WG2 – Pre-market: IVDD

AHWP TC Meeting
24 November, 2016, Cebu

Membership Status

- Chair: Dr. Wen-Wei TSAI
- Co-Chair: Ir Prof. Albert KF POON
- Advisor: Ms. Shelley TANG
- No. of WG members: 31
  - 13 regulators
  - 18 industries

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

ASIAN HARMONIZATION WORKING PARTY

	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 ~
(7)	Advertising and promotion		Jan 2017 ~

Proposed Work Plan 2015-2017

	Work Item	Deliverables	Action Plan and Timeline
2	Environmental scanning and survey for IVD premarket regulatory controls	Survey Report	Mar 2015 to Jun 2016
3	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 - 2016

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)

WG Progress Update (I)

since AHWP Bangkok Annual Meeting in 2015

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	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	to Nov 2016	31 members in total • 13 Regulator Members; • 18 Industry Members
2	Development of AHWP Guidance Document	1) Definition of MD/ IVD	Mar 2015 to Nov 2016	• TC has no further comment on the document. For endorsement in Cebu Annual meeting, 2016
		2) Classification of IVDs	Jun 2015 to Nov 2016	• The IVD CTSD, IVD conformity assessment and IVD classification daft documents were circulated with WG2, seek comments from TC and request for public comments during Q2 and Q3 of 2016. No further comment was received for the final document
		3) Conformity Assessment for IVDs	Aug 2015 to Nov 2016	
		4) IVD Common Template for a Submission Dossier	Aug 2015 to Nov 2016	
		5) In Vitro Companion Diagnostic Devices	Mar 2016 to Nov 2017	• Training on IVD companion diagnostic device is organized for the Cebu building • Working draft is for further revision

WG Progress Update (II)

since AHWP Bangkok Annual Meeting in 2015

ASIAN HARMONIZATION WORKING PARTY

	Work Item	Deliverables	Timeline	Progress Update

3	Participation in International/ Global Organization collaboration and activities	1) Provide recommendations on the specific WHO IVD PQ program guidance
		
		2) Participate in WHO
			2015 to 2016	• Collect and consolidate comments from WG2 members on the following WHO documents (response date):
				  • Establishing stability of an in vitro diagnostic for WHO Prequalification (Feb. 2016)
				  • Reportable Changes to a WHO Prequalified In Vitro Diagnostic (Mar. 2016)
				  • WHO Global Model Regulatory Framework for medical devices including IVDs (Sept 2016)
				• Side meeting with Ms. Irena Prat of WHO IVD PQ program to discuss collaboration between the two group on 27 Apr.
				• Participate in WHO expert consultation on G6PD IVDs, 26~28 Sept

WG Progress Update (III)

since AHWP Bangkok Annual Meeting in 2015

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	Work Item	Deliverables	Timeline	Progress Update
4	Survey on IVD regulation status and premarket requirements for AHWP member economies	Survey Report	Mar 2015 to Nov 2016	• Partial results have been reported in Bangkok AHWP annual meeting. • Adding more countries' data in the report draft. • Seek TC/Secretariat's comment on the next step of the Survey Report. Follow up the comments..
5	Collaboration with other WGs		2015 to 2017	• WG1: Guidance Document of MD/ IVD Definition • WG5: Conference on IVD Medical Devices Regulation and Clinical Performance Evaluation

WG Document towards Endorsement at the 21st AHWP Annual Meeting 2016

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No.	Title/ Content	Type of Document
1	Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'	Guidance Document
2	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	Guidance Document
3	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	Guidance Document
4	Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	Guidance Document

WG2 highlights and notables

- Conference on IVD Medical Devices Regulation and Clinical Performance Evaluation: 13 July
  - Joint WG2 - WG5 activities
  - Invites collaboration with ANVISA, Brazil

- Environmental scanning and survey on IVD regulatory control framework

- WHO technical consultation on G6PD IVDs, 26~28 Sept, Geneva

(Next Albert will elaborate more details on the last two items)

Survey on IVD regulatory control framework

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Survey Context

- Survey assisted by Ms. Shelley TANG, WG2 Advisor
- Conducted during May – June 2015
- Sent to 24 member economies & WG2 members
- 14 respondents
- Questions on
  - Set up of Regulatory Authority
  - Definition of IVD medical device
  - Classification
  - Conformity Assessment requirements
  - Post-market surveillance requirements

Respondents

- Australia
- China
- Chinese Taipei
- Germany
- Ghana
- Hong Kong
- Indonesia
- Kenya
- Korea
- Malaysia
- Philippines
- Singapore
- Tanzania
- United Kingdom

IVD Regulation and Regulatory Authority

- 9 out of 14 respondents (64%) have one principal authority for control of IVD medical devices.
- Of the other five, two have affiliated laboratories, one outsources some product technical reviews

Note: Member economies interested in the information regarding the final survey report might inquire further with the AHWP Secretariat afterwards.

Report on AHWP Representation to WHO's technical consultation meeting on G6PD IVDs

WHO Meeting in Geneva

on 26-28 September 2016

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Background

- WHO Prequalification (PQ) Team invited AHWP for AHWP representation to a Technical Consultation Meeting on WHO PQ requirements for IVDs to detect G6PD deficiency.
- WHO PQ Team currently assesses the safety, quality and performance of Rapid Diagnostic Tests (RDTs) for diagnosis of infectious diseases, of which malaria is among one of them.
- The AHWP representation was to assist review and finalize the WHO proposed requirements for IVDs for detection of G6PD deficiency, which might cause significant obstacle to treatment of malaria through the traditional Primaquine process.

The Representation

Meeting was held on 26-28 September 2016 and Mr. Albert POON has been nominated to represent AHWP to the WHO for the IVD technical consultation. The Meeting

- Reviewed dossier requirements for WHO PQ of G6PD IVDs; finalized recommendations on the WHO Technical Specification Series (TSS) for G6PD IVDs
- Developed, agreed and finalized on performance evaluation protocol for WHO PQ of G6PD IVDs.
- Circulated outcome documents to members of the technical consultation meeting
- The project is now in process of open circulation for comments on WHO web and anticipating finalization of formal guideline document and TSS by end December 2016.

Possible Way Forward

- To establish future AHWP liaison to WHO Technical Meetings on IVDs
- To secure AHWP representation to WHO on technical aspects and consultations in IVDs
- To have direct technical contribution to the IVD field through inputs to WHO PQ meetings
- To align AHWP guidance document in line with directions of the global approach of WHO in IVDs
- To assist development of WHO guidance document and technical specification for PQ for IVDs
- To provide a common platform for AHWP mission tasks in IVD area for cooperation or shared directions with WHO global tasks.

< Thus enabling a "win-win" situation for global IVD development >

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Thank you