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PMDA Updates

February, 2019

News

1. PMDA-ATC MRCT Seminar 2019

From January 21 to 24, PMDA held a seminar entitled "PMDA-ATC Multi-Regional Clinical Trial (MRCT) Seminar 2019". This seminar, 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 APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

Group photo of participants and PMDA directors
Front row from left to right, Dr. Ryuta Nakamura, Senior Coordinator for International Training (3rd), Yoshikazu Hayashi, Senior Executive Director (4th), Dr. Eriko Fukuda, Office Director, Office of International Cooperation (5th)

The seminar was participated by 21 regulators from Bangladesh, Brazil, Hong Kong, Indonesia, Malaysia, Nepal, Nigeria, Philippines, Saudi Arabia, South Africa, Sri Lanka, Thailand and Uganda.

The program of the seminar included lectures by staff members from PMDA, Japan Pharmaceutical Manufacturers Association (JPMA) and academic institutions. The topics included points to consider of protocol designing and planning of MRCT, clinical operation, clinical data evaluation, regulatory review based on results of GCP inspections, post-market safety evaluation of approved drugs based on MRCT, international cooperation and regulatory convergence among regulatory authorities. Besides the lectures, group work with case studies, introduction of review systems and regulations by participants and clinical site tour were provided as well. The participants had active discussions throughout the seminar.

At the end of the seminar, the course completion certificates were handed to each participant by Dr. Yoshikazu Hayashi, Senior Executive Director of PMDA.

Please refer to the following web site for the details of PMDA-ATC MRCT Seminar 2019.
http://www.pmda.go.jp/english/symposia/0138.html

2. PMDA-ATC Pharmaceuticals Review Seminar 2019 in Jakarta, Indonesia

From January 28 to 31, 2019, PMDA and Japan International Cooperation Agency (JICA) co-hosted a seminar entitled "PMDA-ATC Pharmaceuticals Review Seminar 2019 in Jakarta, Indonesia". This seminar is one of the basic course on pharmaceuticals for regulatory agencies, which was organized at the request of National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan: BPOM). 48 regulators from BPOM (19central and 29 local) participated in the seminar.

Group photo of participants and PMDA directors
Front row from left to right, Mr. Masahiko Yokota, Chief Adviser JICA (3rd), Ms. Reri Indriani, Actining Deputy Chairperson Office Director, BPOM (4th) and Dr. Eriko Fukuda, Office Director, Office of International Cooperation (5th)

The seminar opened with remarks by Dr. Eriko Fukuda (Director of International

Cooperation, PMDA), Mr. Masahiko Yokota (Chief Adviser, JICA) and Ms. Reri Indriani (Acting Deputy Chairperson, BPOM). The program of the seminar included lectures by staff members from PMDA on the topics including the consultation, clinical trials, toxicity, GCP / GLP inspection, review for regulatory approval (new drugs, generics, biosimilars), post-marketing safety measures, relief service, recent efforts of pharmaceutical regulation in Japan as well as a lecture on CMC by an expert dispatched by the Japan Pharmaceutical Manufacturers Association (JPMA) from the industrial view.

In sessions on GCP/GLP inspection, review for regulatory approval (new drugs and generics) and post-marketing safety measures, there were also sessions where experts from BPOM made basic lectures on regulations in Indonesia and global harmonization as an introduction of lectures by PMDA. Besides the lectures, case studies of reviewing generic products was conducted.

At the end of the seminar, the Course completion certificates were handed to each participant by Dr. Eriko Fukuda, Ms. Ratna Irawati (Director of Distribution Control, BPOM) and Mr. Masahiko Yokota.

Please refer to the following web site for the details of PMDA-ATC Pharmaceuticals Review Seminar 2019 in Jakarta, Indonesia.

http://www.pmda.go.jp/english/symposia/0139.html

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
Sovaldi	sofosbuvir	January 21
Rebetol	ribavirin	January 21
Copegus	ribavirin	January 21
Stelara	ustekinumab (genetical recombination)	January 25
Amenalief	amenamevir	January 29
Ilaris	canakinumab (genetical recombination)	February 8

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 360, February 5, 2019

1. Package Inserts of Prescription Drugs under the Revised Instructions
2. Important Safety Information
   1. Nusinersen sodium
   2. Axitinib
3. Revision of Precautions (No. 300)
   Nusinersen sodium (and 5 others)
4. 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

Pharmaceuticals Revisions of PRECAUTIONS, February 8, 2019

- Eculizumab (genetical recombination)

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0006.html

Pharmaceuticals Revisions of PRECAUTIONS, February 12, 2019

- Eliglustat tartrate
- Trastuzumab (genetical recombination)
- Trastuzumab (genetical recombination) follow-on biologic 1
- Trastuzumab (genetical recombination) follow-on biologic 2
- Trastuzumab (genetical recombination) follow-on biologic 3
- Nivolumab (genetical recombination)
- Palbociclib
- Pembrolizumab (genetical recombination)
- Glecaprevir hydrate/pibrentasvir

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0006.html

PMDA Medical Safety Information No. 56 (February 2019)

Precautions when Using Compression Stockings

http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
February 27 - March 1	APEC-LSIF-RHSC Meeting	Santiago
March 18-21	IMDRF Management Committee Meeting	Moscow
April 1-2	ICH Management Committee Interim Meeting	Brussels

Reports from overseas

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

EMA is to soon be relocated to Amsterdam

The relocation of EMA to Amsterdam will be completed by 29 March 2019. Since August last year, some EMA staff have already moved to Amsterdam and are carrying out part of its activities remotely, but a large operation related to relocation of most EMA staff is expected in March.

As a result of this relocation, the main operations of EMA will be transferred to Amsterdam beginning of March 2019, but at that time EMA will use a temporary building. Its permanent building, which is still under construction, is expected to be in operation by November 2019. Once the permanent building is operational, EMA will relocate from the temporary building by end of December 2019 or beginning of 2020.

To mitigate the impact of Brexit and its relocation, EMA has set up a business continuity plan to execute its operations appropriately and handled them in a planned and stepwise manner. Although it is a challenging period for EMA, stakeholders are working to continuously promote collaborative activities between Japan and Europe with as-needed support from Japan.

The progress of EMA relocation operations can be found using the following EMA tracking tool.
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/03/WC500244941.pdf

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

CASSS CMC Strategy Forum and WCBP 2019

I attended CASSS CMC Strategy Forum[1] and WCBP 2019[2] on January 28th-31st, 2019, in Washington D.C. This meeting is held annually in order to discuss on new analytical technologies and regulations related to biologics (including gene therapy and cell therapy) between industry, academia and regulator, and to struggle with issues related to biologics development by science-based approach. The meeting theme of this year was "Patient-Centric CMC Development." The United States Pharmacopeial Convention had an exhibition table and disseminated information.

According to the meeting theme, participants mainly discussed on the following sessions:

- Ideas for specification setting
- To share experience on development and data collection of designated "Breakthrough Therapy"
- Activities for continuous manufacturing
- Use of novel analytical technology such as Multi-Attribute Methodology (MAM) and next generation sequencer.

I'd like to pay attention to the movement related to new thoughts about quality control and analytical technology.

1) http://www.casss.org/page/CMCJ1901
2) http://www.casss.org/page/WCBP1900

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