厚生労働省
Ministry of Health, Labour and Welfare

Recent updates of International Regulatory Activities in Japan

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4th October 2016 in Sao Paulo, Brazil

International Regulatory Harmonization Strategy

– Regulatory Science Initiative (RSI) – (June 2015)

Objective

Proactively contribute to the international regulatory harmonization and cooperation by sharing Japan's knowledge on regulations (regulatory science) with the world.

⇒ **Aim to resolve the global drug/device lag and contribute to global health**

⇒ **Revitalize the pharmaceutical and medical device industries**

Implementation of the International Strategy

1. Establishment of the basis for approving innovative products – SAKIGAKE Project–

2. Establishment of office and center for international regulatory cooperation in MHLW and PMDA

3. Engagement in bilateral to strengthen international cooperation

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SAKIGAKE Designation System

– To put innovative products into practice in Japan first in the world –

Designation Criteria

- Medical products for diseases in dire need of innovative therapy
- Applied for approval firstly or simultaneously in Japan
- Prominent effectiveness can be expected based on non-clinical study and early phase of clinical trials

Designation Advantage

1. Prioritized Consultation [Waiting time: 2 months→1 month]

2. Substantialized Pre-application Consultation [de facto review before application]

3. Prioritized Review [12 months → 6 months]

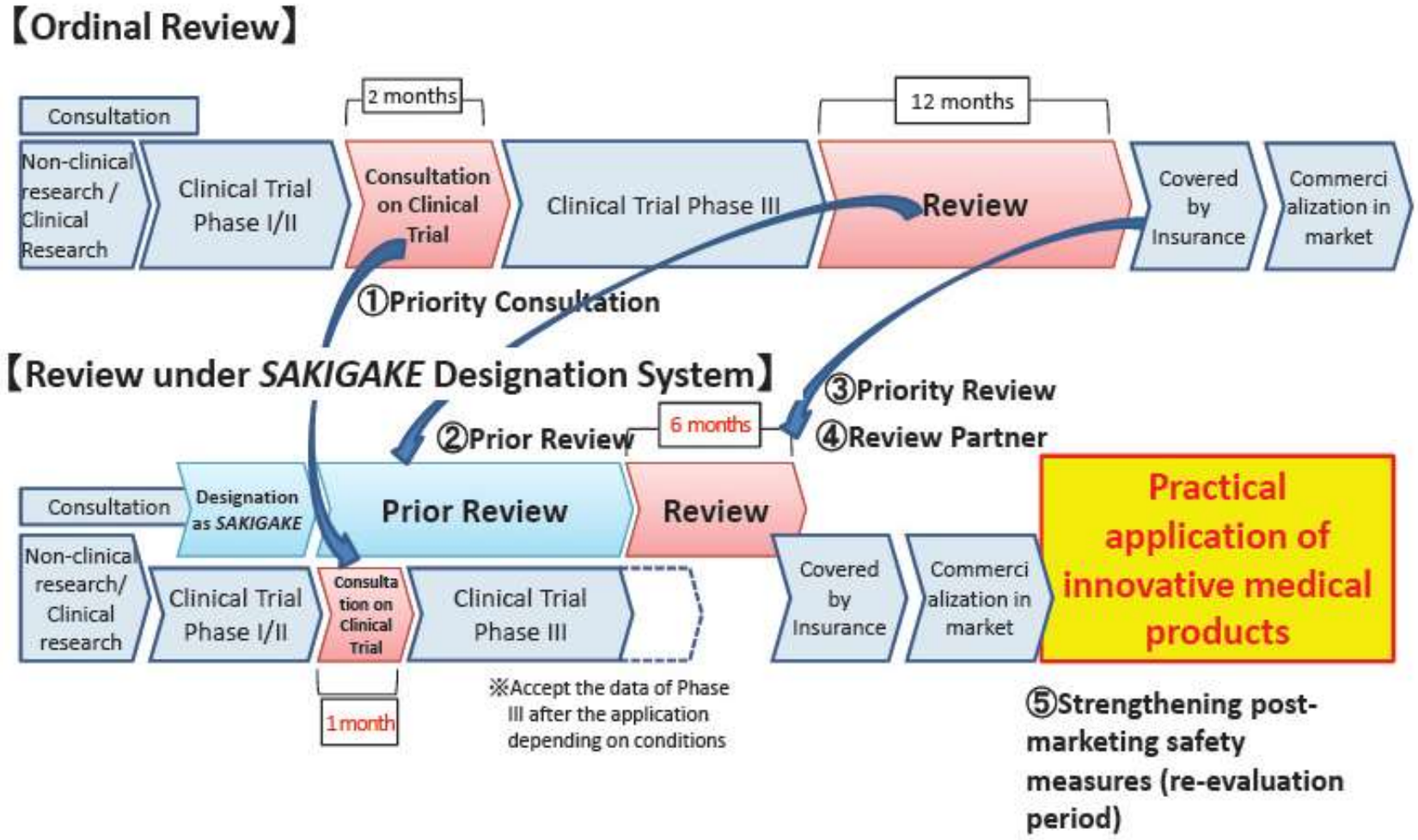
4. Review Partner [PMDA manager as a concierge]

5. Substantial Post-Marketing Safety Measures[Extension of re-examination period]

Designation Procedure

1. Initiation by applicant 2. Initiation by the MHLW

SAKIGAKE General Timeframe



SAKIGAKE Designation (1): Pharmaceuticals
(27 October 2015)

No.	Product name	Expected indication	
1	**Sirolimus (NPC-12G)**	Angiofibroma associated with nodular sclerosis	Nobelpharma
2	**NS-065/NCNP-01**	Duchenne muscular dystrophy (DMD)	Nippon Shinyaku
3	**S-033188**	Influenza A or B virus infection	Shionogi
4	**BCX7353**	Management of angioedema attacks in patients with hereditary angioedema (HAE)	Integrated Development Associates
5	**ASP2215**	First-relapsed or treatment-resistant FLT3 mutation-positive acute myeloid leukaemia	Astellas
6	**Pembrolizumab (genetical recombination)**	Unresectable, advanced and recurrent gastric cancer	MSD

SAKIGAKE Designation (2): Medical Devices and Regenerative Medical Products (10 February 2016)

[Medical Devices]

No.	Product name	Expected indication	
1	**Titanium Bridge** (Hinged titanium plate)	Adduction-type spasmodic dysphoria	Nobelpharma
2	**Bioresorbable adhesion barrier** (Trehalose solution)	Post-operative adhesion reduction	Otsuka Pharmaceutical Factory

[Regenerative Medical Products]

No.	Product name	Expected indication	
1	**STR01** (Autologous bone marrow-derived stem cells)	Improvement of neurological syndrome and dysfunction associated with spinal cord injury	Nipro
2	**G47△** (Genetic recombination herpes virus)	Malignant brain tumor (glioma)	The Institute of Medical Science, The University of Tokyo Daiichi-Sankyo
3	**Autologous cardiac stem cells**	Improvement of cardiac function in patients with pediatric congenital cardiac disease	Japan Regenerative Medicine

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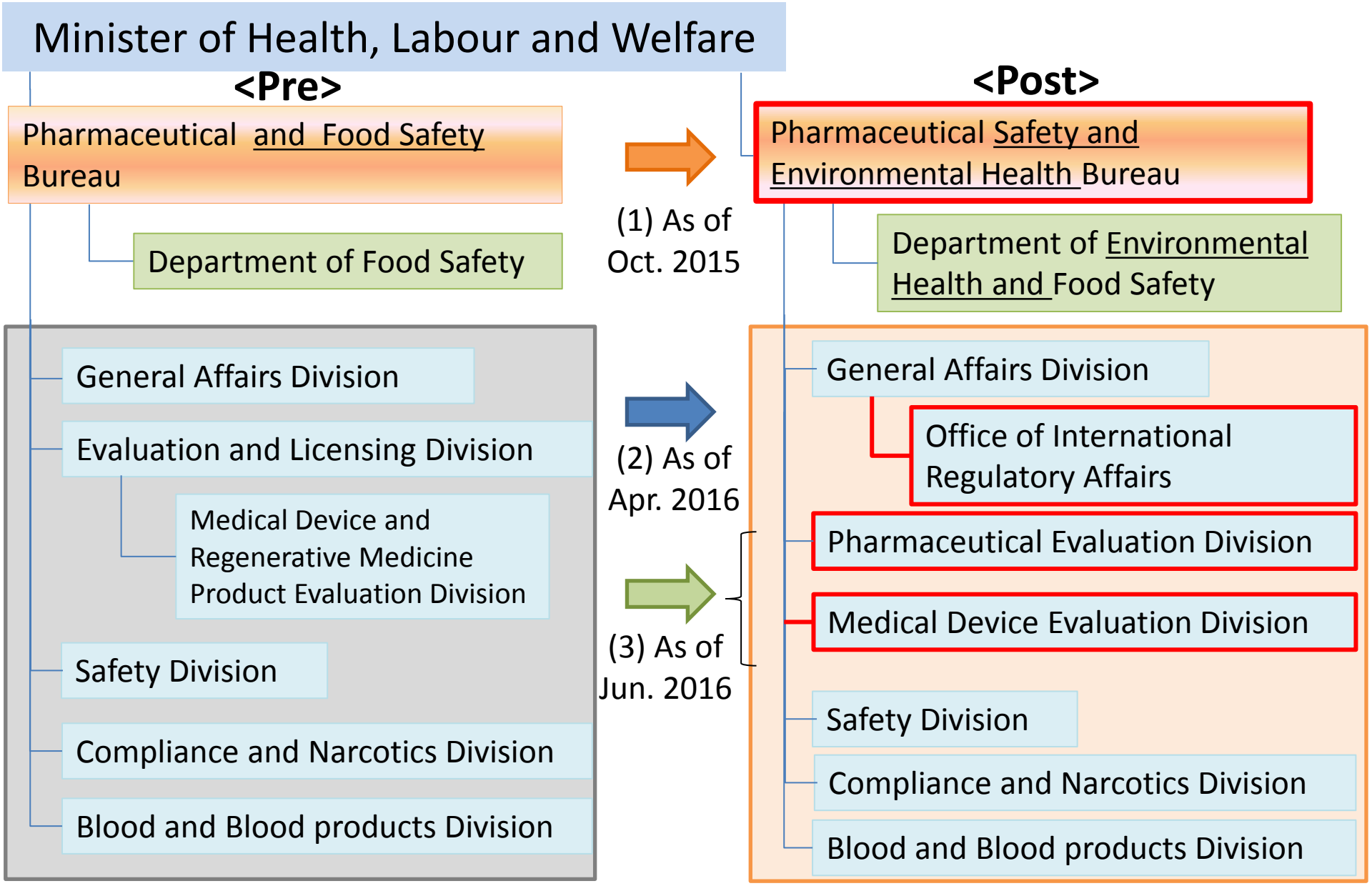
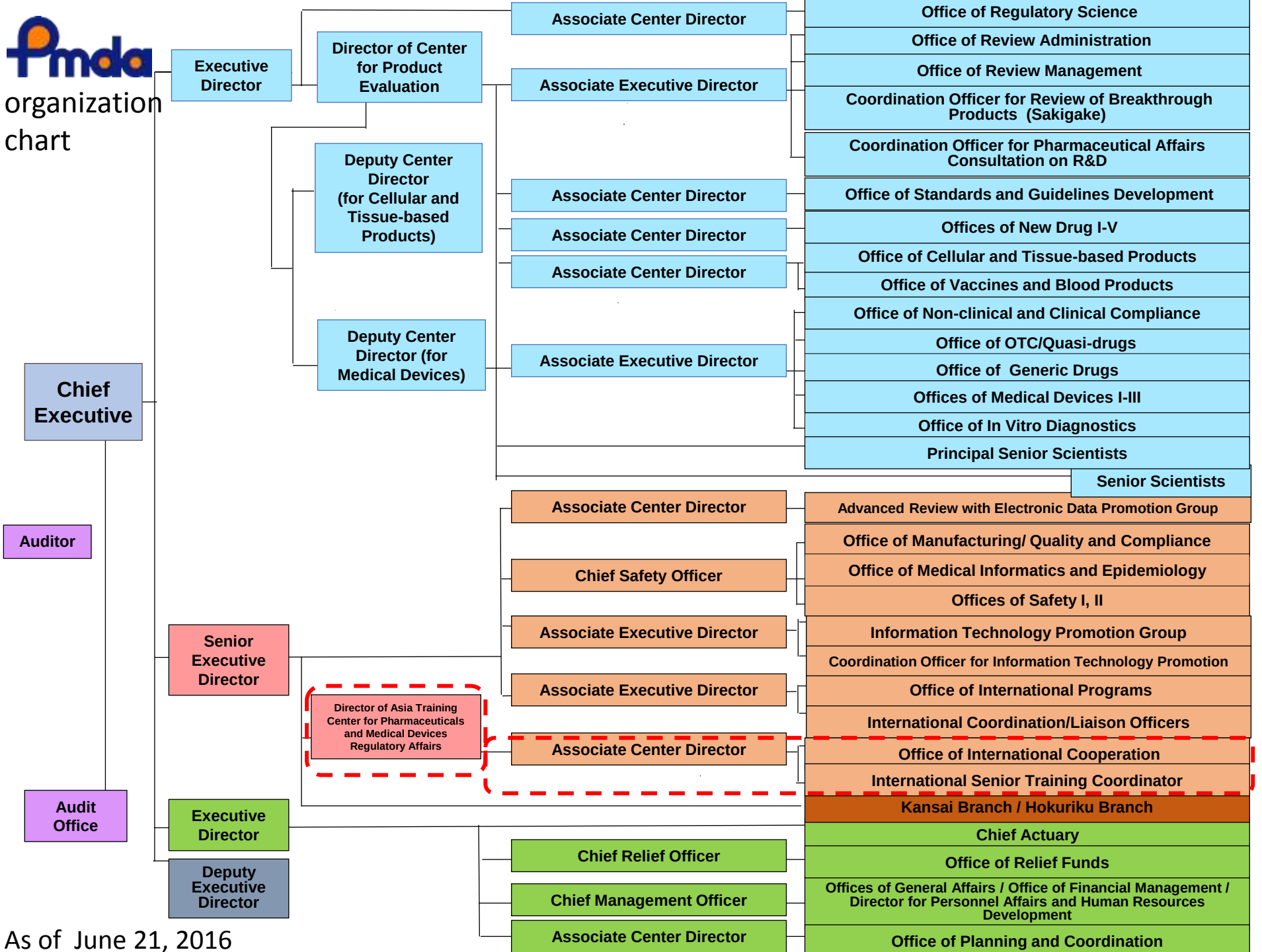
Reform of Pharmaceutical Safety and Environmental Health Bureau



organization chart



As of June 21, 2016

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (As of Apr. 2016)

- Plan, design and coordinate training for Asian regulatory authority staff
- Provide **training opportunities** including **on-site training**

➡ Help raise the level of regulations in Asia as a whole.

Asia Training Center (within PMDA)

Japan

(1) Training seminar by PMDA, local prefectures and industry

APEC

Local Asian site

(2) Assign to local site

(3) APEC Training Centre for Clinical Trial and Pharmacovigilance

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

- Managed by Office of International Cooperation (established in April 2016)
- Organize training programs held at PMDA and overseas
- Exchange staff members for on-the-job training
- Training themes:
  - Best Regulatory Practices in Product Review, Safety Info Analysis, etc.
  - ICH, IMDRF, IGDRP, ICCR, PIC/S Guidelines
  - Specific topics per request by partner country

Training Seminars held in FY2016

[PMDA-ATC Seminars]

- Pharmaceutical Review (Jul7 25-29, PMDA)
- Pharmaceutical Review (September 26-29, Bangkok, Thailand)
- Medical Devices (November 7-11, PMDA)
- GMP Inspection (December 5-9, Toyama Prefecture, Japan) [co-hosted with PIC/S]

[APEC-LSIF-RHSC CoE Pilot Workshop]

- Good Registration Management (November 15-17, Chinese Taipei)
- MRCT/GCP Inspection (January 23-26, 2017, PMDA)
- Pharmacovigilance (February 6-9, 2017, PMDA)

https://www.pmda.go.jp/english/int-activities/training-center/0001.html

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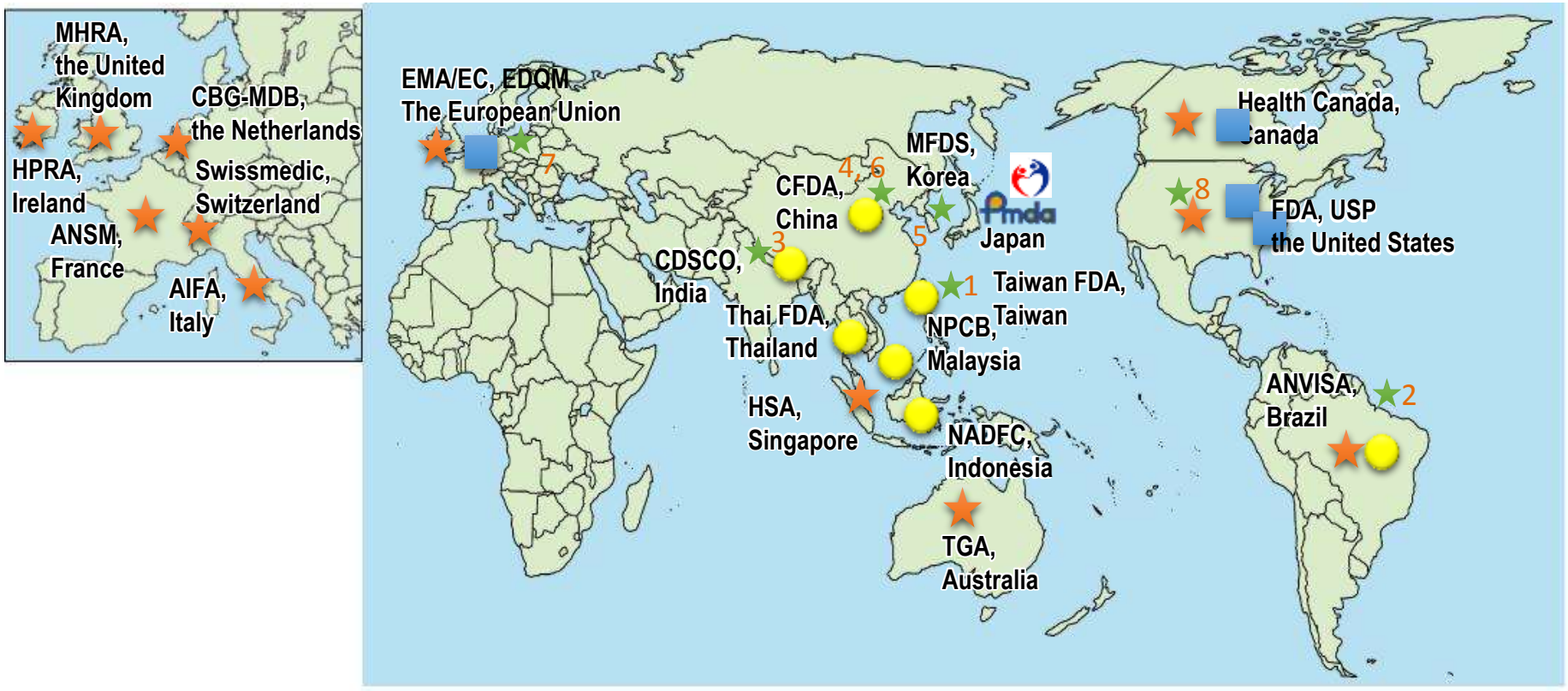
Summary of Bilateral Activities

As of 15th September, 2016



Confidentiality Arrangement signed

Joint symposium held

Cooperative Arrangement (MOC) signed

PMDA staff stationed at agencies outside Japan

1 Taiwan: MOU on Medical Products Regulation in 2013
[between the Interchange Association of Japan and the East Asia relations of Taiwan]

2 Brazil: MOC on Pharmacopoeia, 2015

3 India: MOC on Medical Products Regulatory Dialogue, 2015

4 China: MOU on framework for Dialogue, 2009

5 Korea: MOC on Medical Products Regulatory Dialogue, 2015

6 China: MOC on Pharmacopoeia, 2016

7 EU: MOC on Pharmacopoeia, 2016

8 US: MOC on Pharmacopoeia, 2016

Recent interactions between Japan and Brazil

Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices

- 1st Seminar in August 2014, in Sao Paulo, Brazil
- 2nd Seminar in September 2015, in Tokyo, Japan

MOC between ANVISA and MHLW on cooperation of Pharmacopoeias

- Signed in Tokyo, on 11th September, 2015
- Means of Cooperation:
  - Bilateral meetings, workshop and internship to share experiences and information on development of monographs and methods

Muito Obrigado!