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PMDA Updates

July, 2016

News

1. ICH Meeting in Lisbon (June 10 to 16)

Dr. Tominaga

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was held in Lisbon, Portugal from June 10 to 16. Thirty-two staffs in total from PMDA, including Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs), who served as Vice-Chair of the Assembly and the Management Committee and Mr. Naoyuki Yasuda (Office Director, Office of International Programs) and also Dr. Nobumasa Nakashima (Office Director for International Regulatory Affairs) and other staff from Ministry of Health, Labour and Welfare (MHLW) attended the meeting. In the Assembly, the approval of new Members and Observers was done for the first time, and two topics, "Biopharmaceuticals Classification System-based Biowaivers" and "Bioanalytical Method Validation" were agreed to be developed for new ICH guidelines. The key achievements of the Working Group meetings included ICH M4E (R2) on standardizing benefit-risk information in regulatory submissions, ICH E2B on "Electronic Submission of Individual Case Safety Reports (Questions and Answers)" and ICH M8 on "Electronic Common Technical Document (Questions and Answers)" which all reached Step 4, as well as ICH E17 on "Multi-Regional Clinical Trials" and ICH S9 on "Nonclinical Evaluation for Anticancer Pharmaceutical (Questions and Answers)" which reached Step 2b.

The next ICH meeting will be held on November 5 -10, 2016 in Osaka, Japan.

2. 1st Japan-Korea Joint Symposium on Medical Products (June 23)

Group photo of speakers and participating regulators:
(front row) Dr. Tominaga (third from left), Mr. Mori (forth from left), and Mr. Kwan Sung Kim (center), Director-General, MFDS, (back row) Mr. Yasuda (fifth from left) and Dr. Nakashima(seventh from left)

On June 23, the 1st Japan-Korea Joint Symposium on Medical Products was held in Tokyo, which was attended by about 200 people from PMDA, Ministry of Health, Labour and Welfare (MHLW), Ministry of Food and Drug Safety (MFDS), Health Insurance Review Agency and industry. This symposium was initiated as part of the cooperation activities as set out in the "Memorandum of Cooperation on Medical Products Regulatory Dialogue and Cooperation Framework" signed between MFDS and MHLW in August 2015. Those who participated in the symposium from PMDA included Ms. Tomiko Tawagari (Chief Management Officer), Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs), Mr. Naoyuki Yasuda (Office Director, Office of International Programs) and 6 other staffs, and from MHLW included Mr. Kazuhiko Mori (Councilor for Pharmaceutical Affairs, Minister's Secretariat) and Dr. Nobumasa Nakashima (Office Director for International Regulatory Affairs). There were presentations delivered by the regulators of both countries on the regulatory overview and updates as well as by the industries on the recent trends in the pharmaceutical and medical device industries, and there were active exchanges of views among the participants on each topic.

MHLW's press release is available at the following link.
http://www.mhlw.go.jp/stf/houdou/0000129964.html (in Japanese)

3. DIA 2016 52nd Annual Meeting (June 26 to 30)


Dr. Kondo
at DIAmond session

From June 26 to 30, the DIA 2016 52nd Annual Meeting was held in Philadelphia, U.S.A., and attended by Dr. Tatsuya Kondo (Chief Executive), Ms. Tomiko Tawaragi (Chief Management Officer), Dr. Toshiyoshi Tominaga (Associate Executive Director for International Programs), Dr. Junko Sato (Office Director, Office of International Cooperation), Dr. Yoshiaki Uyama (Office Director, Office of Medical Informatics and Epidemiology) and 10 other staffs from PMDA as well as Dr. Nobumasa Nakashima (Office Director for International Regulatory Affairs) and a staff from Ministry of Health, Labour and Welfare (MHLW). In the PMDA Town Hall session chaired by Dr. Tominaga, presentations were delivered on "New Regulation in Japan and Future Direction of PMDA" by Dr. Kondo, "MHLW's Approaches to the Approval of Innovative Products" by Dr. Nakashima, "International Strategy and International Contribution of PMDA" by Dr. Tominaga, and "Strategic Approach to Post-Marketing Safety Measures" by Ms. Tawagagi. There were approximately 130 participants in the PMDA Town Hall session, and active discussions about PMDA's recent activities were held. In the DIAmond sessions, which were newly introduced this year in the meeting, Dr. Kondo participated in the "Role of regulators to stimulate and support innovation" session as a panelist where he spoke about the importance of seamless measures throughout the process from development to application and regulatory science as their foundation. Also, Dr. Tominaga delivered a presentation on "Rolling Reviews in SAKIGAKE and Breakthrough Therapy Designation" in the "Expedited Reviews and Other Pathways to Speed up Access to Medicines" session. In total, PMDA staffs participated in 7 sessions as a chair, panelist or speakers, and a poster presenter, tutor and the PMDA booth exhibitors.


From the left, Ms. Tawaragi, Dr. Nakashima, Dr. Kondo and Dr. Tominaga

The next meeting will be held on June 18-22, 2017 in Chicago, U.S.A.

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	Generic Name	Posting date
Farydak	panobinostat lactate	June 27
Actair	-	July 14

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 334, June 2016

1. Risk Management Plans (RMPs) Outline Sheets
2. Surveillance on Access to, Dissemination, and Utilization of Drug Safety Information in Clinics and Pharmacies

3. Important Safety Information
(1) Telaprevir, Simeprevir Sodium, Daclatasvir Hydrochloride, Asunaprevir, Vaniprevir, Sofosbuvir, Ledipasvir Acetone Adduct/Sofosbuvir, Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir
(2) Levetiracetam
4. Revision of Precautions (No. 275)
Alendronate sodium hydrate,
Ibandronate Sodium Hydrate,
Etidronate Disodium,
Zoledronic Acid Hydrate,
Pamidronate Disodium Hydrate,
Minodronic Acid Hydrate,
Risedronate Sodium Hydrate
5. List of Products Subject to Early Post-marketing Phase Vigilance
http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0014.html

Pharmaceuticals Revisions of PRECAUTIONS, July 5, 2016

- Diclofenac sodium (Oral tablets)
- Diclofenac sodium (Suppositories)
- Diclofenac sodium (Capsules)
- Diclofenac sodium (Enema ointment)
- Oxytocin
- Benzoyl peroxide
- Clindamycin phosphate hydrate / Benzoyl peroxide
- Apixaban
- Nintedanib ethanesulfonate
- Fingolimod hydrochloride
- Carmustine
- Ombitasvir hydrate / Paritaprevir hydrate / Ritonavir
- Sofosbuvir
- Ribavirin
- Ledipasvir acetonate / Sofosbuvir

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0004.html

Risk Information which some safety measures might be taken (July 15, 2016)

- Azosemide
- Olanzapine (Tablets)
- Olanzapine (Tablets)
- Olanzapine (Fine granules)
- Olanzapine (Injection)
- Sitafloxacin Hydrate
- Imatinib Mesilate
- Nilotinib Hydrochloride Hydrate
- Dasatinib Hydrate
- Bosutinib Hydrate

http://www.pmda.go.jp/english/safety/info-services/drugs/risk-communications/0001.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
August 15-18	APEC-LSIF-RHSC SOM3	Lima
September 6-9	GCRSR/GSRS	Washington D.C.
September 13-14	7th International Meeting of World Pharmacopoeias	Tokyo
September 15	JP 130th Anniversary Symposium	Tokyo
September 17-21	RAPS' 2016 Regulatory Convergence	San Jose
September 27-28	Ph. Eur. : Tackling future challenges of the Quality of Medicines together	Tallinn

Reports from overseas

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

Greater importance of support for SMEs in drug development

EMA has announced a report[1] on its experience of support for small and medium-sized enterprises (SMEs) that are involved in drug development, as it marks the 10th anniversary of the SME initiative. In the report, the outstanding point is the increase of use of Scientific Advice by SMEs year by year with the increased success rate in the marketing authorisation process, according to an EMA representative at the announcement[2].

In Japan, PMDA has implemented Pharmaceutical Affairs Consultation on R&D Strategy, which mainly targets early-stage support for academia and venture companies that have a drug candidate, since July 2011. As is the case with EMA, the number of the consultations provided by PMDA has increased year by year, which indicates the support for SMEs through such consultations is becoming more essential in drug development.

EMA plans to establish an action plan based on findings from the report and a survey in 2015 of SME stakeholders. In Japan as well, the importance of measures to support for venture companies, including those involved in drug development, is highlighted again in Japan Revitalization Strategy (Growth Strategy) 2016 issued this June. I would like to focus on this area and seek a possibility of cooperation between EMA and PMDA.

1) Report on the 10th anniversary of the SME initiative:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/05/WC500206029.pdf
2) Press release:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/05/news_detail_002525.jsp&mid=WC0b01ac058004d5c1

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

Dispatched to U.S.FDA

I'm Hiroshi Sakaguchi, reviewer in Advanced Review with Electronic Data Promotion Group. I'm now dispatched to Office of Strategic Programs, U.S.FDA for 3 months, so I'm going to introduce my task and information that I have received in U.S. FDA. From October 2016, PMDA will start to accept study data for more versatile review in addition to previous dossier (CTD) for new drug submission, and PMDA is planning to analyze clinical trial results by ourselves.

In order to analyze study data efficiently and consistently, study data should be submitted in a specific format. U.S.FDA has already accepted electronic data based on Clinical Data Interchange Standards Consortium (CDISC) standards for many years. PMDA also requests sponsors to submit clinical study data in a format conforming to the CDISC standards.

U.S.FDA actively also participates in the development of data standards (such as CDISC standard) to ensure the standards provide values to the regulatory review process. PMDA needs to make sure the standards meet PMDA requirements and also would like to contribute to develop the global data standards, so I'm now learning U.S.FDA's process for the data standard program. U.S.FDA/CDER has already established the framework for data standards program, and published online[1)]. Besides follow the framework to develop and implement data standards, U.S.FDA meets with CDISC frequently to share information and plan forward. As PMDA accumulate the experience of study data analysis, I think PMDA will have some requests for data standard for more efficient analysis. To prepare for this situation, I believe that we have to consider and establish the process to engage in data standard development that go along with FDA and CDISC processes in the future.

1) http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM462770.pdf

Mr. Hiroshi Sakaguchi
Office of Strategic Programs, U.S. FDA in the U.S.A.

Health Canada Dispatch report

My name is Ryosuke Kuribayashi and I am a principal reviewer in the Office of Generic Drugs at PMDA. I am currently working in the Bureau of Pharmaceutical Sciences of the Therapeutic Products Directorate at Health Canada for a three-month period from June 27 to September 30. During this time, I will discuss the bioequivalence requirements for the Complex Generic Drugs (CGDs), and share our experiences. I also would like to learn Health Canada's experiences and how to manage the Biopharmaceutics Classification System (BCS) and BCS based biowaiver[1)].

I hope to utilize this opportunity to make a stronger cooperative relationship between Health Canada and PMDA.

1) Health Canada. 2014. Release of Guidance Document: Biopharmaceutics Classification System Based Biowaiver: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/bcs_guide_ld_scb-eng.pdf

Mr. Ryosuke Kuribayashi
Bureau of Pharmaceutical Sciences of the Therapeutic Products Directorate
Health Canada in Canada
