

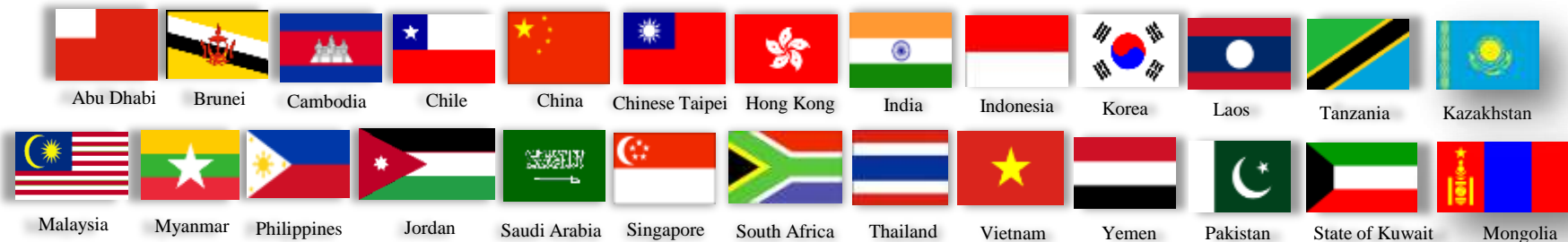
Update on AHWP Work

March 2016



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Expansion of Membership



- Mongolia and Kazakhstan newly joined the AHWP.
- AHWP consists of 26 member economies as of Nov 2015.



AHWP Annual Meeting in Bangkok (2-6 Nov 2015)

- **241 delegates**
 - 40 delegates from government authorities
 - 201 industrial delegates
- **28 countries**
 - from Africa, America, Asia-Pacific, Europe, Middle East
- **9 other international organizations' representatives**
- **36 speakers**
- **12 endorsed AHWP guidance documents**
- **11 main themes & 6 panel discussion sessions**
- **2 new member economies**

- **AHWP Playbook Workshop**
- **AHWP TC Workshop**
- **AHWP-DITTA Joint Workshop**
- **19th AHWP TC Meeting**
- **20th AHWP Annual Meeting**



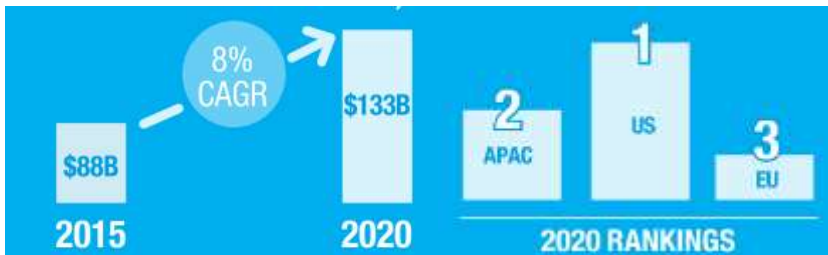
Enhance Global Partnership

- **Participating International Organizations in the AHWP Annual Meeting**
: APEC, ASEAN, IEC, IMDRF, PAHWP, WHO, etc.
- **Network with International Associations of Industry of Medical Devices**
: APAC Med, DITTA, GS1

Unmet Needs in AP



AP Med Tech Market



* McKinsey Report 2015

International Organizations

APEC
ASEAN
IEC/ISO
IMDRF
PAHWP
WHO etc..



Associations Industry

APAC Med
DITTA
GMTA
GS1



Regulatory Harmonization

New 12 AHWP Guidance Documents

- Clinical Evaluation
- Clinical Evidence for Medical Device – Key Definitions and Concepts
- Clinical Evidence for IVD Medical Device – Key Definitions and Concept
- Clinical Evidence for IVD Medical Device – Scientific Validity Determination and Performance Evaluation
- Distributor Auditing Checklist
- Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies
- Regulatory Audit Report
- Medical Device Naming Rule

Capacity Building on the Foundation of AHWP Playbook

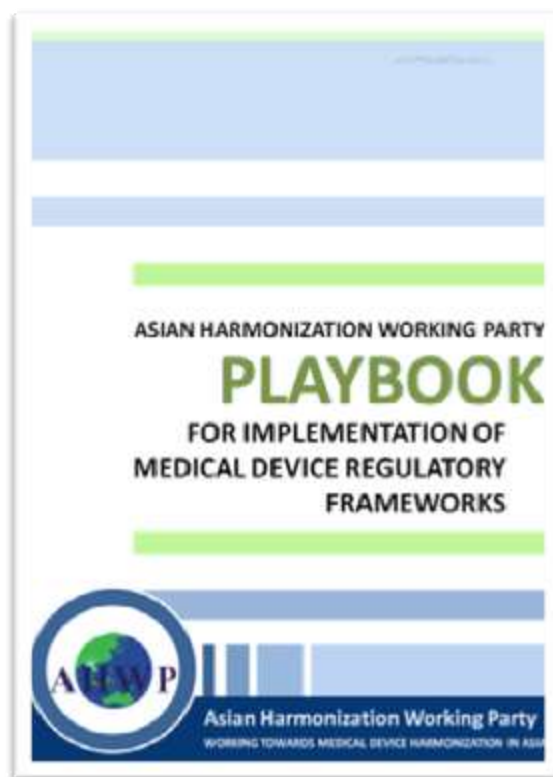
**Legislative
Controls**

**Post Market
Considerations**

**Manpower
& Resources**

**Premarket
Essential
Principles**

**Implementation –
Phased in
Approach**



**Clinical Studies
& Evaluation**

www.ahwp.info



AHWP Capacity Building Project

Phase I - On-going for the term 2015-2017

Kick-off workshop based on 'AHWP Playbook' was held in Nov 2015
50,000 USD was approved as seed money

In-country Trainings: 2 or 3 AHWP member economies annually
Training Workshops: AHWP Annual Meeting in 2016 & 2017

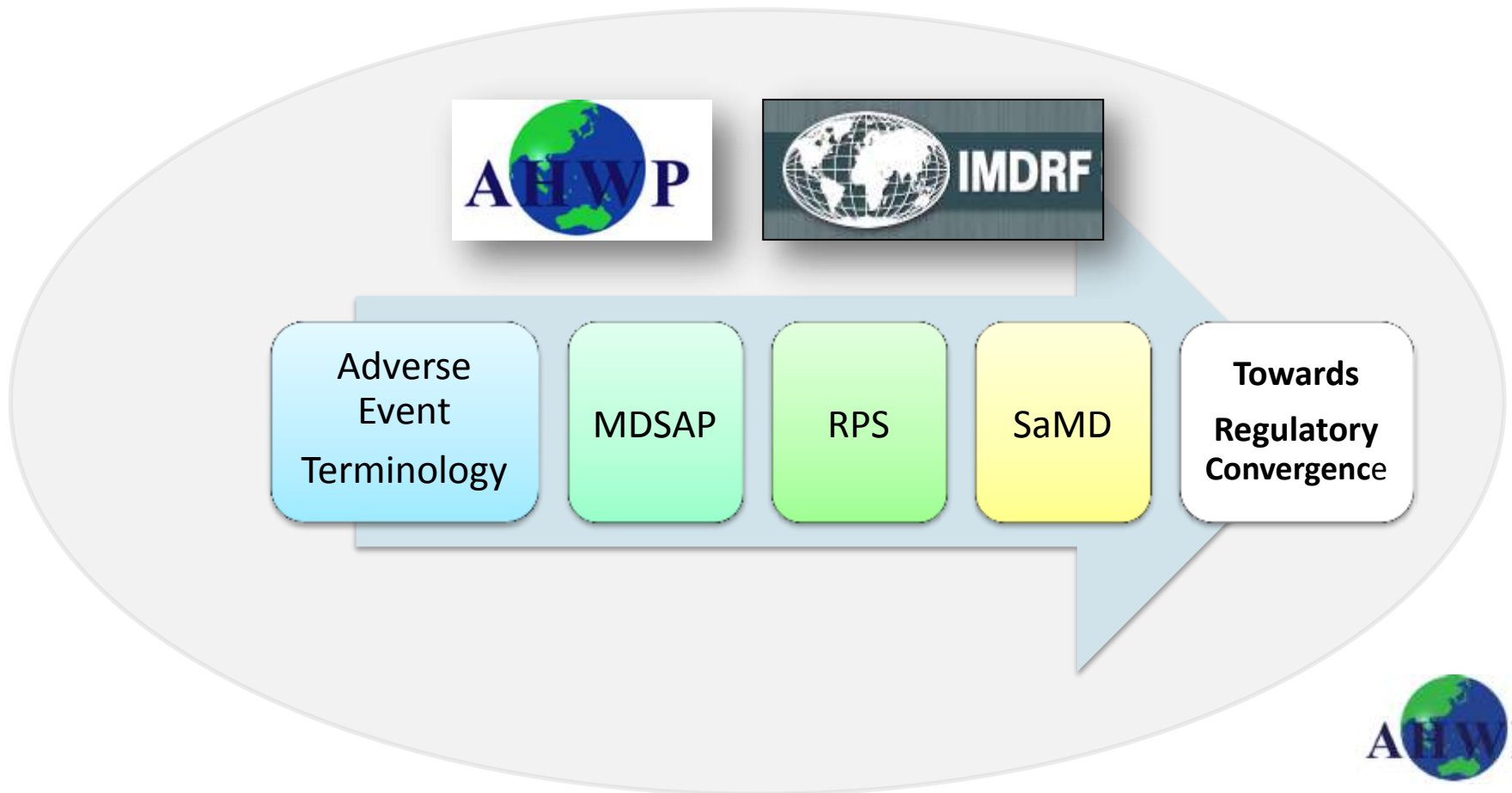
Phase II - Planning in progress

Develop Handbook and Build Curricula: Target for 2017

Develop Competency Assessment Tools: Collaborative efforts

Collaboration with IMDRF

- Continuous Participation in IMDRF MC Meetings and Working Groups



Upcoming Meetings



AHWP TC Leaders Meeting & AHWP Regulators Forum

- Date / Location : 28~29, April / Seoul, Korea
- AHWP Technical Committee Leaders Meeting
- AHWP Regulators Forum



21th AHWP Annual Meeting

- Date / Location : 5 days, November(TBD) / Philippine
- Annual Meeting of 26 Member Economies
- Technical Committee Meeting of 9 Working Groups
- Workshops for Regulatory Capacity Building
- Joint Workshops with International Organizations on Special Topics



**20th AHWP Annual Meeting
on Nov 2-6, 2015**

Thank you !

