# PMDA Updates

August, 2020

# News

## 1. Thailand-Japan Bilateral Meeting

PMDA held Thailand-Japan Bilateral meeting together with Thai Food and Drug Administration (Thai FDA) via the internet on July 15.

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, from Ministry of Health, Labour and Welfare (MHLW), Mr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs) participated. Key participants from Thai FDA included Dr. Paisarn Dunkum (Secretary-General), Dr. Surachoke Tangwiwat (Deputy Secretary-General), Dr. Poonlarp Chantavichitwong (Deputy Secretary-General).

In the bilateral meeting, Dr. Dunkum and Dr. FUJIWARA made opening remarks and then measures against COVID-19 in Thailand and Japan were shared. After that, any other topics of Thailand –Japan cooperation concerned with pharmaceutical and medical device regulation were discussed by the participants. PMDA and Thai FDA decided to continue the effective cooperation, but it is actually difficult to hold face-to-face events due to COVID-19 outbreak.



The photo of the participants. From left to right, Dr. FUJIWARA from PMDA, Dr. Surachorke, Dr. Dunkum and Dr.Poonlarp from Thai FDA.

## 2. International Medical Device Regulators Forum (IMDRF) Activities

International Medical Device Regulators Forum (IMDRF) was established in October, 2011 to accelerate international harmonization of medical device regulation based on the activities of Global Harmonization Task Force (GHTF) established in 1992.

IMDRF is organized by Management Committee (MC) and Working Groups (WG). Regulators of Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea, and United States of America are current members of MC, and WHO joins as the official observer. The main discussion in MC is a direction of the forum itself and administration of activities in WGs. On the other hand, WGs discuss specific topics to harmonize medical device regulations internationally.

Specially, 8 WGs, GRRP (Good Regulatory Review Practices) WG, Personalized Medical Devices WG, Adverse Event Terminology (AE) WG chaired by Japan, Medical Device Cybersecurity Guide WG, Regulated Product Submission (RPS) WG, Medical Device Clinical Evaluation WG, Principles of In Vitro Diagnostic (IVD) Medical Devices Classification WG, and AI WG established this August are actively progressing. 60 documents have been published so far, and implementation of technical documents has been considered in each country/region.

In globalization of medical device innovation, manufacturing, and distribution, harmonization of regulations and requirements in each country/region is expected to facilitate patients to access breakthrough/innovative medical devices and to take safety measures in prompt timing and right way. Japan has been actively joining international harmonization activities of medical device regulation since establishment of GHTF. PMDA shall

actively continue to participate IMDRF activities and contribute to their efforts toward to global harmonization of medical device regulation.

### 3. Call for Application to PMDA-ATC Medical Devices Webinar 2020 Starts


PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold the "PMDA-ATC Medical Devices Webinar 2020" from November 16 to 20, through web conferencing system. This webinar is designed for reviewers of medical devices and in vitro diagnostics from overseas regulatory authorities, and the participants will be required to join in the live sessions for Q&A and case studies after viewing pre-recorded lectures and e-learning contents as self-study. The objective of the webinar is to provide the participants with opportunities to further enhance the regulatory systems in their respective country/region by learning the basics of regulations and review/approval process, such as risk based classification, scientific review, QMS/standards and safety measures, as well as obtaining up-to-date information about international regulatory harmonization effort for medical devices, such as IMDRF.

This webinar is offered as a Workshop of APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee), Center of Excellence (CoE), however, the webinar is open to non-APEC economies, as well.

Please refer to the following web site for the details of PMDA-ATC Medical Devices Webinar 2020.
http://www.pmda.go.jp/english/symposia/0178.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 |
|---|---|---|
| Orkedia<br>[Initial Approval] | evocalcet | July 20 |
| Benlysta<br>[Partial Change Approval] | belimumab (genetical recombination) | July 29 |
| Trerief<br>[Initial Approval] | zonisamide | August 3 |
| Trerief<br>[Partial Change Approval] | zonisamide | August 3 |

| | | |
|---|---|---|
| Relumina [Initial Approval] | relugolix | August 13 |

# Safety Information

## PMDA Medical Safety Information No.31 Revised version (July, 2020)

Precautions in Handling of Radiopharmaceuticals for Injection
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

# Events

## Conferences/Meetings PMDA hosts or participates in:

| Date | Title | Location |
|---|---|---|
| September 9-11 | PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020 | Virtual |
| September 13-16 | RAPS (Regulatory Affairs Professionals Society) Convergence 2020 | Virtual |
| September 21-25 | IMDRF Management Committee Meeting etc. | Virtual |
| September 28 - October 1 | PMDA-ATC & U.S. FDA Pediatric Review Webinar 2020 | Virtual |
| October 15-16 | The 8th Joint Conference of Taiwan and Japan on Medical Products Regulation | Virtual |

# Reports from Overseas

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

## Recent evaluations under the Article 5(3) of Regulation (EC) No 726/2004

The Article 5 (3) of Regulation (EC) No 726/2004 of the European parliament and of the council [1] lays it down that the Committee for Medicinal Products for Human Use (CHMP) shall draw up an opinion on any scientific matter concerning the evaluation of medicinal products for human use at the request of the Executive Director of the EMA, the European Commission or EU Member States.

Under this procedure, EMA finalized its opinion on the presence of nitrosamines, classified as probable human carcinogens, in human medicines last month [2]. It was requested by the Executive Director of the EMA taking into account that N-nitrosamines have been found in new products as well as products previously investigated [3]. More recently, EMA has started to review the results from the RECOVERY study (clinical trial to identify treatments that may be beneficial for people hospitalized with suspected or confirmed COVID-19) [4] to provide an opinion on the results of the RECOVERY study and in particular the potential use of dexamethasone for the treatment of adults with COVID-19 [5].

The assessment reports adopted so far by CHMP under the Article 5(3) of Regulation (EC) No 726/2004 are publicly available on the EMA website [6]. The assessment report for nitrosamines [7], for example, contains a lot of scientific data and opinions from various perspectives and we can see EMA's robust scientific discussion during its evaluation.

1) https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF
2) https://www.ema.europa.eu/en/news/ema-finalises-opinion-presence-nitrosamines-medicines

3) https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group
4) https://www.nejm.org/doi/full/10.1056/NEJMoa2021436
5) https://www.ema.europa.eu/en/news/ema-starts-review-dexamethasone-treating-adults-covid-19-requiring-respiratory-support
6) https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/article-53-opinions
7) https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf

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