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# PMDA Updates

**March, 2014**

## News

### 1. APEC LSIF RHSC (February 18-21)

The APEC Life Science Innovation Forum（LSIF）Regulatory Harmonization Steering Committee（RHSC）meeting was held in Ningbo, China from February 18 to 21, 2014. The officials from regulatory agencies in the relevant countries and representatives from the industry participated. Mr. Naoyuki Yasuda, International Planning Director, Ministry of Health, Labour and Welfare (MHLW) and 2 staff members of the Office of International Programs, PMDA, participated as representatives of Japanese regulatory agency. This steering committee was established in 2008 and has mainly discussed on drug/medical device regulatory harmonization in the APEC economies. Currently, the development of roadmap for 9 topics including cellular therapies, Good Clinical Practice inspection, safety measures, etc. is in progress. In this meeting, lively discussions were made toward holding a workshop for Multi-Regional Clinical Trial Roadmap championd by Japan.

The next meeting is scheduled to be held in Harbin, China in August, 2014.


### 2. CRT 2014 (February 22-25)

Cardiovascular Research Technologies (CRT) 2014 took place from February 22 to 25 in Washington, D.C., and Dr. Yuka Suzuki, Director of Office of Medical Devices II and 3 reviewers participated from PMDA. In the Japan-US Synergies in Global Medical Device Evaluation & Innovation meeting held on February 24, a video message on global clinical trial was delivered from Ms. Tomiko Tawaragi, Associate Executive Director, PMDA, and a PMDA's reviewer of Office of Medical Devices I introduced PMDA's efforts toward post marketing registry of Transcatheter Aortic Valve Implantation which was approved in 2013 in Japan. The discussions were lively made and CRT 2014 successfully came to an end.

## 3. Chief Executive, Dr. Kondo visits ANVISA (February 25 – 26)

Dr. Tatsuya Kondo, Chief Executive, and Dr. Nobumasa Nakashima, Director of Office of International Programs, PMDA, and a staff member of Health Policy Bureau, MHLW, visited Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA) on February 25 and met Dr. Dirceu Barbano, President and other executives of ANVISA. In the meeting, a certain consensus has been reached on mutual interests including pharmacopeia, Good Manufacturing Practice, and accelerated review. Also, further enhancement of mutual collaboration between ANVISA and MHLW/PMDA by developing cooperation scheme was confirmed. To pursue the further discussion between ANVISA and MHLW/PMDA, Dr. Barbano's visit to Japan also will be explored. Working-level consultations will be proceeded toward implementing specific activities such as opinion exchange among experts and a co-hosted symposium.

On the following February 26, they visited Ministry of Health in Brazil and shared opinions on promoting good health and prevention of illness in Brazil. At the same time, strengthening collaborative relationship was mutually recognized.

From left, Dr. Barbano (ANVISA), Dr. Kondo (PMDA)

## 4. PMDA Workshop on Prospect of the drug development for IBD in Japan (February 25)

PMDA hosted a workshop on "Prospect of the drug development for Inflammatory Bowel Disease (IBD): Clinical Evaluation in Japan on the Era of Global Development" in Tokyo on February 25. The purpose of the workshop was to contribute to the future progress of clinical development of IBD drugs in Japan by having a public meeting and exchanging issues and views among academia, industry and regulators on clinical evaluation.

In the morning session, opening remarks by Dr. Takao Yamori, Director of the Center for Product Evaluation, PMDA and introduction of the workshop by Mr. Shinobu Uzu, Director of the Office of New Drug I, PMDA, were made. Prof. Toshifumi Hibi, Director of the Center for Advanced IBD Research and Treatment, Kitasato Institute Hospital, Kitasato University, delivered the keynote speech. Subsequently, Dr. Richard Veselý (EMA) and Dr. Andrew E. Mulberg (FDA, participated online), made presentations on the current status of clinical evaluation in EU and the United States. In the afternoon session, three topics, "Evaluation for Crohn's disease", "Evaluation for Ulcerative Colitis" and "Issues around paediatrics development" were actively discussed. Each of the topic presentations were made by academia, industry and PMDA from their respective viewpoints, then intensive panel discussions followed. Three reviewers from the Office of New Drug I made presentations from PMDA. The workshop ended with a closing remarks by Mr. Masanobu Yamada, Associate Center Director, PMDA.

This workshop with approximately 250 participants was highly evaluated by the participants as the first opportunity to share issues in clinical development of drug for IBD among the academia, industry and regulators and future continuous discussions were expected.

Please refer to the following URL for the presentation files.
http://www.pmda.go.jp/operations/shonin/info/report/ibd-workshop2013.html (Japanese only)


From left, Prof. Hibi (Kitasato University), Dr. Veselý (EMA), Dr. Mulberg (FDA), and a panel discussion

## 5. International Liaison Officer Dispatched to Swissmedic (March 2)

On March 2, Dr. Jun Kitahara (Coordination Director, Office of International Programs, PMDA) was sent to Switzerland as a liaison officer stationed at Swissmedic. He is expected to serve for one year to promote further collaboration between Swissmedic and MHLW/PMDA. This is the second personnel dispatch to Swissmedic following the first one from October to December 2013 and resolved the concern of long-term dispatch to Swissmedic which had been a pending issue.

## 6. The 1st PMDA Medical Devices Training Seminar (March 3-7)

PMDA held the 1st PMDA Medical Devices Training Seminar for foreign regulatory officials from March 3 to 7. Nineteen officials in total from 9 foreign authorities, i.e. Korea (Ministry of Food and Drug Safety); Hong Kong (Medical Device Control Office); Malaysia (Medical Device Authority); Saudi Arabia (Saudi Food & Drug Authority); Singapore (Health Sciences Authority); Switzerland (Swissmedic); Taiwan (Taiwan FDA, Center for Drug Evaluation); Uganda (National Drug Authority), participated in the seminar. Overview of Japanese Regulations on Medical Devices were introduced as well as the points to consider for technical review, Quality Management System inspection, Good Clinical Practice inspection and so on. Active discussions took place between PMDA staff members and the participants as well as among the participants.

Please refer to the following URL for the details of the seminar.
http://www.pmda.go.jp/english/events/1st_pmda_medical_devices_training_seminar.html
PMDA plans to hold the PMDA Medical Devices Training seminar annually and the 2nd Seminar would be scheduled around March 2015.

## 7. EMA/FDA/MHLW-PMDA orphan medicinal product workshop (March 10)

EMA/FDA/MHLW-PMDA orphan medicinal product workshop was held at EMA in London on March 10. From Japan, staff members from MHLW, National Institute of Biomedical Innovation (NIBIO) and Orphan Working Group of PMDA participated in the workshop. MHLW and PMDA have periodically performed teleconference with EMA and FDA to exchange information and opinions regarding the orphan drug designation system and supportive measures for the development and to enhance their collaboration. This workshop is a part of the collaborative activities and was the first co-held workshop by EU/U.S./Japan. In the morning session, the participated regulatory agencies and NIBIO explained orphan drug designation systems, incentives to encourage orphan drug development, and other support measures of each country/region. In the afternoon session, pharmaceutical companies had opportunities to have face-to-face consultations with each agency at their booth. There were approximately 150 participants from industries in Japan, U.S., and EU in the workshop and lively discussion was made.

## 8. The 6th Science Committee Meeting (March 11)

On March 11, the 6th Science Committee (parent committee) meeting was held and summaries of their activities in the first term were reported from each of the subcommittees. The Committee discussed and accepted the "Summary of the discussions on assessment of the current status of personalized medicine relating to drug development and review," which was jointly summarized by the Pharmaceuticals and Bio-products Subcommittees, and submitted to PMDA.

In preparation for the Science Committee for the 2nd term, which will start from April, the Office of Review Innovation introduced the candidate list of the parent committee, and the proposed subjects in the areas of pharmaceuticals and bio-products, medical devices, and cellular and tissue-based products were discussed. The working group leaders for the selected subjects were appointed.

The meeting agenda and list of the handouts are available at:
http://www.pmda.go.jp/guide/kagakuiinkai/kagakuiinkai/h260311gijishidai.html (Japanese)
http://www.pmda.go.jp/english/scienceboard/scienceboard/20140311.html (English)

## 9. English translation of review reports (March 19)

PMDA released 20 review reports (18 pharmaceuticals and 2 medical devices) in English in the fiscal year 2013.

**Pharmaceuticals** http://www.pmda.go.jp/english/service/drugs.html

| Brand Name | Generic Name | Posting date |
|---|---|---|
| Poteligeo | Mogamulizumab (genetical recombination) | May 28 |
| Bridion | Sugammadex sodium | May 29 |
| Tenelia | Teneligliptin hydrobromide hydrate | July 18 |
| Orencia | Abatacept (genetical recombination) | August 29 |
| Seebri | Glycopyrronium bromide | September 12 |
| Tresiba | Insulin degludec (genetical recombination) | September 13 |
| Lixiana | Edoxaban | October 18 |
| Votrient | Pazopanib hydrochloride | November 15 |
| Ryzodeg | Insulin degludec/Insulin Aspart (genetical recombination) | November 27 |
| Xeljanz | Tofacitinib citrate | December 6 |
| Nouriast | Istradefylline | December 17 |
| Acofide | Acotiamide hydrochloride hydrate | December 26 |
| Metreleptin | Metreleptin (genetical recombination) | January 29 |
| Perjeta | Pertuzumab (genetical recombination) | February 19 |
| Xalkori | Crizotinib | March 13 |
| Lyxumia | Lixisenatide | March 13 |
| Vyndaqel | Tafamidis Meglumine | March 17 |
| Stivarga | Regorafenib Hydrate | March 19 |

### Medical devices http://www.pmda.go.jp/english/service/medical_devices.html

| Brand Name | Generic Name | Posting date |
|---|---|---|
| DuraHeart | Implantable ventricular assist device | July 2 |
| Evaheart | Implantable ventricular assist device | July 2 |

# Safety Information

## Pharmaceuticals and Medical Devices Safety Information No.310, February 27, 2014

1. Thrombosis with YAZ Combination Tablets for Dysmenorrhea
2. Rivaroxaban and Interstitial Pneumonia
3. Direct Patient Reporting System for Adverse Drug Reactions
4. Important Safety Information
5. Revision of Precautions (No. 253)
6. List of Products Subject to Early Post-marketing Phase Vigilance (as of February 2014)

http://www.pmda.go.jp/english/service/precautions_2013.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/service/drugs.html

| Brand Name | Generic Name | Posting date |
|---|---|---|
| Xalkori | Crizotinib | March 13 |
| Lyxumia | Lixisenatide | March 13 |
| Vyndaqel | Tafamidis Meglumine | March 17 |
| Stivarga | Regorafenib Hydrate | March 19 |

# Events

## Conferences/Meetings PMDA hosts or participates in:

| Date | Title | Location |
|---|---|---|
| March 17-19 | APEC MRCT CoE Pilot training | Singapore |
| March 25-27 | The 26th Annual EuroMeeting Vienna 2014 | Vienna |
| March 25-27 | IMDRF Steering Committee Meeting | San Francisco |
| April 10-11 | The 3rd Asia Partnership Conference of Pharmaceutical Association | Tokyo |
| May 11-14 | The 6th DIA China Annual Meeting | Shanghai |
| May 22-23 | The 8th DIA Annual Conference in Japan for Asian New Drug Development | Tokyo |
| May 31-June 5 | ICH Minneapolis meeting | Minneapolis |

# Letters from the liaison officers

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

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Do you know EMA's Executive Director Guido Rasi received European Rare Disease Leadership Award 2014[i] ? A total of 12 medicines for the treatment of rare diseases were recommended for marketing authorisation by the CHMP over the past twelve months. The EURORDIS Awards Jury recognised the contribution to development and approval of rare disease therapies and the access to medicines through the innovative approaches. Global collaboration is required for the development of rare disease therapies. EMA has strong communication with MHLW/PMDA and US FDA.

As one of the output of our communication, 'Joint EMA, US FDA, and MHLW-PMDA Orphan Medicinal Product Workshop' has been held in EMA on 10th March 2014[ii]. In the morning session, the presentations on orphan designation, the incentives and the grants were made by delegates from each agency. In the afternoon session, face to face consultations on specific product development were held between each agency and participants from pharmaceutical companies. It is usually difficult to understand the description of regulatory documents in any regions. These specific consultations will promote better understanding on the regulations. We are confident the workshop will accelerate rare disease therapies in each region.

[i] EURORDIS Awards Recipients
http://www.eurordis.org/content/eurordis-awards-recipients
[ii] Joint European Medicines Agency (EMA), US Food and Drug Administration (FDA), and Japanese Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) orphan medicinal product workshop
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2013/12/event_detail_000810.jsp&mid=WC0b01ac058004d5c3

Dr. Junko Sato
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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