AHWP WG1a IVDD Update

The 17th AHWP TC Meeting

Kuala Lumpur, Malaysia

Dec 4, 2013

Members of AHWP WG1a

	Position	Name	Member Economy	Organization	Remark
1	**Chair**	Ms. Li Ling LIU	Chinese Taipei	Division of Medical Devices and Cosmetics, Food and Drug Administration, DOH	Reg
2	**Co-Chair**	Mr. Jeffrey CHERN	Chinese Taipei	Center for Measurement Standards, Industrial Technology Research Institute	Ind
3	**Advisor**	Nancy SHADEED	Canada	Health Canada, Device Licensing Division Medical Devices Bureau	Reg
4	**Advisor**	Dr. Petra KAARS-WIELE	Germany	Abbott GmbH & Co, International Regulatory Affairs & Division Labeling	Ind
5	**Advisor**	Ms. Shelley Tang	Australia	Stellar Consulting	Ind
6	**Advisor**	Mr. Benny Ons	Belgium	BD Europe	Ind
7	Member	Ms Maria Cecilia MATIENZO	Philippines	Center for Device Regulation, Radiation Health, and Research - Food and Drug Administration - Department of Health	Reg
8	Member	Mr. Shekhar GANU	India	Ortho Clinical Diagnostics, a Johnson & Johnson Company	Ind
9	Member	Ms. Fan-Yin LIU	Chinese Taipei	Division of Medical Devices and Cosmetics, Food and Drug Administration, DOH	Reg
10	Member	Mr. Albert Ka-Fat POON	Hong Kong, China	Hong Kong Government (retired)	Reg

Members of AHWP WG1a

	Position	Name	Member Economy	Organization	Remark
11	Member	Dr. Jane TSAI	Chinese Taipei	Biomedical Technology and Device Research Laboratories, Industrial Technology Research Institute	Ind
12	Member	Mr.Lun Au Yeung	Hong Kong, China	Medical Device Control Office, Department of Health Hong Kong	Reg
13	Member	Dr.Phana Chieng	Cambodia	Ministry of Health	Reg
14	Member	Mrs. SAR Kuy Heang	Cambodia	Ministry of Health	Reg
15	Member	Ms.Jeong Jin JO	Korea	Korea Food & Drug Administration	Reg
16	Member	Ms. Suhoung Thitastthayakorn	Thailand	Food and Drug Administration	Reg
17	Member	Ms. Marriamah Krishnasamy	Malaysia	Medical Device Bureau, Ministry of Health	Reg
18	Member	Mr. Sanoj Prabhakaran	UAE	Becton Dickinson	Ind
19	Member	Mr.Ming-Che Wang	Chinese Taipei	Center for Drug Evaluation	Ind
20	Member	Mr.Bryan So	Hong Kong	Hong Kong Productivity Council	Ind
21	Member	Ms. Lisa Yang	Singapore	PharmEng Technology Pte. Ltd.	Ind

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 facilitate capacity building and training activities for AHWP member economies and other developing countries on IVD medical devices regulations**
  - Capacity building and training through AHWP as a common platform
  - Regulations updates and gap analyses
  - Experience sharing and case studies on IVD medical devices regulations

AHWP WG1a Projects

To assist AHWP member economies and other developing countries to implement regulatory framework of IVD medical devices			
Project	**Kick-off (DD/MMM/YY)**	**Checkpoint (DD/MMM/YY)**	**Actual Date of Completion (DD/MMM/YY)**
Development of GHTF Guidances on IVDs	1/1/2012	2/6/2012	2/6/2012
Revision of GHTF Documents	1/3/2012	13/7/2012	13/7/2012
List of Recognized Standards for IVDs	1/5/2012	30/6/2013	30/9/2012
Best practices for clinical evaluation and investigation	1/5/2012	30/6/2013	30/12/2012
Development of AHWP Guidances on IVD Medical Devices	1/1/2013	30/11/2013	Not yet

To facilitate capacity building and training activities for AHWP member economies and other developing countries on IVD medical devices regulations			
Project	**Kick-off (DD/MMM/YY)**	**Checkpoint (DD/MMM/YY)**	**Actual Date of Completion (DD/MMM/YY)**
Training for AHWP Member Economies	30/9/2012	30/10/2014	Not yet
Affordable and Accessible IVD Medical Devices (Collaboration with LSHTM and GHTF)	1/1/2013	30/10/2014	Not yet

Completed

Undergoing

2012 Achievements

- 3 GHTF Final Documents
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices made
- 2 international conferences on IVD medical devices regulations 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"

2013 Milestones

- Development of Regulatory Guidances on IVD Medical Devices
- Capacity Building and Training Activities for AHWP Member Economies and Other Developing Countries

2013 Milestones

6 IVD Regulatory Guidances

1 Training Workshop

- *AHWP/WG1a/PD001-004 have been drafted and to be endorsed*
- *3 draft documents subject to future work*

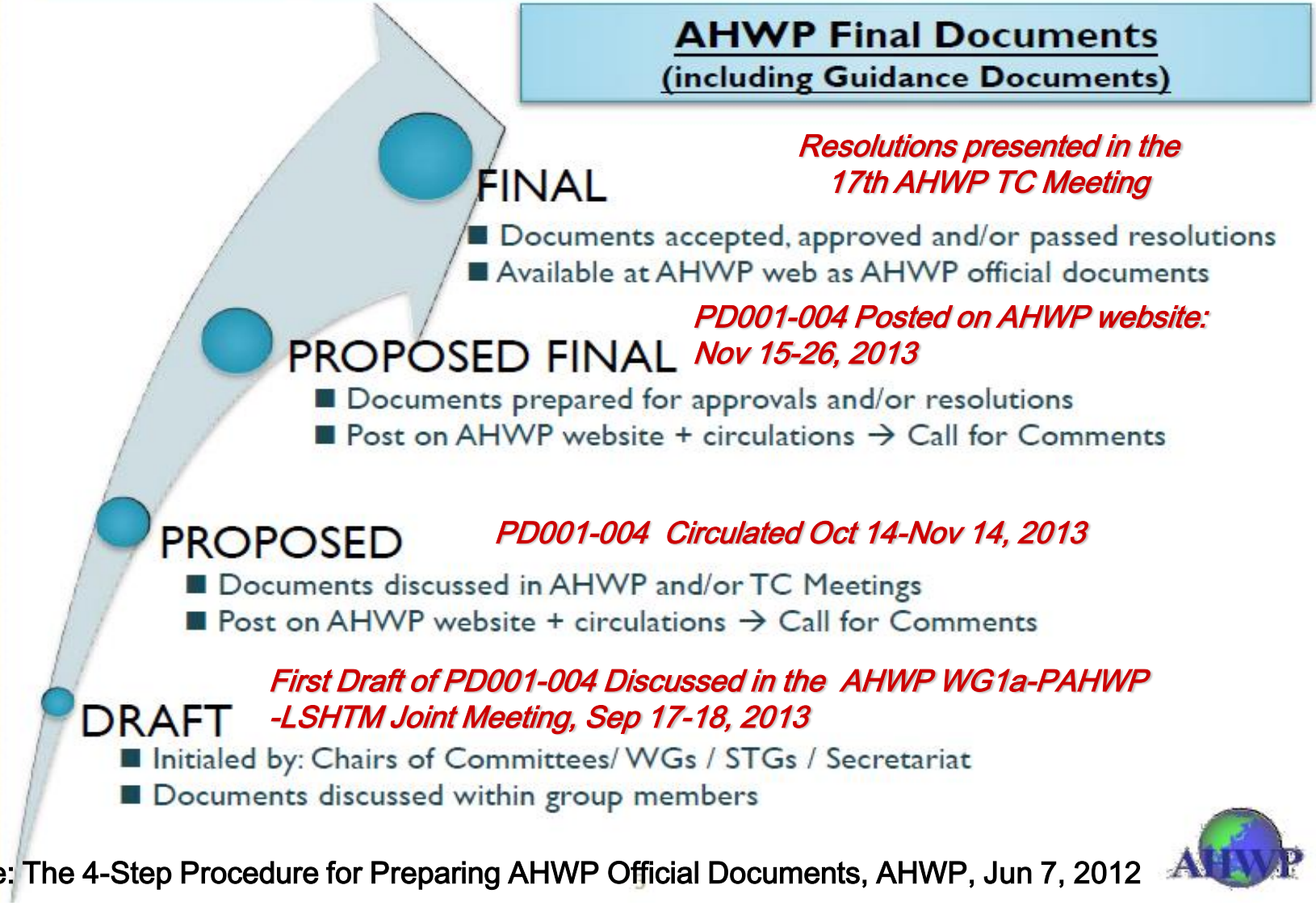
- *AHWP WG1a Working Meeting*
- *The 1st ARFMD & Pre-Forum Workshop*
- *The AHWP WG1a-PAHWP-LSHTM Joint Conference*
- *AHWP WG1a-PAHWP-LSHTM Joint Conference*

Development of Regulatory Guidances on IVD Medical Devices

Development of Regulatory Guidances on IVD Medical Devices

Regular Regulatory Framework Doc.	Additional Guidance	AAIVD
AHWP/WG1a/PD001 AHWP Regulatory Model for IVD (To be endorsed by AHWP)		AHWP/WG1a/PD001(AAIVD) Strategies for Implementing Regulatory Model for AAIVD **(Future work item)**
AHWP/WG1a/PD002 IVD EP (To be endorsed by AHWP)	AHWP/WG1a/PD002(EPSTD) EP applicability and Recognized Std. Checklists **(Future work item)**	
AHWP/WG1a/PD003 IVD STED (To be endorsed by AHWP)	AHWP/WG1a/PD004 Comparison btn STED and CSDT (To be endorsed by AHWP)	Pilot program for Common Registration File **(Future work item)**

The 4-step Procedure with 4-Type of Doc



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

Capacity Building and Training Activities for AHWP Member Economies and Other Developing Countries

Capacity Building and Training Activities for AHWP Member Economies and Other Developing Countries

- 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
- The AHWP WG1a-PAHWP-LSHTM Joint Meeting on POC IVD Medical Devices, Sep 17-18, 2013

AHWP WG1a Working Meeting, May 15-16, 2013

- The meeting was held in **Taipei** and was attended by 2 AHWP WG1a advisors and 7 members
- **Achievements:**
  - Review of the Draft White Paper on Affordable Access to In Vitro Diagnostics through Regulatory Harmonization Approaches
  - Revision of the **AHWP/WG1a/PD001D Strategies for Implementing Regulatory Framework and Affordable Access to IVD Medical Devices**
  - Revision of the **AHWP/WG1a/PD002D Essential Principles of Safety and Performance of Medical Devices**
  - Revision of the **AHWP/WG1a/PD003D Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices**
  - Planning of the IVD Medical Devices Regulations Training Program in September, 2013

The 1st African Regulatory Forum for Medical Diagnostics & Pre-Forum Workshop, Jul 24-26, 2013

- The Forum was held in Nairobi, Kenya and was attended by 90s people from EAC, AU/NEPAD, ASLM, WHO, LSHTM, etc.
- Two representatives of AHWP WG1a were sent
- Experiences sharing from AHWP WG1a's perspective
- Training session on premarket registration, QMS, PMS and clinical evidence for the PAHWP countries representatives
- Four priority areas determined:
  - ✓ Common Registration File
  - ✓ Clinical Evidence
  - ✓ QMS
  - ✓ PMS

The AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations, Sep 16, 2013

- The Conference was held in Taipei and attended by 24 experts from AHWP, PAHWP, LSHTM, etc. and 200 people from local regulatory agencies and industry
- Main Topics:
  - **Update on IVD Medical Devices Regulations**: USA, EU, Japan, Taiwan, Malaysia, Indonesia, Philippines, Thailand
  - **Common Registration File for IVD Medical Devices:** EP & STED
  - **Clinical Evidence for Infectious Diseases Diagnostics:** Clinical Evaluation and State-of-the-art Technology
  - **Quality Management System (QMS):** ISO13485, QC/QA & Process Validation
  - **Post Market Surveillance:** NCAR & SADS

The AHWP WG1a-PAHWP-LSHTM Joint Meeting on POC IVD Medical Devices, Sep 17-18, 2013

- The Conference was held in Taipei and attended by 20 experts from AHWP, PAHWP, LSHTM, etc.
- Achievements:
  - Definition of "**Medical Device**" and **IVD Medical Device**" revisited
  - Discussion on the AHWP Regulatory Model for IVD Medical Devices and **Comparison between STED and CSDT**
  - **Potential Inter-Regional Collaboration Initiatives**
  - **Common Registration File and IVD STED**
  - Evaluation of IVD tests
  - Clinical performance data on POC IVD Medical Devices
  - Discussion **on the EP and Labeling Requirements** for IVD Medical Devices

Interregional Collaboration Items Agreed in the AHWP WG1a-PAHWP-LSHTM Joint Meeting

No.	Action Item	Deadline	Organization in Charge	Progress
1	Questionnaire on the definitions of “medical device” and “IVD medical device”	Oct 10, 2013	AHWP WG1a, PAHWP	▪ Sent to AHWP and PAHWP member economies
2	Circulation of AHWP/WG1a/PD001-PD004 in AHWP TC	Oct 31, 2013	AHWP WG1a	▪ Have gone through TC and public consultation ▪ **To be endorsed by AHWP**
3	Position paper on the priority working items for AAIVD program	Oct 31, 2013	LSHTM	Undergoing, **will be discussed in the AHWP Annual Meeting**
4	Position paper on the need for IVD medical devices common registration file format	Oct 31, 2013	AHWP WG1a	Undergoing, **will be discussed in the AHWP Annual Meeting**

Interregional Collaboration Items Agreed in the AHWP WG1a-PAHWP-LSHTM Joint Meeting

No.	Action Item	Deadline	Organization in Charge	Progress
5	Applying for participating members or observers of ISO/TC 212	Oct 31, 2013	ISO/TC 212	▪ ISO/TC agreed to send an invitation letter to AHWP ▪ Benny Ons will present at the AHWP annual meeting on GCP initiative in ISO/TC212 ▪ Will confirm with LSHTM on drafting POCT standards
6	A New Work Item Proposal to ISO/TC 212	Oct 31, 2013	AHWP WG1a, LSHTM	
7	Collecting comments on ISO 22870:2006	Oct 31, 2013	AHWP WG1a, LSHTM	
8	Circulation of the aforementioned questionnaire on definitions in AHWP and PAHWP member economies	Nov 30, 2013	AHWP WG1a, PAHWP	▪ Sent to AHWP and PAHWP member economies
9	Circulation of AHWP/WG1a/PD001-PD004 in AHWP member economies	Nov 30, 2013	AHWP WG1a	▪Have gone through TC and public consultation ▪ To be endorsed by AHWP
10	AWHP WG1a will request mandate on the use of proper definitions, EP, CRF, etc. in the coming AHWP Annual/TC Meeting	Dec 10, 2013	AHWP WG1a	To be conducted
11	Clarifications and additional guidelines on AAIVD medical devices	Jun 30, 2014	LSHTM, AHWP WG1a,	To be conducted

FDA
食品藥物管理局
Food and Drug Administration

Thank you for your attention!