



*Adonis ramosa*

# PMDA Updates

February, 2016

## News

### 1. PMDA provides JICA training program “Strengthening the National Regulatory Authorities (NRA) for Vaccine's Quality and Safety (Collaboration with WHO)” (January 14, 15, and 18)

On January 14, 15, and 18, PMDA accepted nine officers from regulatory agencies of Bangladesh, Indonesia, Mongolia, Pakistan, and Vietnam and provided lectures on 1) outlines of PMDA's organization and the roles of PMDA in the vaccine regulation, 2) Good Clinical Practice (GCP) inspections, 3) Relief Services for Adverse Health Effects, 4) Good Manufacturing Practice (GMP) inspections, and 5) post-marketing safety measures. This training was provided as a part of the specific training program, “Strengthening the National Regulatory Authorities (NRA) for Vaccine's Quality and Safety (Collaboration with WHO)” by the Japan International Cooperation Agency (JICA), and the training was well appreciated by the participants for being very productive. The objective of this training is enhancement of NRA function through capacity development of officials for manufacturing and use of vaccines. PMDA supports this training by providing relevant training contents to contribute to public health of the country/ region of the participants and the world.

### 2. JICA FY2015 Training on “Economic Partnership Program (EPP) on Medical Device Regulatory Program” for Malaysian regulators (January 27 to 29)

From January 27 to 29, PMDA accepted five officers from the regulatory agency of Malaysia, and provided lectures on the themes including clinical trials and approval review of medical devices (including case studies of new and generic medical devices), GCP, Quality Management System (QMS), post-marketing safety measures, PMDA's international initiatives, and surveillance of medical devices.

This training was provided upon the request from the Japan International Corporation of Welfare Services (JICWELS), as a part of the specific training program, “EPP on Medical Device Regulatory



Group photo of trainees

Program”, arranged for Malaysia by JICA, and the training was well appreciated by the participants for being very productive. Japan is a reference country for an abbreviated review of medical devices in Malaysia. This training is expected to enhance the participants' understanding of medical device regulations in Japan to further promote the utilization of an abbreviated review in Malaysia.

## 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
Opdivo	nivolumab (genetical recombination)	January 25
Orfadin	nitisinone	February 5
Rituxan	rituximab (genetical recombination)	February 8
Cyramza	ramucirumab (genetical recombination)	February 9
Rapalimus	sirolimus	February 15
Adcetris	brentuximab vedotin (genetical recombination)	February 17

### Medical Devices

<http://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.htm>

Brand Name	Generic Name	Posting date
Jarvik 2000 Implantable Ventricular Assist Device	implantable ventricular assist device	January 27

## Safety Information

### Pharmaceuticals and Medical Devices Safety Information No. 330, February 9, 2016

1. Preventative Measures for Accidental Ingestion of Pharmaceuticals by Children
2. Important Safety Information
  - (1) Amlodipine besilate
  - (2) Itraconazole
3. Revision of Precautions (No. 271)
  - Azilsartan (and 12 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance (as of December 2015)

<http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0013.html>

### Pharmaceuticals Revisions of PRECAUTIONS, February 16, 2016

- Eribulin Mesilate
- Entecavir Hydrate
- Methylphenidate Hydrochloride
- Esomeprazole Magnesium Hydrate

<http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0003.html>

**PMDA Medical Safety Information No. 48, January 22, 2016**

Precautions in handling of Three-way Stopcocks

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

## Events

**Conferences/Meetings PMDA hosts or participates in:**

Date	Title	Location
March 1-4	APEC MRCT/GCP Regulatory Science Centre of Excellence Pilot Program	Singapore
March 8-10	International Medical Device Regulators Forum (IMDRF) MC Meeting	Brasilia
March 16	International Regulatory Forum of Human Cell Therapy and Gene therapy Products	Osaka
March 24-25	The 3rd Thailand-Japan Symposium	Bangkok
April 4-6	DIA 28th Annual EuroMeeting	Hamburg
April 7-8	The 5th Asia Partnership Conference of Pharmaceutical Associations (APAC)	Tokyo
April 13-14	10th DIA Asia New Drug Conference	Tokyo
April 28-30	3rd International Conference on the Progress of Regenerative Medicine and Its cultural Impact	Vatican

## Reports from overseas

*Our officers deliver lively reports of their activities at their stationed overseas authorities.***Meeting on anti-cancer immunotherapeutic drugs**

EMA held a meeting on anti-cancer immunotherapeutic drugs with regulatory authorities, academia and pharmaceutical industry in collaboration with the Cancer Drug Development Forum (CDDF) at EMA's offices on February 4-5<sup>1)</sup>. The objective of the meeting was to discuss appropriate patient population selection in clinical trials, clinical trials designs, rational for the mechanism of action in different tumour types, concomitant use of immunotherapeutic drugs, and assessment of relative efficacy in relation to immunotherapeutic drugs and to address their impact on the regulatory environment. The meeting had seven sessions including sessions on lessons learnt, population selection, and immunotherapeutic drugs of peptides and cell therapy. In each session, academia, pharmaceutical industry and regulators gave presentations and these were followed by very interesting discussions. The following topics, in particular, were raised: requirements for adaptive pathway to accelerate approval process, measures to prevent adverse drug reactions that could affect long-term compliance, and the importance of research on biomarkers to select target patients rapidly and appropriately in clinical settings and the importance of developments of diagnostic drugs.

In view of the global nature of research and development of drugs, the discussions at the meeting are applicable to Japan as well. If this type of meeting is held from now on, I will continue to report them as a liaison officer stationed at EMA.

- 1) Challenges for the approval of anti-cancer immunotherapeutic drugs  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/events/2015/12/event\\_detail\\_001244.jsp&mid=WCob01ac058004d5c3](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/12/event_detail_001244.jsp&mid=WCob01ac058004d5c3)

Mr. Yoshihiko Sano  
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

---

### Completion of station at USP

I have been working at USP as a liaison for the purpose of strengthening the relationship between USP and JP and collecting information regarding USP's activities for a year starting March 2015 and ending March 2016. During this time, USP transferred to the new 2015-2020 cycle, therefore I was able to attend critical meetings and events that took place at USP at the beginning of the new cycle, including USP Convention, Expert Committee Orientation and Training for newly elected Expert Committee members. I was able to collect information regarding USP's activities for harmonization through these meetings and events. Since the relationship between USP and JP will continue through the Pharmacopoeial Discussion Group (PDG) and ongoing bilateral prospective harmonization projects, I would like to continue to contribute to harmonization of JP in the future by taking advantage of knowledge, experience and personal relationship which I have obtained through my activities as a liaison. Last but not least, I will express my sincere appreciation to Dr. Kevin Moore and Excipient team who supported my activities at USP and everyone who supported my dispatch.

Dr. Chie Mizumaru  
PMDA's International Liaison Officer stationed at USP in the U.S.A.

---

### Dispatch to Center for Devices and Radiological Health, U.S. FDA

I am Hiromi Kumada from the Division of Registered Certification Bodies Assessment, Office of Manufacturing/Quality and Compliance, PMDA. Since January 20 2016 I have been dispatched to the Medical Device Single Audit Program (MDSAP) Team, Division of International Compliance (DICO), Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), U.S. FDA. The dispatch period will be about three months. The MDSAP was launched by regulatory authorities of Australia, Brazil, Canada and the U.S. in 2012. This program aims to reduce the burden on medical device manufacturers of redundant audits/inspections by multiple regulatory authorities by enabling participating regulatory authorities to accept audit results from third-party certification bodies (in MDSAP which are called "Auditing Organizations"). Participating MDSAP regulatory authorities work together to assess Auditing Organizations to ensure their ability to conduct MDSAP audits in accordance with specified MDSAP policies and procedures. Japan (PMDA and Ministry of Health, Labour and Welfare) joined MDSAP as a participating country in June, 2015. I would like to learn the U.S.FDA's methods, policies, procedures and other controls regarding the assessment of third-party certification bodies during this dispatch.

Also I will learn about CDRH/OC interactions and collaborative relationships. I would like to contribute in developing a stronger cooperative relationship between FDA and PMDA.

Ms. Hiromi Kumada  
Visiting assessor, Office of Compliance at CDRH, U.S. FDA in the U.S.A.

---

