PMDA Updates

March, 2020

News

1. PMDA-ATC Pharmacovigilance Seminar 2020

From February 3 to 6, PMDA held a seminar entitled "PMDA-ATC Pharmacovigilance (PV) Seminar 2020". This seminar, focusing on pharmacovigilance system, was designed for staff members of overseas regulatory authorities who are engaged in pharmacovigilance activities, and was held as a Center of Excellence Workshop for the pharmacovigilance Priority Work Area, in the APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

The seminar was participated by 25 regulators from Azerbaijan, Cambodia, Hong Kong, India, Indonesia, Laos, Malaysia, Maldives, Myanmar, Nepal, Philippines, Russia, Taiwan, Thailand, and Uganda.

The program of the seminar included lectures by staff members from PMDA, U.S.FDA, Japan Pharmaceutical Manufacturers Association (JPMA), and medical/academic institutions on the topics such as comparison of PV systems among the US, EU and Japan, international cooperation, labeling management, risk management plan, evaluation of benefit/risk balance, pharmacoepidemiology, healthcare professionals involvement, relief service for adverse drug reaction, etc. Also included were the group work discussion on the theme of risk minimization activity and the introduction by the participants of the pharmacovigilance system of his/her own economy, and vigorous discussions took place throughout the seminar.

At the end of the seminar, the course completion certificates were handed to each participant by Dr. FUJIWARA Yasuhiro (Chief Executive of PMDA).

Please refer to the following website for the details of PMDA-ATC Pharmacovigilance Seminar 2020.
https://www.pmda.go.jp/english/symposia/0159.html

Group photo of participants, U.S.FDA lecturer and PMDA directors
Front row from left to right, Dr. FUKUDA Eriko (Office Director, Office of International Cooperation) (1st), Mr. ONIYAMA Yukio (Senior Coordinator for International Training) (2nd), Dr. HAYASHI Yoshikazu (Senior Executive Director) (3rd), Dr. NAKASHIMA Nobumasa (Associate Executive Director) (4th), Dr. Gerald Dal Pan (Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S.FDA) (5th)

2. The 4th India-Japan Medical Products Regulatory Symposium

On February 5, the 4th Japan-India Medical Products Regulation Symposium which was held in Tokyo, Japan, was attended by the Japanese representatives from Ministry of Health, Labour and Welfare (MHLW)/PMDA, the Indian representatives from the Ministry of Health and Family Welfare (MoHFW), the Central Drugs Standard Control Organization (CDSCO), and the industries. The symposium was held as part of the cooperation activities under the "Memorandum of Cooperation on Medical Products Regulation Dialogue and Cooperation Framework"

signed in December 2015 between CDSCO and MHLW. We shared the details of the latest regulations of medical products such as pharmaceuticals, medical devices, *in vitro* diagnostics, generic drugs, and regenerative products. The speakers also took many questions to support the audience. In a bilateral meeting on the following day, the Japanese and Indian regulators exchanged views on future bilateral cooperation.

Details of the symposium are available on the following website.

http://www.pmda.go.jp/int-activities/symposia/0085.html (in Japanese)

Group photo of participants and PMDA directors
Front row from left to right, Dr. HAYASHI Yoshikazu (Senior Executive Director) (3rd), Mr. TARUMI Hideki (Director General, MHLW) (4th), Dr. V. G. Somani (Drugs Controller General, CDSCO) (5th), Ms. Mona K C Khandhar (Minister (Economic & Commerce), Embassy of India in Japan) (6th)

3. PMDA-ATC Pharmaceuticals Review Seminar 2020 in Jakarta, Indonesia

From February 13 to 14, 2020, PMDA and Japan International Cooperation Agency (JICA) co-hosted a seminar entitled "PMDA-ATC Pharmaceuticals Review Seminar 2020 in Jakarta, Indonesia". This seminar was organized for regulatory agency, Indonesian Food and Drug Authority (Badan Pengawas Obat dan Makanan: BPOM). The seminar was participated by 27 regulators from BPOM (25 central and 2 provincial offices).

Group photo of participants, JICA lecturer and PMDA directors
Front row from left to right, Ms. Dian Putri Anggraweni (Deputy Director, Drug Safety and Efficacy Standardization, BPOM) (1st), Ms. Diana E. Sutikno (Head, Cooperation Bureau, BPOM) (2nd), Ms. Ratna Irawati (Director, Directorate of Drug, Narcotics, Psychotropics and Precursor Distribution and Service Control, BPOM) (3rd), Ms. Togi Hutadjulu (Director, Directorate of Drug, Narcotics, Psychotropics, Precursor and Addictive Substances Standardization, BPOM) (4th) , Mr. UZU Shinobu (Associate Executive Director for New Drug Review) (5th), Dr. FUKUDA Eriko (Office Director, Office of International Cooperation) (6th), Mr. SANO Yoshihiko (Chief Adviser, JICA) (7th)

The seminar opened with remarks by Mr. UZU Shinobu (Associate Executive Director for New Drug Review, PMDA), Mr. SANO Yoshihiko (Chief Adviser, JICA) and Ms. Togi Hutadjulu (Director, Directorate of Drug, Narcotics, Psychotropics, Precursor and Addictive Substances Standardization, BPOM). The program of the seminar included lectures by staff members from PMDA and BPOM, experts dispatched by the Japan Pharmaceutical Manufacturers Association (JPMA), and academic institution. The topics were review of Chemistry, Manufacturing and Control (CMC), new drugs, generics, and innovative review pathways in Japan. Besides the lectures, case studies on CMC and clinical review were conducted.

At the end of the seminar, the course completion certificates were handed to each participant by Mr. UZU.

Please refer to the following website for the details of PMDA-ATC Pharmaceuticals Review Seminar 2020 in Jakarta, Indonesia.

https://www.pmda.go.jp/english/symposia/0164.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
Revolade [Partial Change Approval]	eltrombopag olamine	February 25
Signifor [Partial Change Approval]	pasireotide pamoate	February 28
Darzalex [Initial Approval]	daratumumab (genetical recombination)	March 4

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (February 25, 2020)

- Rotigotine
- Allopurinol
- Arsenic trioxide
- Asunaprevir
- Glecaprevir hydrate/pibrentasvir
- Sofosbuvir
- Daclatasvir hydrochloride
- Ledipasvir acetonate/sofosbuvir
- Elbasvir
- Grazoprevir hydrate
- Sofosbuvir/velpatasvir
- Daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride
- Fosravuconazole L-lysine ethanolate
- Aminolevulinic acid hydrochloride

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0007.html

Reports from overseas

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

COVID-19

Approximately one month has passed since I came to EMA and I started attending several EMA meetings. I was supposed to introduce some of these meetings but the priority has switched to COVID-19, the biggest concern the world is facing today (This report was based on the information as of 17 March).

EMA has published a specific website to share information related to COVID-19 [1)] as well as some press releases, providing stakeholders latest information.

EMA has created a task-specific email address at an early stage to encourage developers of therapeutics or vaccines against COVID-19 to contact EMA and discuss its development strategy [2)]. It was also announced on the 13th of March that EMA will provide free and rapid scientific advice for developers of potential therapeutics or vaccines against COVID-19 [3)]. In addition, EMA keeps an eye on the impact on the pharmaceutical supply chains in the European Union (EU) [4)]. Furthermore, EMA has communicated not only with EU partners but also with international partners on these topics.

As organization management, EMA has activated its plan for managing emerging health threats [5)] and has taken some precautionary measures; it has been decided that all EMA meetings will be held virtually until the end of April 2020 and stakeholder's events hosted by EMA in March and April will either be held virtually or postponed

until later in the year [6]. Moreover, with the exception of some tasks which need to be performed at EMA office, EMA staff members have started teleworking from 16th March to the end of April (planned as of 16th March).

In my view, these actions have been taken in a systematic and timely manner. I reinforced my belief that being prepared for emergencies is important. In my position as MHLW/PMDA liaison official, I will do what I can now and would like to contribute to facilitate international cooperation in case of emergency by deepening our mutual understanding of each other through daily work.

1) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19
2) https://www.ema.europa.eu/en/news/ema-support-development-vaccines-treatments-novel-coronavirus-disease-covid-19
3) https://www.ema.europa.eu/en/news/covid-19-developers-medicines-vaccines-benefit-free-scientific-advice
4) https://www.ema.europa.eu/en/news/addressing-potential-impact-novel-coronavirus-disease-covid-19-medicines-supply-eu
5) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats#health-threats-plan-section
6) https://www.ema.europa.eu/en/news/covid-19-ema-meetings-delegates-experts-will-be-held-virtually-until-end-april-2020

Dr. KISHIOKA Yasuhiro
PMDA's International Liaison Officer stationed at EMA in the Netherlands

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