WG2 – Pre-market: IVDD

AHWP Annual Meeting
7th Dec 2017

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Membership Status

- Chair: Dr. Wen-Wei TSAI
- Co-Chair: Ir Prof. Albert KF POON
- Advisor: Ms. Shelley TANG
- No. of WG members: 38
  - 15 regulator members
  - 23 industry members

Objectives 2015-2017

- To assist AHWP member economies in implementing regulatory framework of IVD medical devices by
  - Developing AHWP documents on premarket regulatory control of IVD medical devices.
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices.
- To support regulatory convergence through
  - Participating in International/Global Organization collaboration and activities. (e.g. ISO/TC 212, WHO etc.)
  - Encouraging interest and participation of the AHWP member economies in establishing and reviewing the specific requirement of IVD premarket regulatory control.

Proposed Work Plan 2015-2017

	Work Item	Deliverables	Action Plan and Timeline
I	Develop AHWP documents	Guidance Document	
(1)	Definition of MD/ IVD		Collaborate with WG1 Mar 2015 to Dec 2015
(2)	IVD Submission Dossier		Jun 2015 to Nov 2016
(3)	Conformity Assessment for IVDs		Aug 2015 to Nov 2016
(4)	Classification of IVDs		Aug 2015 to Nov 2016
(5)	In Vitro Companion Diagnostic Devices (IVD-CDx)		Mar 2016 to Nov 2017
(6)	IVD Labelling		Jan 2017 ~

Proposed Work Plan 2015-2017

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	Work Item	Deliverables	Action Plan and Timeline
2	Participate in International/Global Organization collaboration and activities (e.g. ISO/TC 212, WHO etc.)	Standard Guidance Comment	Attend the activities of ISO/TC 212/WG3 to work on standard regarding technical requirements for IVDs

WG2 Activities 2015 - 2017

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2015

1. WG2 1st Teleconference: 11 Mar
2. WG2 1st FTF meeting: 11-13 Aug (Taipei)
3. WG2 2nd Teleconference: 13 Aug
4. WG2 2nd FTF meeting: 2 Nov (Bangkok)
5. Side meeting with WHO IVD PQ program team: 6 Nov (Bangkok)

2016

1. WG2 1st Teleconference: 17 Mar
2. Side meeting with WHO IVD PQ program team: 27 April (Seoul)
3. Conference on IVD Medical Devices Regulation and Clinical Performance Evaluation: 13 July (Taipei)
4. WG2 1st FTF meeting and 2nd teleconference: 14 ~ 15 July (Taipei)
5. AHWP Annual meeting + WG2 2nd FTF meeting: 21 ~ 25 Nov (Cebu)

2017

1. WG2 1st Teleconference, 16 Feb
2. WG2 1st FTF meeting: 1st March (Hong Kong)
3. WG2 2nd FTF meeting: 11th -13th July (Taipei)
4. WG2 3rd FTF meeting: 4th Dec (India)

WG Progress (I)

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	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	to Nov 2017	38 members in total • 15 Regulator Members; • 23 Industry Members
2	Development of AHWP Guidance Document	1) Definition of MD/ IVD	Mar 2015 to Nov 2016	• Documents endorsed in Cebu Annual meeting, 2016
		2) Classification of IVDs	Jun 2015 to Nov 2016	
		3) Conformity Assessment for IVDs	Aug 2015 to Nov 2016	
		4) IVD Submission Dossier	Aug 2015 to Nov 2016	
		5) Companion In Vitro Diagnostic Devices	Mar 2016 to Nov 2017	• Documents to be endorsed in New Delhi Annual meeting, 2017
		6) Label and Instructions for Use for IVD Medical Devices	Mar 2017~	• Comments received from WG2 members on draft document being reviewed

WG Progress (II)

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	Work Item	Deliverables	Timeline	Progress Update

3	Participation in International/ Global Organization collaboration and activities	1) Establish IVD WG representation to ISO/TC 212/WG3 regarding technical requirements for IVDs
		2) Provide recommendations on the specific WHO IVD PQ program guidance
			2015 to 2017	• AHWP WG2 has joined ISO/TC 212 as liaison member to participate in standard discussion and contribution from regulators and industry's point of view.
				• Side meetings with WHO IVD PQ team to discuss collaboration between the two groups
				• Participate in WHO expert consultation on G6PD IVDs, 26~28 Sept 2015
				• Collect and consolidate comments from WG2 members on the WHO documents, including:
				  • Technical guidance series documents
				  • Technical specifications series documents

WG Progress (III)

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	Work Item	Deliverables	Timeline	Progress Update
4	Collaboration with other WGs		2015 to 2017	• WG1: Guidance Document of MD/ IVD Definition, 2015 • WG1: Survey on regulation and treatment of e-IFU and e-Label of MD and IVD MD, 2017 • WG5: Conference on IVD Medical Devices Regulation and Clinical Performance Evaluation, 2015

WG Document towards Endorsement at the 22nd AHWP Annual Meeting 2017, India

No.	Title/ Content	Type of Document
1	Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices	Guidance Document

AHWP/WG2/P001:2017 – Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices

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- Scope of paper:
  - This document applies to all products that fall within the definition of Companion In vitro Diagnostic Medical Devices.
- Objective of paper:
  - This guidance document is intended to guide staff of RAs and CABs who are assessing Companion In Vitro Diagnostic Medical Devices (IVD-CDx) for possible premarket regulatory pathways and assist manufacturers of the IVD-CDx to develop and demonstrate relevant performance characteristics for their products.
- Rationale:
  - Recent development of scientific technology has led to the development of personalized medicine for treatment. The process for selecting appropriate therapeutic products, based on a patient's characteristics has grown in importance. IVD-CDx provide information that is essential for the safe and effective use of a therapeutic product, for example such information can be based on the expression levels of genes, or the occurrence of any mutations. Guidance is required on the process for collecting, documenting and assessing the performance of an IVD-CDx in relation to the therapeutic product with which it is intended to be used.

WG2 Project highlights 2015-2017

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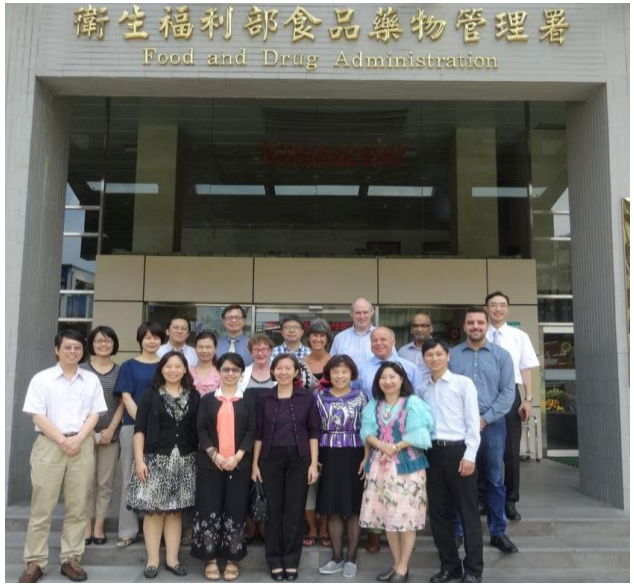
- 4 guidance documents adopted and 1 guidance document to be endorsed in the current AHWP meeting
- Extensive collaboration with WHO, ISO and IMDRF (with RPS Work Item representative).



Proposed Work Plan 2018-2020

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- 3 guidance documents and 1 future trend study:
  1. Label and Instructions for Use for In vitro Diagnostic Medical Devices
  2. Advertising and promotion for In vitro Diagnostic Medical Devices
  3. Guideline for Approval of Reagent for Instrument Family

  Future trend study: Bridging LDT and IVD

- Support AHWP and TC in promoting and reaching out for harmonization with AHWP IVD regulatory framework.

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Thank you

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