AHWP
ASIAN HARMONIZATION WORKING PARTY

WG2: Pre-market – IVDD

(former WG1a- IVDD)

Chair: Ms. Emily Wu

Acting Co-Chair: Ms. Sheryl Hsiao

Secretary: Dr. Wen-Wei Tsai

No. of WG members: 23

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New Members (5 recruited this year)

Name	Member Economy	Position	Organization
Yu-Jiun Chan M.D., Ph.D.	Chinese Taipei	Director, Division of Microbiology	Department of Pathology & Laboratory Medicine , Taipei Veterans General Hospital
Ms. Samara Zhu	China	Medical Affairs Director of China & Regulatory Affairs Director of Distribution Asia	Alere

2012-2014
Missions of AHWP WG1a

- To assist AHWP member economies and other developing countries to implement regulatory framework of IVD medical devices
  - Developing AHWP guidances on IVD medical devices on a TPLC basis
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices
  - Facilitating harmonization and regulatory convergence

- To establish a platform of regulations updates and gap analyses for AHWP Member Economies and Other Developing Countries
  - Capacity building and training through AHWP as a common platform
  - Experience sharing and case studies on IVD medical devices regulations

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2012-2013 Achievements

- Collaboration with GHTF to draft 3 GHTF Final Documents in 2012
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices in 2012
- 3 AHWP guidance documents were developed and endorsed in 2013 (AHWP/WG1a/F001, F002, F004)
- 3 international conferences on IVD medical devices regulations were held
  - May 17-18, 2012 "Conference for Convergence on IVD Medical Devices Regulations"
  - Nov 6, 2012 "Conference for Regulatory Convergence on New and Emerging IVD Medical Devices"
  - Sep 16, 2013 “AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations”
- Establishing a platform of regulations updates and gap analyses
  - AHWP WG1a Working Meeting, May 15-16, 2013
  - The 1st African Regulatory Forum for Medical Diagnostics & Pre-Forum Workshop, Jul 24-26, 2013
  - The AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations, Sep 16, 2013

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2014 Milestones

- Development of Regulatory Guidances on IVD Medical Devices
- Establishing a platform of regulations updates and gap analyses

2014 Milestones

3 IVD Regulatory Guidances

- *AHWP/WG1a/PD005-007 have been drafted*

1 Training Workshop

- *1 international conferences on IVD medical devices regulations*

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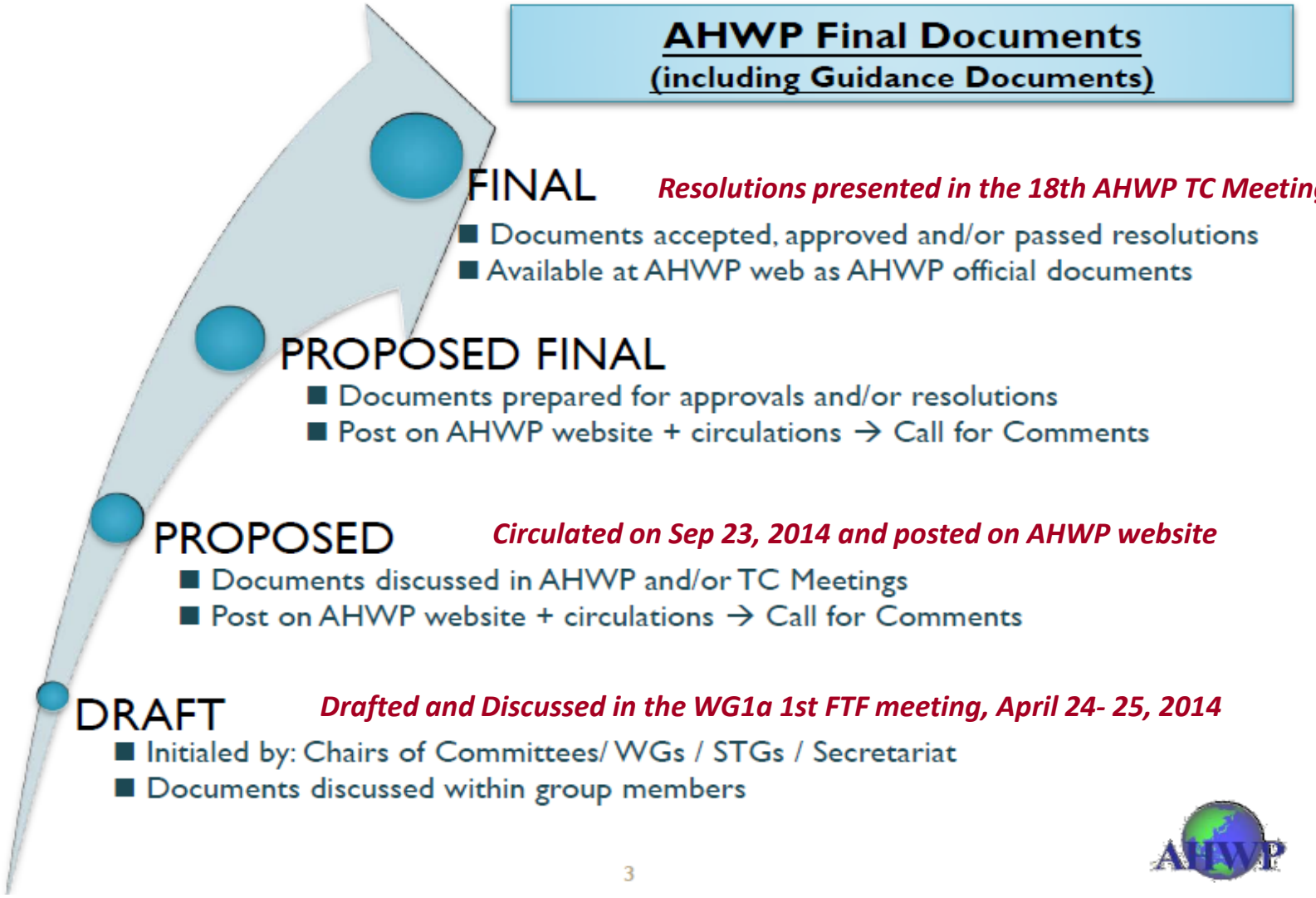
Development of Regulatory Guidances on IVD Medical Devices

AHWP WG1a Proposed Documents

Doc. No.	Title	Status
AHWP/WG1a/D001:2014 *Guidance document*	Comparison between Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices	■ Have gone through TC and public consultation ■ To be endorsed by AHWP
AHWP/WG7-WG1a/D001:2014 (in collaboration with WG7) *Guidance document*	Role of Standards in the Assessment of Medical Devices	■ Have gone through TC and public consultation ■ To be endorsed by AHWP

The 4-step Procedure with 4-Type of Doc



Source: The 4-Step Procedure for Preparing AHWP Official Documents, AHWP, Jun 7, 2012

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Establishing a platform of regulations updates and gap analyses

Establishing a platform of regulations updates and gap analyses

- AHWP WG1a 1st Working Meeting, April 24-25, 2014
- AHWP TC Leaders Meeting, Singapore, May 9-10, 2014
- ad hoc Working Group Meeting with representatives of LSHTM, PAHWP and ALADDIV in Hong Kong, May 19-20, 2014
- Conference on International IVD Medical Devices Regulations, Taipei, Sept. 2, 2014
- AHWP WG1a 2nd Working Meeting, Sept. 3, 2014
- ad hoc Working Group Meeting with representatives of LSHTM in Seoul, Nov 18, 2014

AHWP WG1a Working Meeting, April 24-25, 2014

- **The meeting was held in Taipei and was attended by 2 AHWP WG1a advisors and 7 members**
- **Achievements:**
  - Revision of the AHWP/WG1a/PD005D Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices
  - Revision of the AHWP/WG1a/PD006D Strategies for Implementing a Regulatory Framework for Affordable Access to IVD Medical Devices for Infectious Diseases
  - Revision of the AHWP/WG1a/PD007D Role of Standards in the Assessment of Medical Devices
  - Discussion and agreement on joint review pilot programs plan
  - Planning of the IVD Medical Devices Regulations Training Program in September, 2014

Conference on International IVD Medical Devices Regulations, Sept. 2, 2014

- The Conference was held in Taipei and attended by 239 people from AHWP, ISO/TC 212, MHRA and local regulatory agencies and industry.
- Topics covered:
  - Regulatory Updates and Convergence
  - Product Realization: from Concept to Commercialization

AHWP WG1a 2nd Working Meeting, Sept. 3, 2014

- The meeting was held in Taipei and was attended by 3 AHWP advisors and 9 members
- Achievements:
  - Discussion on AHWP Proposed Documents
    - AHWP/WG1a/PD005 – Comparison between IVD CSDT & IVD STED
    - AHWP/WG1a/PD006 – Strategies for Implementing a Regulatory Framework for AAIVD for Infectious Diseases
    - AHWP/WG1a/PD007 – Role of Standards in the Assessment of Medical Devices
  - Discussion on Future Work Items
    - AHWP/WG1a/PD00X– MD & IVD Definition
    - AHWP common submission file for IVD medical devices
    - Future Work Plan

Affordable Access to IVD Medical Devices (Collaboration with LSHTM)

- Development reference document on “Strategies for Implementing a Regulatory Framework for Affordable Access to IVD Medical Devices for Infectious Diseases”
- Representatives of AHWP WG1a and LSHTM had an ad hoc working group meeting to discuss the work plan on affordable access to IVDs (AAIVD) in Hong Kong on May 19-20, 2014.
- Representatives of AHWP WG1a and LSHTM had an ad hoc working group meeting to discuss priorities for action on inter-regional in Seoul on Nov 18, 2014.

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Future Work Plan

Elements of Regulatory model: Premarket	Guidance Documents	Ongoing/ Future Work
Regulatory Framework	AHWP/WG1a/F001 (2013)	AHWP/WG1a/PD006 (AAIVD, 2014)
IVD Definitions		2015 **Will collaborate with WG1**
Classification		2016
Essential Principles	AHWP/WG1a/F002 (2013)	
Standard		• AHWP/WG7-WG1a/D001:2014 • **Will collaborate with ISO/TC 212 to draft IVD Std**
Clinical evidence		**Will collaborate with WG5 (2016-7)**
Conformity Assessment		2015
Common Dossier	AHWP/WG1a/FPD003 (2013) AHWP/WG1a/F004 (2013)	AHWP/WG1a/PD005 (2014)
IVD Labelling (Advertising and Promotion Materials?)		2016-7

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AHWP/WG1a/D001:2014 Comparison between Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices

- Scope of paper:
  - This document applies to all products that fall within the definition of *In Vitro Diagnostic (IVD) Medical Device*.
- Objective of paper:
  - The availability of summary technical documentation in an agreed format should help eliminate differences in documentation requirements between jurisdictions, thus decreasing the cost of establishing and documenting regulatory compliance and allowing patients earlier access to new technologies and treatments.
  - This document is intended to provide information on the differences between the recommended content of the ASEAN CSDT for IVD medical devices and the GHTF STED for IVD medical devices to support building AHWP guidance for common submission file for IVD medical devices.
- Summary:
  - The document contains the comparison table between the two documents. The core content of each document is the required content of the technical documentation to be submitted to a regulatory authority. In this respect, the ASEAN CSDT for IVD medical devices contains detail which may enhance the GHTF STED for IVD medical devices; the combination of the two documents form the basis of the AHWP recommendation for a common submission file for IVD medical devices.
  - The CSDT incorporates the requirements for labeling and instructions for use, as well as for clinical evidence. The GHTF includes these requirements as headings only, with the detailed requirements included in separate guidance documents.

AHWP/WG7-WG1a/D001:2014 Role of Standards in the Assessment of Medical Devices

- Scope of paper:
  - This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*.
- Objective of paper:
  - To:
    - encourage and support the development of international consensus standards for medical devices that may serve to demonstrate conformity with the *Essential Principles of Safety and Performance of Medical Devices*;
    - encourage manufacturers to conform with appropriate standards;
    - persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating conformity with the Essential Principles;
    - support the concept that in general, the use of standards is voluntary and manufacturers have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles.
- Summary:
  - The present guidance services as recommendation to Regulatory authorities, Conformity Assessment Bodies and Industry on the principle of appropriate use of standards in the assessment of medical devices from the development of recognition of standards, the use of these standards during and after the transition period, revision of standards, and thereby the changes of the status, status of devices designed using recognised standard before the end of transition period and alternatives to recognised standards.

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Thank you!