Strategies for regulatory convergence including Asian region in Japan

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(PMDA)

Today's topics

1. International Collaboration
2. Bilateral cooperation
3. PMDA activities in Asia

Environment surrounding medical device regulation

◆ Globalization of development and marketing of products

Regulation control of each country

Different definition and classification of each country

Duplication

Different requirement of each country
- quality
- non-clinical
- clinical etc.

Promotion of global harmonization for regulation

- **Multilateral correspondence**
  Preparation of common standards
- **Bilateral correspondence**
  Cooperation based on reliability maturity

◆ Deviation and complication between International standards and entrepreneurial development requirements

International standards, ISO etc.

Complication

Globalization of development and companies

◆ Difficulties for resource distribution of regulatory agencies

The situation in which one country cannot address with all issues

Management Committee member

IMDRF International Medical Device Regulators Forum

Founding member of GHTF

Brazil

Russia

China

South Korea

Singapore

Official Observer:

WHO

Affiliate Organization:

PAHO
APEC AHC LSIF
AHWP

IMDRF Chair

2012 – Australia, TGA

2013 – European Union, European Commission

2014 – USA, Food and Drug Administration

2015 – Japan, MHLW/PMDA

2016 – Brazil, ANVISA

2017 – Canada, Health Canada

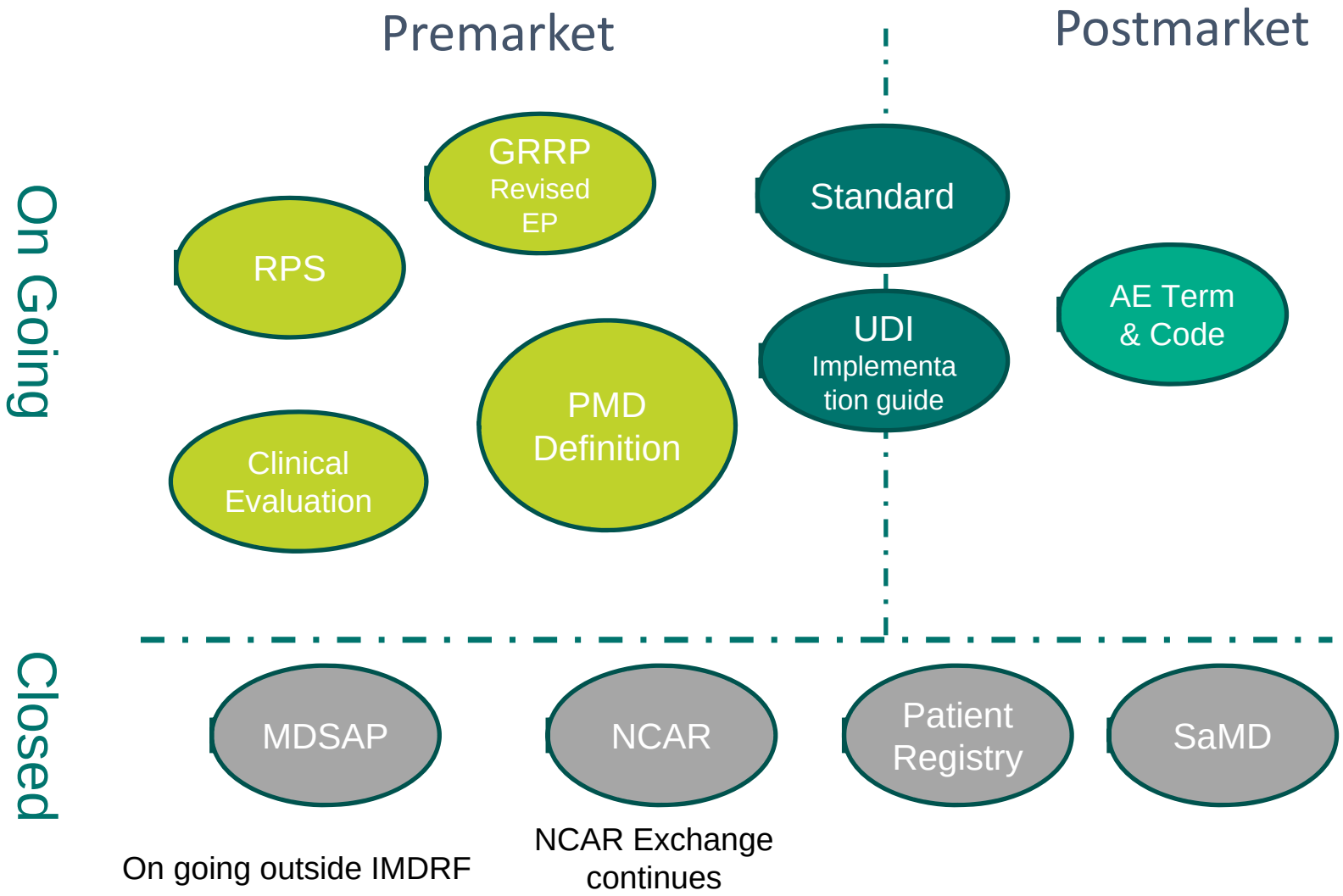
2018 – China, NMPA (Previously CFDA)

2019 – Russia, Roszdravnadzor

IMDRF Work Items

1. Medical Device Single Audit Program (MDSAP)
2. Software as a Medical Device (SaMD)
3. National Competent Authority Report (NCAR) Exchange
4. Patient Registries
5. **Unique Device Identification (UDI) system**
6. **Regulated Product Submission (RPS)**
7. **Adverse Event Terminology and Coding (AE)**
8. **Good Regulatory Review Practice (GRRP)**
9. **Improving the quality of international medical device standards for regulatory use (Standards)**
10. **Personalized Medical Device (PMD)**
11. **Clinical Evaluation**

Current IMDRF Work Items



Unique Device Identification (UDI) system

To promote a globally harmonized approach to the application of a UDI system, supporting the principles laid down in the general IMDRF UDI Guidance Document (IMDRF/WG/N7Final:2013).

- IMDRF/UDI WG/N7: 2013 “UDI Guidance - Unique Device Identification (UDI) of Medical Devices”

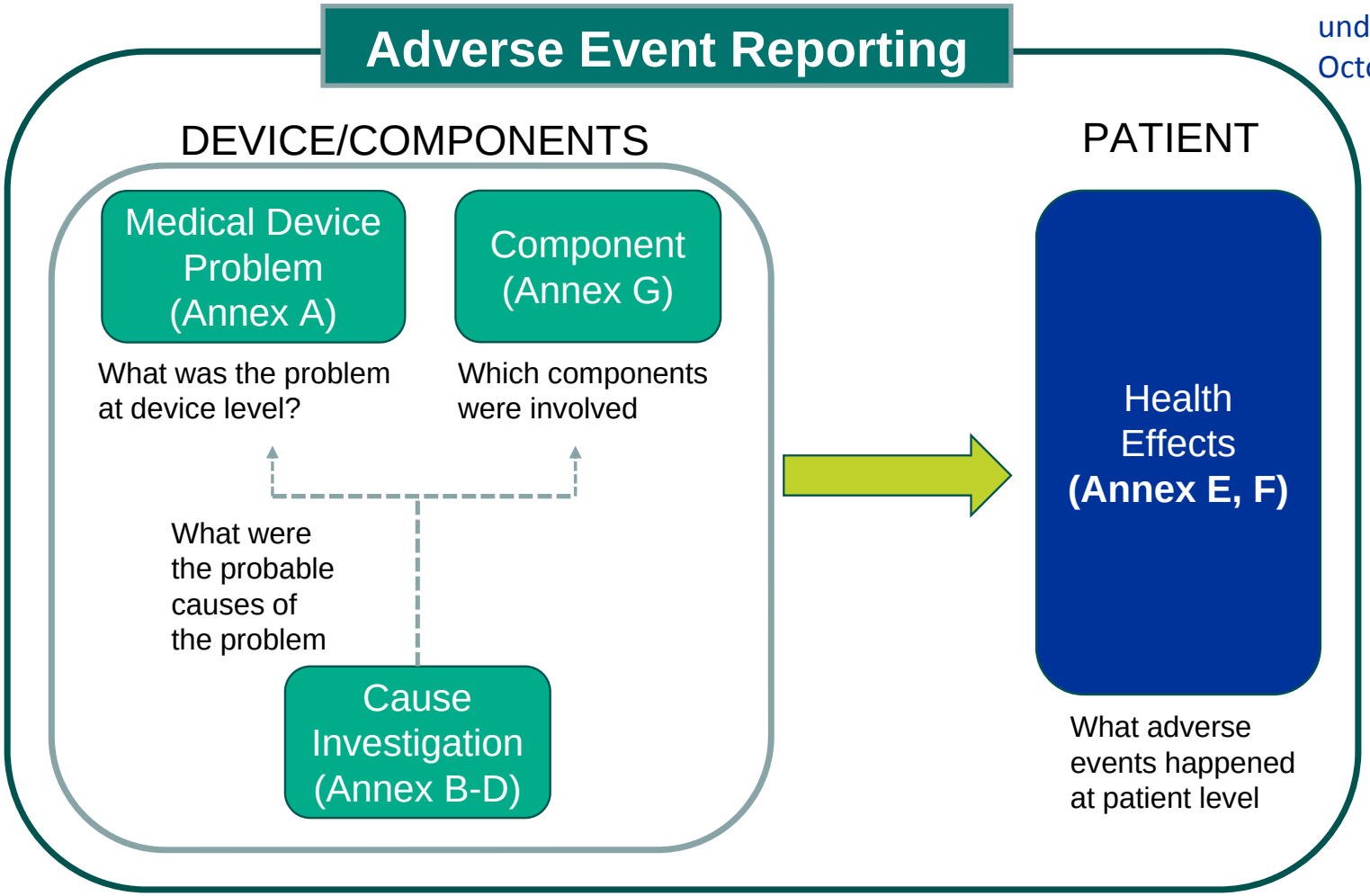
- IMDRF/UDI WG(PD1)/N48 “Unique Device Identification system (UDI system) Application Guide”
- IMDRF/UDI WG(PD1)/N53 “Use of UDI Data Elements across different IMDRF Jurisdictions”
- IMDRF/UDI WG(PD1)/N54 “Recording Unique Device Identifiers in Electronic Health Sources”

under public consultation till October 12

Adverse Event Terminology and Coding (AE)

IMDRF/AE WG/N43 (Edition3)RI “IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes”

* Annexes E,F are currently under public consultation till October 12



Good Regulatory Review Practice (GRRP)

To develop guidance that establishes good regulatory review practices for Regulatory Authorities and/or their Conformity Assessment Bodies and to promote global harmonization in the premarket review processes.

- IMDRF/GRRP WG/N40: 2017 “Competence, Training, and Conduct Requirements for Regulatory Reviewers”
- **IMDRF/GRRP WG (PD)/N47 “Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices ”** ***to be published soon**
- IMDRF/GRRP WG(PD1)/N52 “Principles of Labeling for Medical Devices and IVD Medical Devices” *currently under public consultation till September 12

Improving the quality of international medical device standards for regulatory use

To identify and explore possibilities to improve the process of developing international standards used for regulatory purpose in the medical technology domain.

- **IMDRF/Standard WG(PD)/N51 “Optimizing Standards for Regulatory Use”**
  ***to be published soon**

- Implementation of the N51 document and collaboration with ISO/IEC
- Update the list of international standards recognized by IMDRF members

Personalized Medical Device

To develop guidance that establishes definitions and regulatory pathways for Regulatory Authorities to consider in the regulation of medical devices that are intended for individual patients.

IMDRF/PMD WG (PD)/N49 "Definitions for Personalized Medical Devices"

*to be published soon

3 categories of personalized medical device

Regulated Product Submission (RPS)

To establish standards that supports the electronic transmission of regulatory submissions

- Table of Contents (ToC)
- Common Data Elements (CDE)
- Beta Testing (HL7)

ToC Pilot

- Pilot ended December 2017.
- Applications that have been received and reviewed to-date by region:
  - –Australia: 1
  - –Brazil: 7
  - –Canada: 2
  - –China: 4
  - –EU: 1
  - –USA: 2

Clinical Evaluation

Revision of GHTF SG5 documents focusing on;

1. The Essential Requirements of Demonstrating Equivalence between the Device under Application and the Comparable Device for Clinical Evaluation.

2. The Decision-Making Principals for whether a Medical Device Clinical Trial should be Carried Out.

3. Guidelines for the Acceptance of Overseas Medical Device Clinical Trial Data

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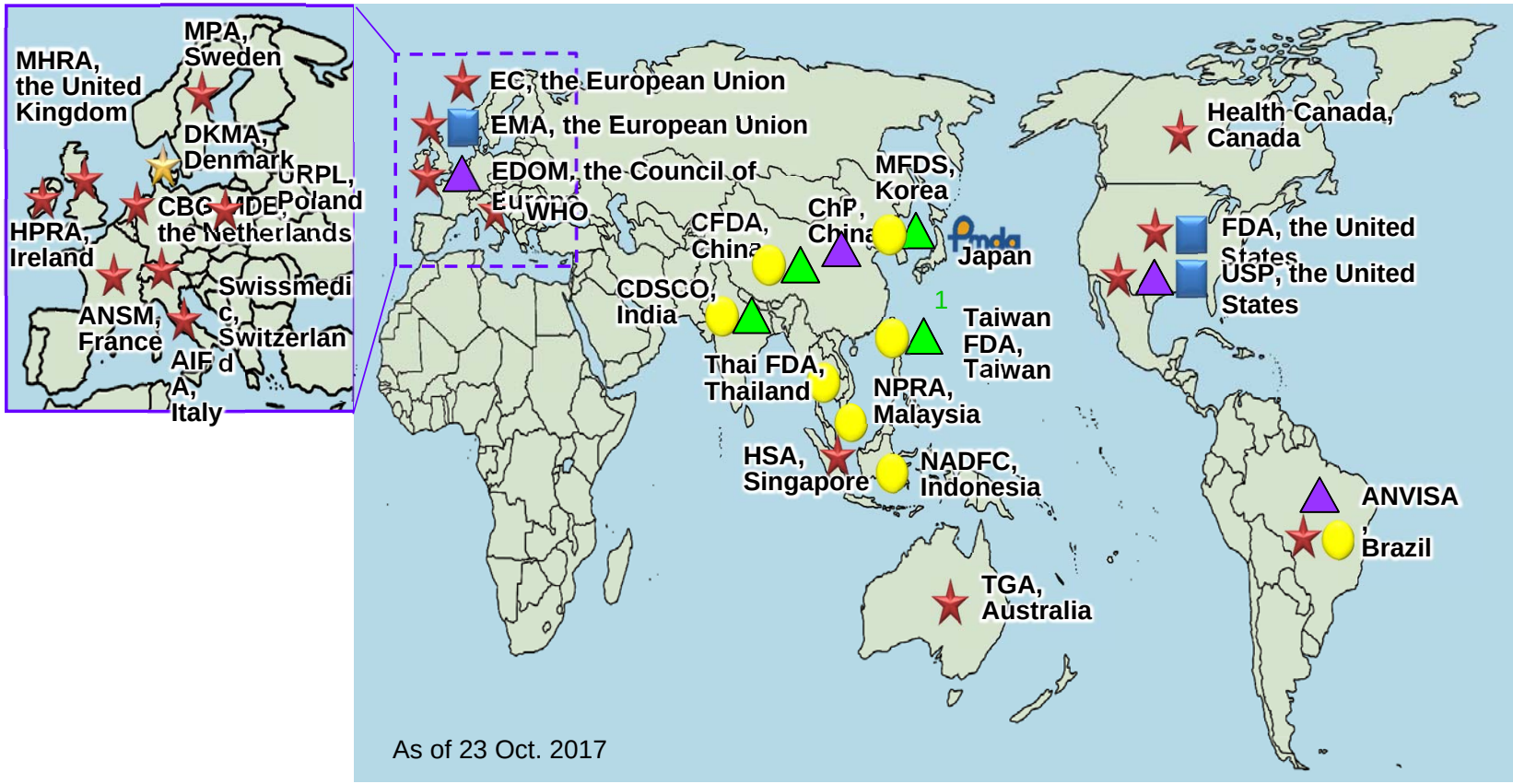
Bilateral cooperation



Confidentiality Arrangement signed

PMDA staff stationed at the agency

Joint symposium held

Cooperative Arrangement signed

Cooperative Arrangement on cooperation of pharmacopoeia signed

1 :Cooperative Arrangement has been signed between the Interchange Association of Japan and East Asia Relations of Taiwan

Bilateral Symposium

(As of August, 2018)

FY 2017 Completed symposium

Month	Country	Contents (Location)
Feb.	Thailand	The 4th Joint Symposium (Bangkok)
Apr.	India	The 2nd Joint Symposium (Tokyo)
May.	Korea	The 2nd Joint Symposium (Seoul)
May.	Indonesia	The 3rd Joint Symposium (Jakarta)
Dec.	Taiwan	The 5th Joint Conference (Taipei)

FY 2018 Planned symposium

Month	Country	Contents (Location)
Apr.	Thailand	The 5th Joint Symposium (Bangkok)
Jul.	Korea	The 3nd Joint Symposium (Tokyo)
Aug.	India	The 3nd Joint Symposium (India)
Oct.	Taiwan	The 6rd Joint Symposium (Tokyo)
Dec.	Brazil	The 4th Joint Conference (Tokyo)

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PMDA Asia Training Center
for Pharmaceuticals and Medical Devices Regulatory Affairs(ATC)

(1) Help raise the level of regulations in Asia as a whole
(2) Training seminar at PMDA, local prefectures in Japan and Asian with manufacturing site visits
(3) APEC Center of Excellence (COE) for Training (Multi-Regional Clinical Trials and Pharmacovigilance)

International Reputation of Asia Training Center

- Attendance (FY 2017)

✓ Nine training seminars and 235 attendees from 27countries/regions

✓ More than 70% of attendees rated as “Very good” according to the questionnaire

- Official certificate of APEC LSIF RHSC Training Centers of Excellence for Regulatory Science from APEC

✓ Area: Global clinical trials/GCP inspection, pharmacovigilance

- Stipulate utilization of ATC in the Joint Statement of ASEAN-JAPAN Health Ministers (July 15th in 2017)

PMDA contributes to mutual understanding and cooperation in Asia

Asia Training Center: Training Seminar 2018

	Contents	Date	Location
1	Pediatric Review	June 11-14, 2018	Tokyo (PMDA)
2	Pharmaceuticals Review	June 18-22, 2018	Tokyo (PMDA) and Toyama Prefecture
3	Good Registration Management (GRM)*	September 26-28, 2018	Taipei
4	Pharmaceuticals Review	October 15-16, 2018	Naypyidaw, Myanmar
5	Medical Devices Review	November 12-16, 2018	Tokyo (PMDA)
6	Good Manufacturing Practice (GMP) **	November 26-30, 2018	Utsunomiya, Tochigi Prefecture
7	Pharmaceuticals Review	December 10-13, 2018	Jakarta, Indonesia
8	Multi-Regional Clinical Trial (MRCT)*	January 21-24, 2019	Tokyo (PMDA)
9	Pharmacovigilance*	February 4-7, 2019	Tokyo (PMDA)

*APEC-LSIF-RHSC CoE Workshop **With the support of PIC/S

AMDC-PMDA Standard Workshop

- Each country of ASEAN has structured their own regulations by the end of 2020 in order to introduce the ASEAN Medical Device Directives (AMDD), which was established in 2014, to their own domestic regulations.

- PMDA proposed to hold the Workshop for utilization of medical device regulation standards in order to enhance the regulation infrastructures in ASEAN regions as one of approaches for Promotion programs of International Standard Acquisition for Innovative medical device.

- PMDA held the Workshop on the utilization of international standards for medical device reviews in three countries of Vietnam（August）, Indonesia（September）, and Malaysia（September）in 2017 with the theme of “Essential Principles”.

- PMDA held workshops in Philippines (July) and Thailand (August) in 2018.

Work Together for patients!!

Thank you for your attention

Pharmaceuticals and Medical Devices Agency