

WG 8 – Standards

Chair:

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British Standards Institution

AHWP 19th TC Meeting
5 Nov 2015, Bangkok



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Updates

- **No. of WG members:**

6 members (include 1 advisor) covers 3 member economies, i.e. the Philippines, Indonesia, Malaysia, Singapore and India




Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Create List of Recognised Standards used in AHWP member economies – Phase 1	Identify & list AHWP individual member economies Recognised Standards used for medical device regulatory purposes.	Apr 2015 – Oct 2015 DRAFT

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Create List of Recognised Standards used in AHWP member economies – Phase 1	Identify & list AHWP individual member economies Recognised Standards used for medical device regulatory purposes.	Apr 2015 – Oct 2015 DRAFT
2	Create List of Recognised Standards used in AHWP member economies – Phase 2	Identify & list AHWP individual member economies <u>not covered under Phase 1</u> Recognised Standards used for medical device regulatory purposes.	Dec 2015 – Mar 2016 DRAFT

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Create List of Recognised Standards used in AHWP member economies – Phase 1	Identify & list AHWP individual member economies Recognised Standards used for medical device regulatory purposes.	Apr 2015 – Oct 2015 DRAFT
2	Create List of Recognised Standards used in AHWP member economies – Phase 2	Identify & list AHWP individual member economies <u>not covered under Phase 1</u> Recognised Standards used for medical device regulatory purposes.	Dec 2015 – Mar 2016 DRAFT
3	Recruitment of core members 	To gain active representation from Regulatory Authorities of member economies and industry member whom will be responsible to review, populate (<i>& eventual maintenance of completed</i>) List of Standards assigned	2015 – 2016 (ongoing – recruitment call out at AHWP Bangkok 2015)

Proposed Work Plan 2015 - 2017

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2	Create List of Recognised Standards used in AHWP member economies – Phase 2	Identify & list AHWP individual member economies <u>not covered under Phase 1</u> Recognised Standards used for medical device regulatory purposes.	Dec 2015 – Mar 2016 DRAFT
3	Recruitment of core members	To gain active representation from Regulatory Authorities of member economies and industry member whom will be responsible to review, populate (<i>& eventual maintenance of completed</i>) List of Standards assigned	2015 – 2016 (ongoing – recruitment call out at AHWP Bangkok 2015)
4	Finalization of contemporary List of Recognised Standards	<ul style="list-style-type: none"> Roll out of final list for AHWP member economies with Recognised Standards in place. Endorsement of Paper by 20th AHWP TC Meeting (2016) 	Ph.1 List Dec 2015 – Mar 2016 Ph.2 List Mar 2016 – Jul 2016

Proposed Work Plan 2015 - 2017

Priority	Work Item	Deliverables	Action Plan and Timeline
5	Progressive	Identification of new work item upon completion of List of Recognised Standards and endorsement of [proposed] AHWP Recognized Standards (<i>including "commonly accepted" Standards</i>).	2016 - 2017

WG Progress Update

List of Recognised Standards used in AHWP member economies – Phase I

Status: List (1st Draft) ready for circulation to member economies for:

1. Confirmation and enhancement.
2. Appointment of representative (from Regulatory Authority (*preferred*) or Industry) for above task.

ASEAN	Middle East & Africa	Asia (non ASEAN) & South America
<ul style="list-style-type: none"> • Indonesia • Thailand • Malaysia • Philippines • Singapore 	<ul style="list-style-type: none"> • Abu Dhabi (UAE) • Jordan • South Africa • Kuwait • Tanzania 	<ul style="list-style-type: none"> • Chinese Taipei • Hong Kong SAR • India • China • South Korea

WG Progress Update

List of Recognised Standards used in AHWP member economies – Phase 2

Status: List collation to commence as of 19th TC meeting:

1. Confirmation on availability of such Recognised Standards by the economy.
2. Appointment of representative (from Regulatory Authority (*preferred*) or Industry) for completion of 1st draft – contingent of item #1 above.

ASEAN	Middle East & Africa	Asia (non ASEAN) & South America
<ul style="list-style-type: none"> • Laos • Myanmar • Cambodia • Vietnam • Brunei 	<ul style="list-style-type: none"> • Saudi Arabia • Yemen 	<ul style="list-style-type: none"> • Pakistan • Chile



**I. Identify Recognised
Standards & Prepare Draft List**
[Ph.I]

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Recognised Standards - Responsibilities

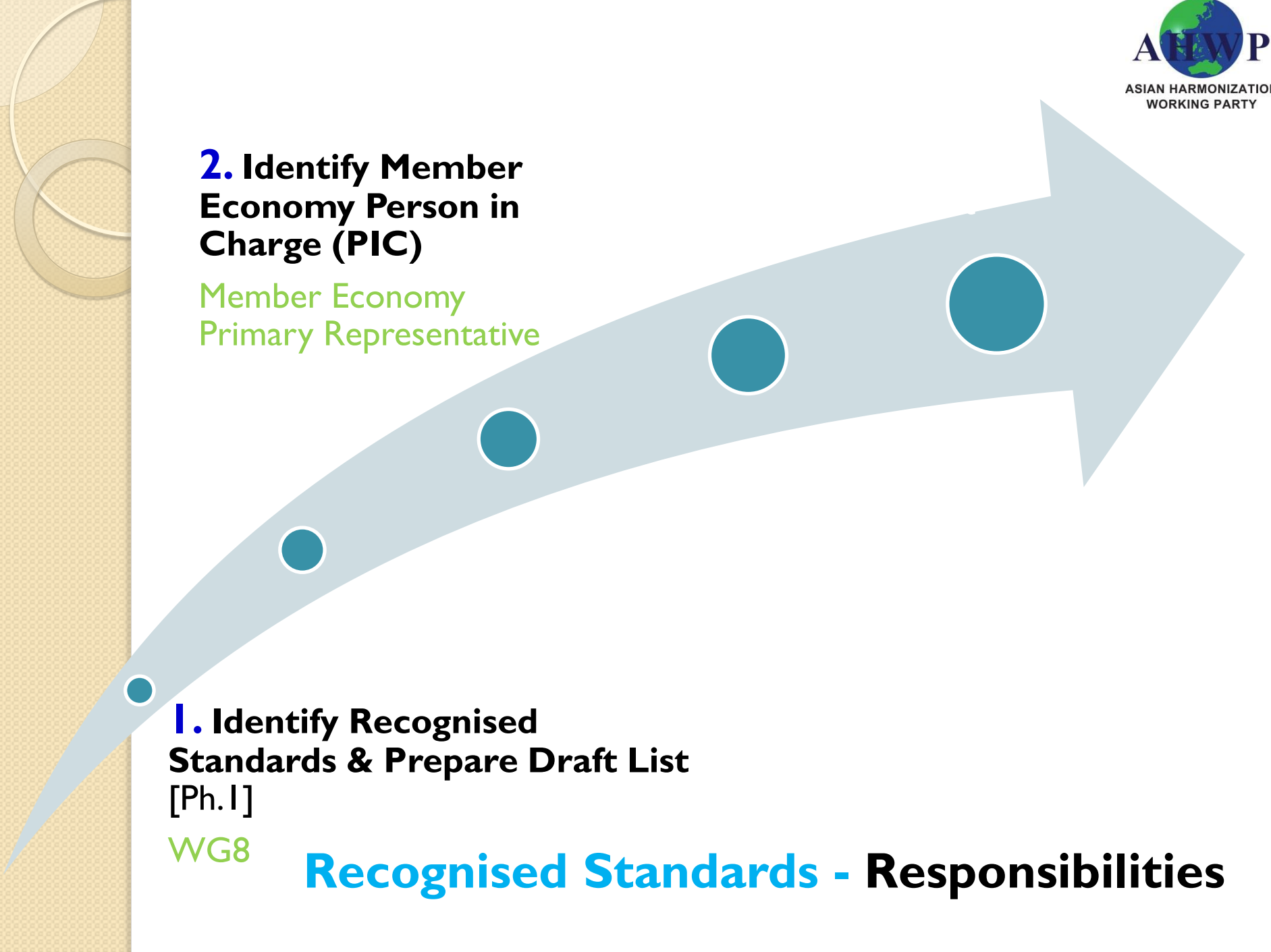
2. Identify Member Economy Person in Charge (PIC)

Member Economy
Primary Representative

1. Identify Recognised Standards & Prepare Draft List [Ph. I]

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Recognised Standards - Responsibilities



2. Identify Member Economy Person in Charge (PIC)

Member Economy
Primary Representative

3. Finalised List Ph. I

Assigned PIC
– Ph.2 List

1. Identify Recognised Standards & Prepare Draft List [Ph. I]

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Recognised Standards - Responsibilities

2. Identify Member Economy Person in Charge (PIC)

Member Economy
Primary Representative

4. Prepare Draft List Ph.2

Assigned PIC – Ph.2 List

3. Finalised List Ph.1

Assigned PIC
– Ph.2 List

1. Identify Recognised Standards & Prepare Draft List [Ph.1]

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Recognised Standards - Responsibilities

2. Identify Member Economy Person in Charge (PIC)

Member Economy
Primary Representative

4. Prepare Draft List Ph.2

Assigned PIC – Ph.2 List

3. Finalised List Ph.1

Assigned PIC
– Ph.2 List

5. Preparation of Final Report / Proposed Paper on the Role and [appropriate] Use of Recognised Standards

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1. Identify Recognised Standards & Prepare Draft List [Ph.1]

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Recognised Standards - Responsibilities



2. Identify Member Economy Person in Charge (PIC)

Nov'15

4. Prepare Draft List Ph.2

Mar'16 – Jul'16

3. Finalised List Ph.1

Dec'15 – Mar'16

1. Identify Recognised Standards & Prepare Draft List [Ph.1]

Apr'15 - Oct'15

5. Preparation of Final Report / Proposed Paper on the Role and [appropriate] Use of Recognised Standards

Aug'16 – Nov'16



Recognised Standards - Timelines

AHWP Recognised Standards

- **Scope of paper:** Create a list of Standards used for medical device regulatory purposes that are recognized by respective AHWP member economies.
- **Objective of paper:** To aid industry market access into AHWP by identifying Standards for meeting Essential Principles of Safety & Performance (EPSP) of Medical Devices – both “**commonly recognised**” as well as jurisdiction specific
- **Summary:** Goal is to ensure patients have access to needed medical devices that are safe & effective.

dank u

Tack ju faleminderit
Asante 谢谢 Tak mulțumesc
kiitos Gracías
Salamat! Terima kasih Aliquam
Merci Dankie Obridado
ありがとう köszönöm grazie
Aliquam Go raibh maith agat
děkuii Thank you



ขอบคุณครับ