessation treatment support system	January 27
Eustachian Tube Plug [Initial Approval]	prosthetic material for eustachian tube	February 15

English translations of Notifications and Administrative Notices

The following 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
Jun. 30, 2020	PSEHB/PED Administrative Notice	Considerations for the Clinical Evaluation of Drugs in Pediatric Patients (10 or 12 Years of Age and Older) Who Can be Evaluated Together with Adults	January 22, 2021
Nov. 16, 2020	PMDA/CPE Notification No. 1116002	Procedure for Remote Inspection as a part of compliance inspection on drugs and regenerative medical products	January 22, 2021

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (January 26, 2021)

- Alemtuzumab (genetical recombination)
- Pomalidomide
- Amiodarone hydrochloride (oral dosage form)
- Sildenafil citrate (preparations indicated for pulmonary arterial hypertension)

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

PMDA Medical Safety Information No.58 Revised version (February)

Introduction of Connectors to Prevent Misconnection (for Enteral Applications)
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
March 15-16	ICH Management Committee Interim Meeting	Virtual
March 15-19	33rd DIA Europe Meeting	Virtual
March 16-25	IMDRF Management Committee Meeting etc.	Virtual
March 19	PMDA-ATC Regenerative medicines Review Webinar 2021 for NPRA, Malaysia	Virtual

Reports from Overseas

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

International collaboration under COVID-19 pandemic

This report addresses the international collaboration in the field of medicines under COVID-19 pandemic. The ongoing unprecedented crisis sheds light on many underlying challenges, whereas it has also led to new initiatives that could be used for future opportunities. One of the best examples is the international collaboration.

As featured in PMDA Updates September 2020 [1)], medicine regulatory authorities worldwide are working together under the umbrella of International Coalition of Medicines Regulatory Authorities (ICMRA) to support the development of COVID-19 vaccines and therapeutics. The EMA Executive Director is currently the chair of ICMRA, and under the strong leadership of EMA, ICMRA has been holding meetings and workshops for international alignment and in-depth discussion between regulators on COVID-19 topics [2)]. On 10th February 2021 the workshop on virus variants, one of the emerging issues, took place. In addition, ICMRA has published several supportive statements to address COVID-19-related challenges.

In addition to ICMRA activities, on 4th February 2021 EMA announced a new pilot initiative, called 'OPEN', to increase international collaboration on the evaluation of COVID-19 vaccines and therapeutics [3)]. Regulators from Australia, Canada, Japan, Switzerland and the World Health Organization (WHO) are participating in the pilot under the terms of existing confidentiality arrangements. More information is available in a Question & Answer document [4)].

I think actively engaging in activities to tackle the global issue even in the time of hardships would lead to the foundation of more pragmatic collaboration among regulators in the future.

1) https://www.pmda.go.jp/files/000236880.pdf
2) http://www.icmra.info/drupal/en/covid-19
3) https://www.ema.europa.eu/en/news/ema-covid-19-assessments-open-non-eu-regulators
4) https://www.ema.europa.eu/en/documents/other/questions-answers-pilot-project-open_en.pdf

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