International trend on medical device regulatory convergence

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Contents

Regulatory Authorities in JAPAN

MHLW

Pharmaceutical Safety and Environmental Health Bureau, MHLW

- **Final Authorization of applications**
- **Publishing Guidelines**
- **Advisory committee**
- **Supervising PMDA Activities**

PMDA

Pharmaceuticals and Medical Devices Agency

- **Scientific Review for Drugs & Medical Devices**
- **GCP, GMP Inspection**
- **Consultation on Clinical Trials etc.**

Global Activities of PMDA

ICMRA	ICH	IMDRF	PIC/S	HBD
APEC LSIF RHSC	OECD	PDG	IDGRP	

and more…

Abbreviation	Official Name
ICMRA	International Coalition of Medicines Regulatory Authorities
ICH	International Conference on Harmonization
IMDRF	International Medical Device Regulators Forum
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
HBD	Japan-US Harmonization By Doing
APEC LSIF RHSC	APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee
OECD MAD	OECD Mutual Acceptance of Data
PDG	Pharmacopoeial Discussion Group
IGDRP	International Generic Drug Regulators Program

MHLW/PMDA's Strategy for Global Regulatory Convergence

Bi-lateral Cooperation

Multi-lateral Cooperation

Important Trends on Medical Device Regulation

- EU Medical Device/IVD Regulations (MDR, IVDR)
- ASEAN Medical Device Directive (AMDD)
- Requirements in Eurasian Economic Union

Contents

Multi-lateral Collaboration

- International Medical Device Regulators Forum (IMDRF)
- Medical Device Single Audit Program (MDSAP)
- APEC LSIF RHSC
- Asian Harmonization Working Party (AHWP)

IMDRF International Medical Device Regulators Forum

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.

It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

Management Committee members

Original members of IMDRF

Founding members of GHTF

Brazil Russia China Singapore

Official Observer
- WHO
- APEC AHC LSIF

Affiliate Organization
- AHWP
- PAHO

Accomplishments of GHTF

GHTF guidance Document (41 available)

- GHTF Regulatory Model
- Definition
- Essential Principle
- NCAR exchange program
- Quality Management System (QMS)
- Regulatory Auditing of QMS
- Clinical Evaluation

etc.

Training

AHWP, APEC, PAHO, LAWP

Conference

13 conferences through 20 years

GHTF/AHWG-GRM/N1R13:2011

GHTF

Final Document

Title: The GHTF Regulatory Model

Authoring Group: Ad Hoc GHTF SC Regulatory Model Working Group

Endorsed by: The Global Harmonization Task Force

Date: 13 April 2011

[Signature], GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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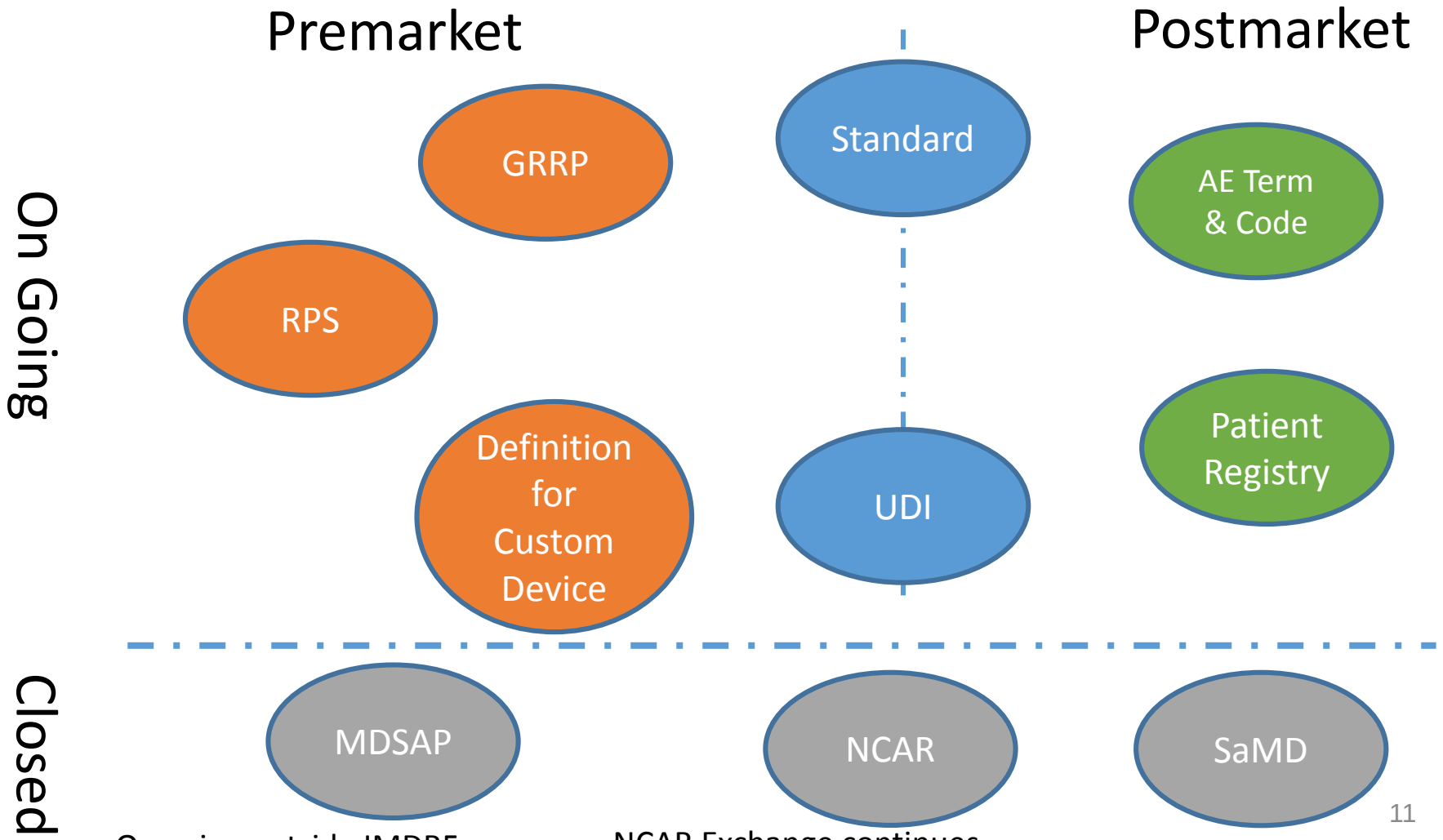
IMDRF International Medical Device Regulators Forum

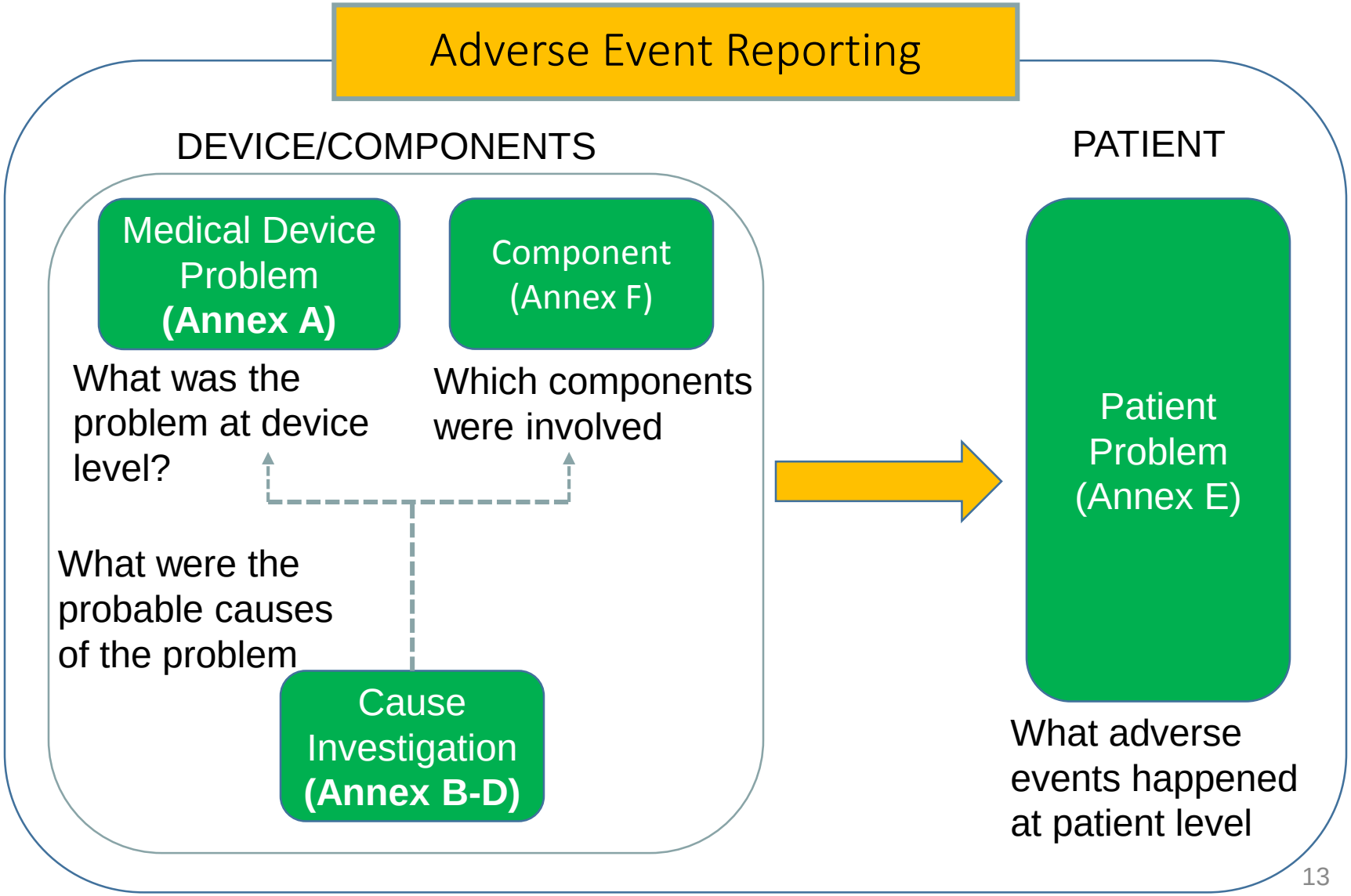
Current IMDRF Work Items



Recent Trend: Enhancement of Post Market Safety Measures

- IMDRF Adverse Event Terminology WG
- IMDRF Registry WG
- APEC LSIF RHSC: Post Market Surveillance/Vigilance for Medical Device

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



Utilization of IMDRF Terminologies in AE Report

Example of AE caused by Artificial Respirator

A home-care patient who had been using artificial respirator suffered dyspnea.

Annex E (Patient Problem): under discussion

Investigation revealed the leakage of oxygen through a crack in the respiratory circuit.

Annex A (Medical Device Problem)

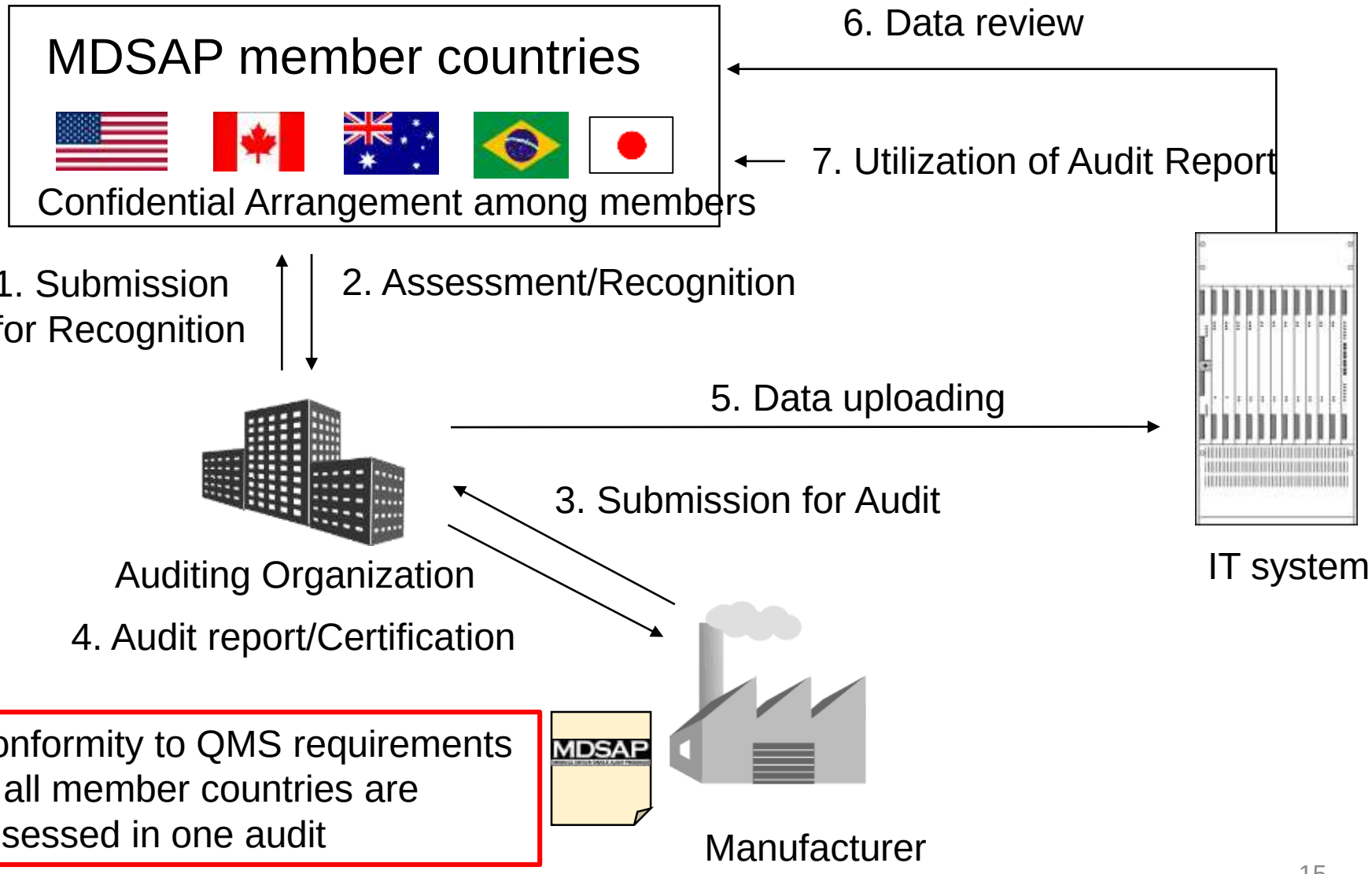
Annex F (Component):
to be discussed after Annex E takes shape

External force and/or repeated bending applied to the respiratory circuit was deduced as the cause.

Annex B – D (Cause Investigation)

Annex B: Type of Investigation
Annex C Investigation Findings ("what were the findings?")
Annex D: Investigation Conclusion ("why did the incident/adverse event occur?")

Overview of MDSAP process



Conformity to QMS requirements of all member countries are assessed in one audit

Contents

AMDC-PMDA Standard Workshop

- ASEAN Medical Device Directives (AMDD) to be implemented into regulation among ASEAN countries by 2020
- PMDA has proposed to provide workshops on use of standards with the aim of advancing regulatory framework for medical devices in ASEAN countries
- The first round of workshops were held in Vietnam (on August 14), Indonesia (on September 5-6) and Malaysia (on September 13)

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (Est. April 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 (ATC)(within PMDA)

Japan

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

Local Asian site

(2) Assign to local site

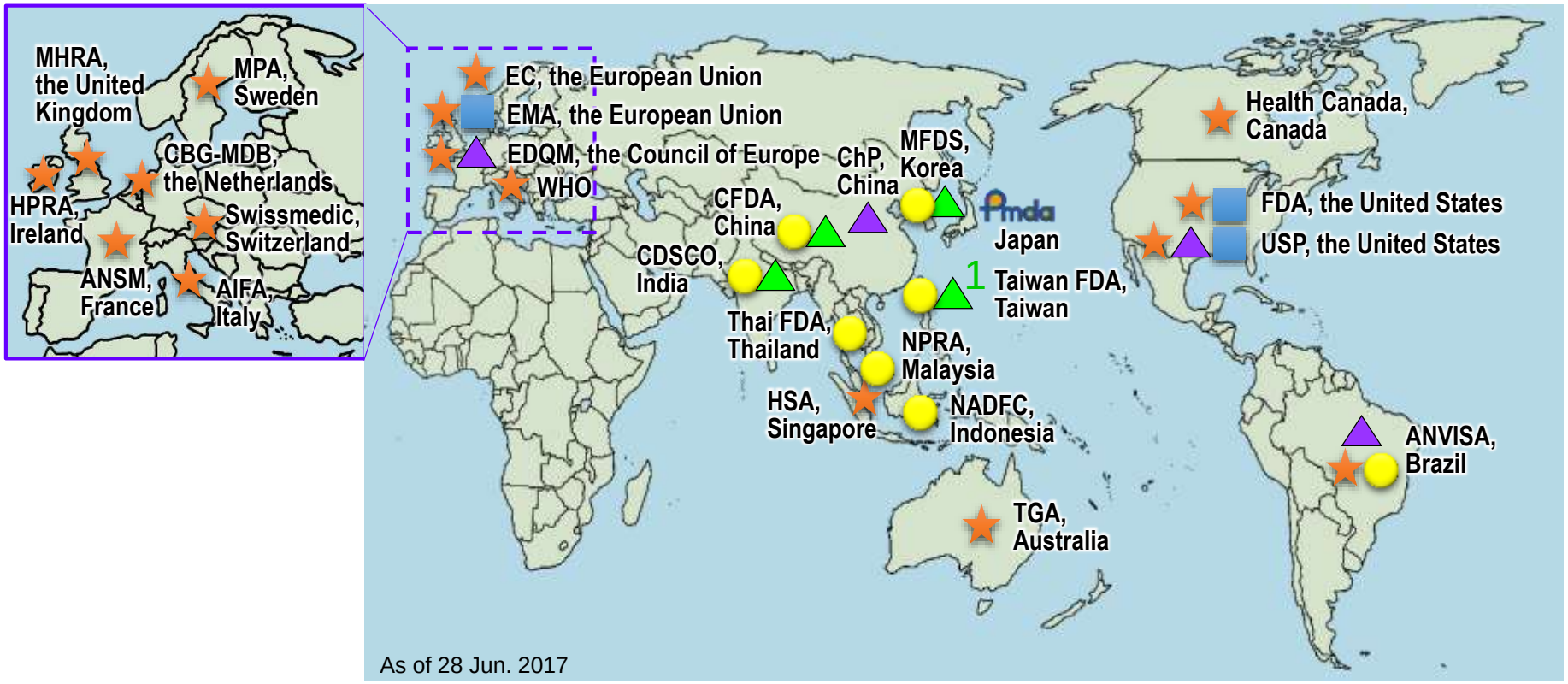
APEC

(3) APEC Training Centre for Clinical Trial and Pharmacovigilance

PMDA - ATC Planned Trainings: FY2017

No.	Contents	Date	Location
1	Risk Management Plan (RMP)	May 18-19, 2017	Jakarta
2	Pharmaceuticals Review	June 26-30, 2017	Tokyo (PMDA)
3	Good Manufacturing Practice (GMP)	July 31- Aug. 4, 2017	Yamaguchi City
4	Anti-infective Drugs	Oct., 2017 (TBD)	Vietnam (TBD)
5	Medical Devices	Nov., 2017 (TBD)	Tokyo (PMDA)
6	Good Registration Management (GRM)	Nov., 2017 (TBD)	Taipei
7	Pharmaceuticals Review	Dec., 2017 (TBD)	Bangkok
8	Multi-Regional Cinical Trial (MRCT)	Jan., 2018 (TBD)	Tokyo (PMDA)
9	Pharmacovigilance	Feb., 2018 (TBD)	Tokyo (PMDA)

Bilateral collaboration



Confidentiality Arrangement signed

Joint symposium held

PMDA staff stationed at the agency

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

MRA: Japan-EC MRA (GLP, GMP)

Scope of GMP is under consideration to expansion .

Joint Symposia with Asian Countries and More

India (2016/5, New Dehli)	1st Joint Symposium (Drugs and Medical Devices)
Taiwan (2016/12, Tokyo)	4th Joint Symposium (Drugs and Medical Devices)
Thailand (2017/2, Bangkok)	4th Joint Symposium (Drugs and Medical Devices)
India (2017/4, Tokyo)	2nd Joint Symposium (Drugs and Medical Devices)
Korea (2017/5, Seoul)	2nd Joint Symposium (Drugs and Medical Devices)
Indonesia (2017/5, Jakarta)	3rd Joint Symposium (Drugs)
Taiwan (2017/12, Tokyo)	5th Joint Symposium (Drugs and Medical Devices)

Specificity to/from Generality
Bi-lateral to/from Multi-lateral

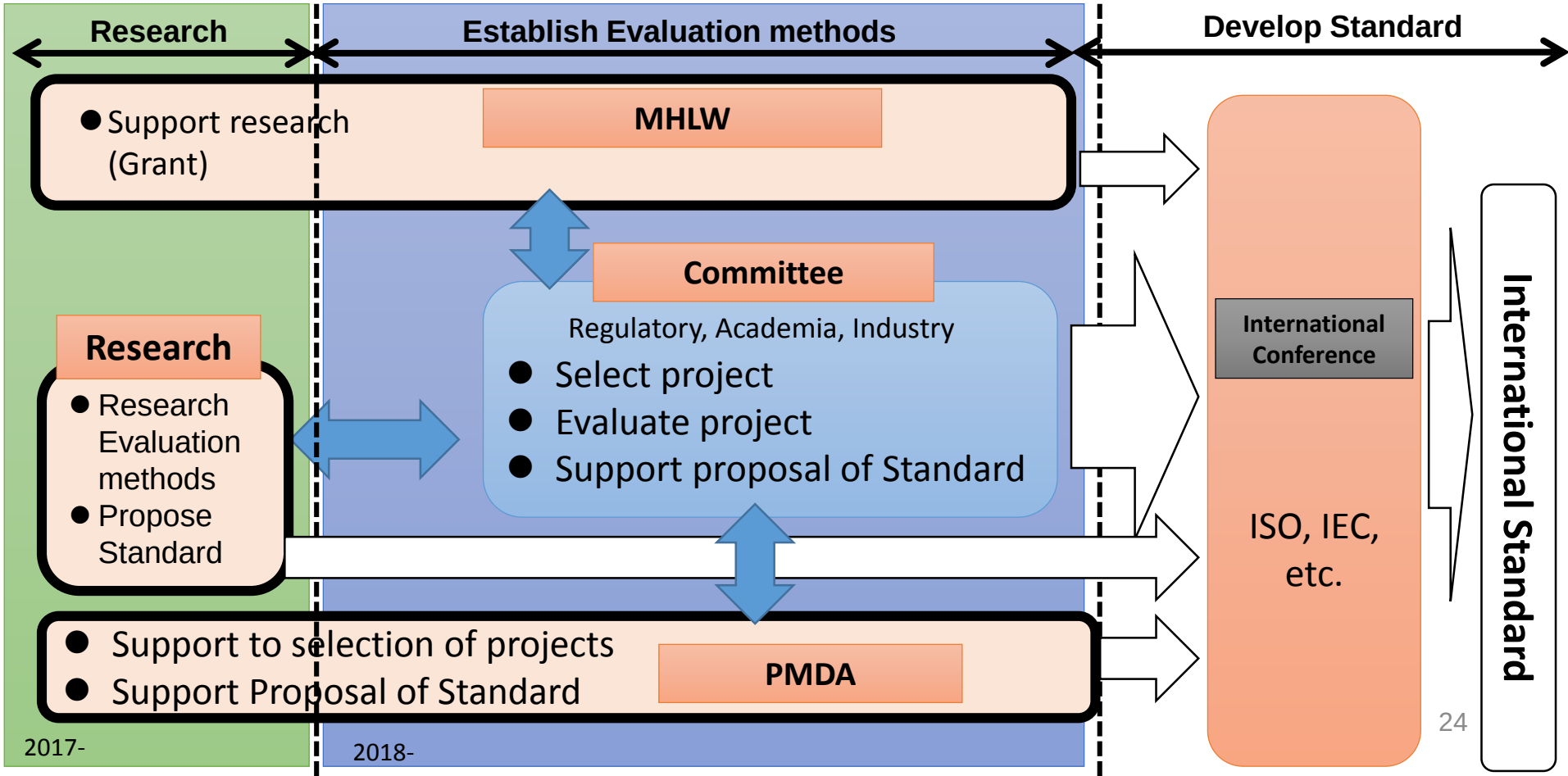
Contents

Facilitate Development of International Standard for Evaluation method for Innovative MDs

To Enable early introduction of innovative MDs all over the world

I. Facilitate development of evaluation method (Practical, non-clinical, properly predict effectiveness and safety)

II. Facilitate development of such evaluation method into International Standard



Publicity / Information Sharing

PMDA promotes information transmission and outreach in English including review reports, safety information, Pharmacopoia, as well as other sharing tools.

Review Report

Safety Information

Pharmacopeia

PMDA Updates

News Release

And more…

多谢

Thank you

Pharmaceuticals and Medical Devices Agency