Update on AHWP Work

September 2016

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Expansion of AHWP Member Economies

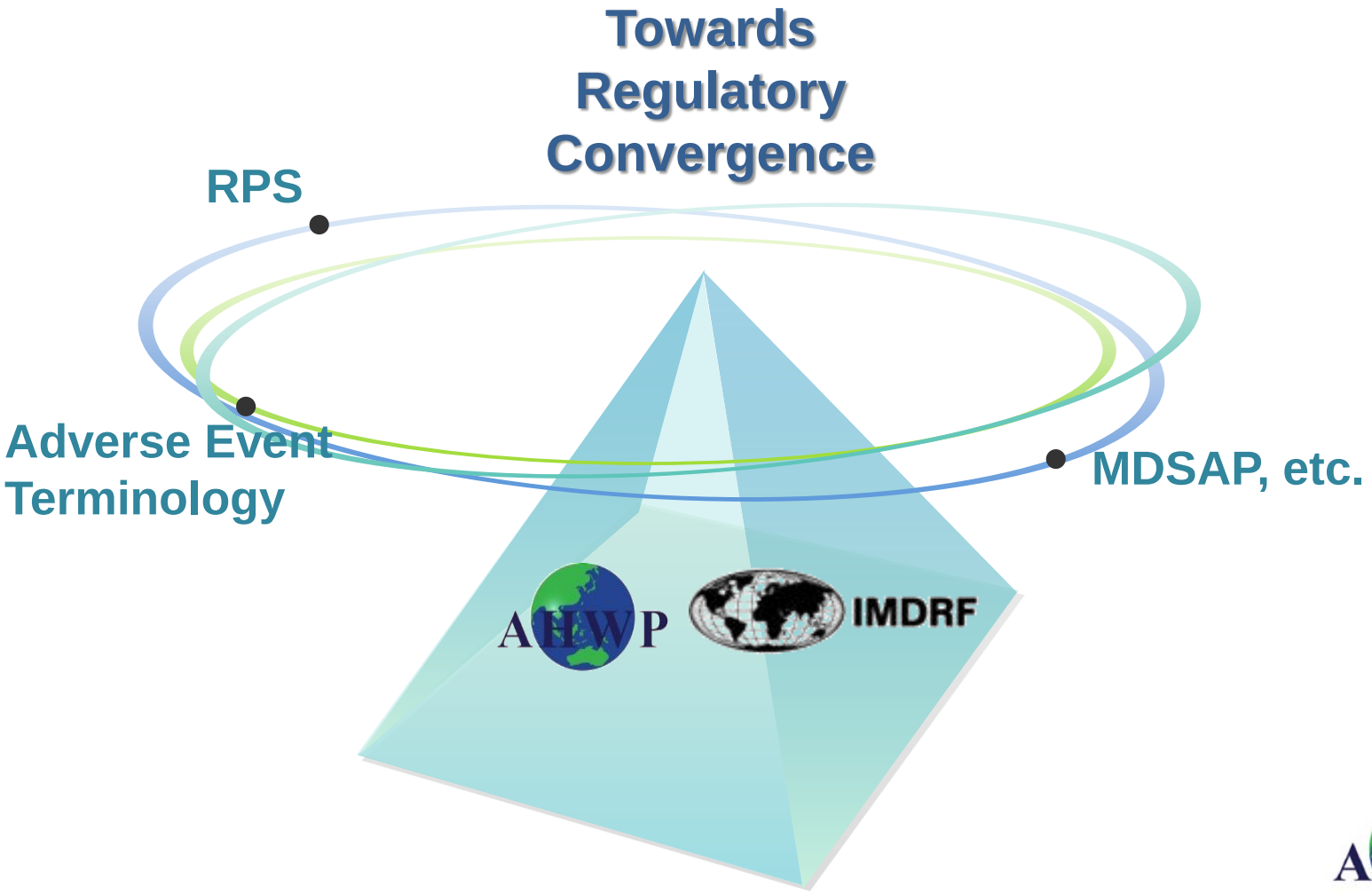
- 26 member economies as of September 2016
- 4 new member applications from Africa and Middle-East

AHWP's Global Partnership

Collaborating International Organizations
& International Associations of Industry

Collaboration with IMDRF

Ongoing Participation in IMDRF MC Meetings and Working Groups



AHWP Meetings & Activities

AHWP Meetings

- AHWP TC Leaders Meeting, April 2016, Korea
- International Workshop on Regulatory Harmonization of Medical Devices, Feb 2016, Korea
- The 2nd International Medical Device Communication Forum, June 2016, Korea

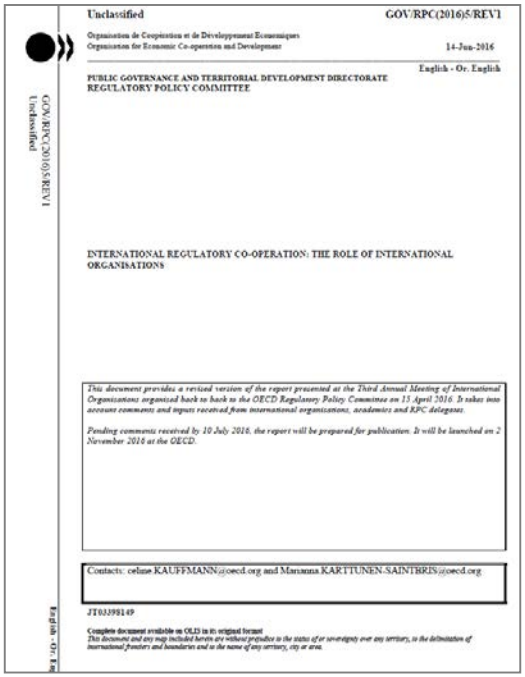
Co-operation with International Organizations

- Asia Pacific Health Care Summit, April 2016, Singapore
- WHO Inter-Country Meeting on Designing & Implementing Regulatory Program for Medical Device, April 2016, Saudi Arabia
- OECD Meeting of International Organizations & Regulatory Policy Committee, April 2016, France

Collaboration with OECD

Co-operative Work with OECD Regulatory Policy Committee

- Draft: OECD Report of International Regulatory Co-operation
- Presentation: AHWP Experiences in Regulatory Harmonization
- Case Study: International Regulatory Co-operation in Medical Device Field


Unclassified GOV/RPC(2016)5/REV1

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development 14-Jun-2016

English - Or. English

PUBLIC GOVERNANCE AND TERRITORIAL DEVELOPMENT DIRECTORATE
REGULATORY POLICY COMMITTEE

INTERNATIONAL REGULATORY CO-OPERATION: THE ROLE OF INTERNATIONAL ORGANISATIONS

This document provides a revised version of the report presented at the Third Annual Meeting of International Organisations organised back to back to the OECD Regulatory Policy Committee on 15 April 2016. It takes into account comments and inputs received from international organisations, academics and RPC delegates.

Pending comments received by 10 July 2016, the report will be prepared for publication. It will be launched on 2 November 2016 at the OECD.

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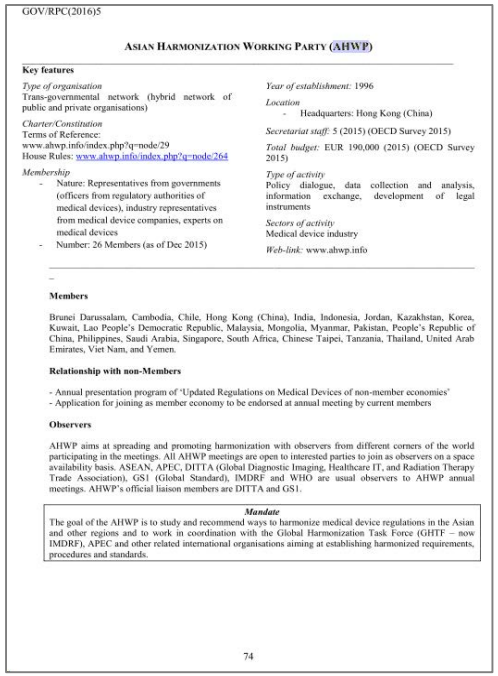
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ASIAN HARMONIZATION WORKING PARTY (AHWP)

Key features

Type of organisation
Trans-governmental network (hybrid network of public and private organisations)

Charter/Constitution
Terms of Reference:
www.ahwp.info/index.php?q=node/29
House Rules: www.ahwp.info/index.php?q=node/264

Membership
- Nature: Representatives from governments (officers from regulatory authorities of medical devices), industry representatives from medical device companies, experts on medical devices
- Number: 26 Members (as of Dec 2015)

Year of establishment: 1996

Location
- Headquarters: Hong Kong (China)

Secretariat staff: 5 (2015) (OECD Survey 2015)

Total budget: EUR 190,000 (2015) (OECD Survey 2015)

Type of activity
Policy dialogue, data collection and analysis, information exchange, development of legal instruments

Sectors of activity
Medical device industry

Web-link: www.ahwp.info

Members

Brunei Darussalam, Cambodia, Chile, Hong Kong (China), India, Indonesia, Jordan, Kazakhstan, Korea, Kuwait, Lao People's Democratic Republic, Malaysia, Mongolia, Myanmar, Pakistan, People's Republic of China, Philippines, Saudi Arabia, Singapore, South Africa, Chinese Taipei, Tanzania, Thailand, United Arab Emirates, Viet Nam, and Yemen.

Relationship with non-Members

- Annual presentation program of 'Updated Regulations on Medical Devices of non-member economies'
- Application for joining as member economy to be endorsed at annual meeting by current members

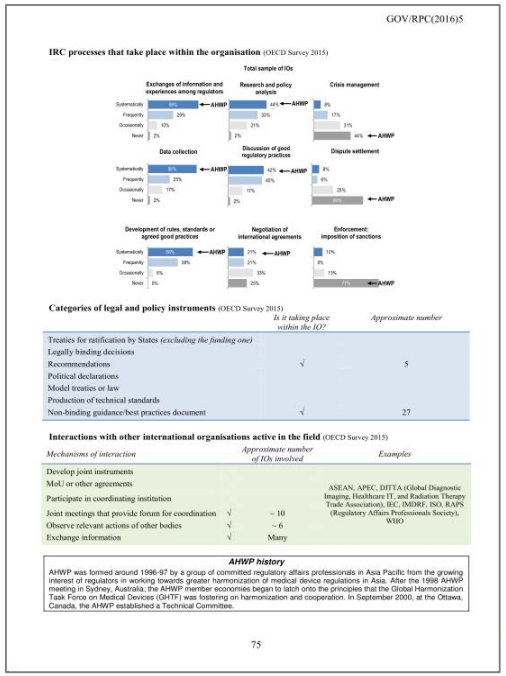
Observers

AHWP aims at spreading and promoting harmonization with observers from different corners of the world participating in the meetings. All AHWP meetings are open to interested parties to join as observers on a space availability basis. ASEAN, APEC, DITTA (Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association), GS1 (Global Standard), IMDRF and WHO are usual observers to AHWP annual meetings. AHWP's official liaison members are DITTA and GS1.

Mandate

The goal of the AHWP is to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force (GHTF – now IMDRF), APEC and other related international organisations aiming at establishing harmonized requirements, procedures and standards.

74


GOV/RPC(2016)5

IRC processes that take place within the organisation (OECD Survey 2015)

Categories of legal and policy instruments (OECD Survey 2015)

	Is it taking place within the IO?	*Approximate number*
Treaties for ratification by States *(excluding the funding one)*		
Legally binding decisions		
Recommendations	√	5
Political declarations		
Model treaties or law		
Production of technical standards		
Non-binding guidance/best practices document	√	27

Interactions with other international organisations active in the field (OECD Survey 2015)

Mechanisms of interaction		*Approximate number of IOs involved*	*Examples*
Develop joint instruments			
MoU or other agreements			
Participate in coordinating institution			ASEAN, APEC, DITTA (Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association), IEC, IMDRF, ISO, RAPS (Regulatory Affairs Professionals Society), WHO
Joint meetings that provide forum for coordination	√	~ 10	
Observe relevant actions of other bodies	√	~ 6	
Exchange information	√	Many	

AHWP history

AHWP was formed around 1996-97 by a group of committed regulatory affairs professionals in Asia Pacific from the growing interest of regulators in working towards greater harmonization of medical device regulations in Asia. After the 1998 AHWP meeting in Sydney, Australia; the AHWP member economies began to latch onto the principles that the Global Harmonization Task Force on Medical Devices (GHTF) was fostering on harmonization and cooperation. In September 2000, at the Ottawa, Canada, the AHWP established a Technical Committee.

75

Regulatory Harmonization

Lists of Working Documents for Regulatory Framework in 2016

WG1

- Qualification of Combination Products and Technical Requirements for Pre-market Submission
- Good Review Practice
- Approval of Medical Devices Manufactured using 3D Printers
- Minor Change Reporting

WG2

- Conformity Assessment for IVD

WG3

- Medical Device Software - Qualification and Classification

WG4

- Adverse Events Reporting Details for Specific Devices
- Guidance Documents on Safety Alert Dissemination System

WG7

- Medical Device Quality Management System - Requirements for Distributors

AHWP

AHWP Capacity Building Project(1)

Objectives

- Provide guidance to AHWP member economies to develop medical device regulatory framework
- Promote better understanding of international best practices towards regulatory harmonization

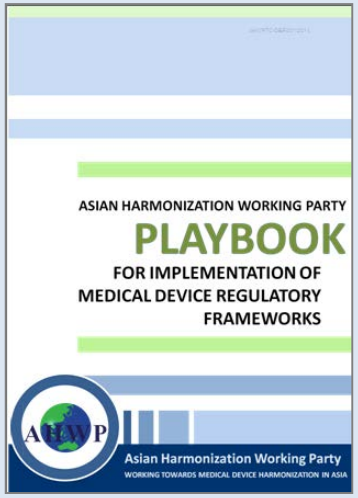
CBP based on the AHWP Playbook

Bring it together with international collaboration & partnership

Legislative Controls

Manpower & Resources

Implementation – Phased in Approach



Post-Market Considerations

Pre-Market Essential Principles

Clinical Studies & Evaluation

Reduce the administrative costs of re-inventing the medical device regulatory framework

AHWP Capacity Building Project(2)

2015

Initial kick-off

AHWP Annual Meeting
Nov 2 – 3
Thailand

2016

1st In-country Training

July 28- 29
Indonesia

2nd In-country Training

August 25 – 26
Vietnam

Workshop

AHWP Annual Meeting
Nov 21 – 22
Philippines

2017

Phase II

- Build Curricula
- Develop Competency Assessment Tools

AHWP Capacity Building Project(3)

1st In-Country Capacity Building Training

- Bandung, Indonesia, July 28 – 29, 2016
- 50 Indonesia Ministry of Health officers
- 20 experts from industry and academia
- AHWP's CSDT, Essential principles of safety and performance, Clinical studies

2nd In-Country Capacity Building Training

- Hanoi, Vietnam, August 25 – 26 , 2016
- 50 Vietnam Ministry of Health officers, experts from industry and academia
- Classification of medical devices & IVD, Pre-market approval, Post-market surveillance

Upcoming AHWP Annual Meeting

- Date: Nov 21-25, 2016
- Venue: Radisson Blu Hotel, Cebu, Philippines
- Program:
  - AHWP Annual Meeting, Working Group Meetings
  - Capacity Building Workshops
  - Reports from Collaborating International Organizations, etc.
- Registration Website: http://pamdrap.org/AHWP2016

Thank you !