出國報告（出國類別：參加國際會議）

體外診斷醫療器材
價格取得合宜性計畫之特設會議

(Ad Hoc Meeting of the Affordable to Access In-vitro Diagnostics Project)

參會報告

服務機關：衛生福利部食品藥物管理署

姓名職稱：吳正寧科長、蔡文偉薦任技正

派赴國家：香港

出國期間：103 年 5 月 18 日 - 21 日

報告日期：103 年 6 月 21 日

摘要

本次「體外診斷醫療器材價格取得合宜性計畫之特設會議」，由我國衛生福利部食品藥物管理署(Food and Drug Administration，簡稱 TFDA)吳科長正寧與蔡技正文偉赴香港出席與會，會議日期為 103 年 5 月 19 日至 5 月 20 日，我國參會代表於本次會議中報告亞洲醫療器材法規調和會(Asian Harmonization Working Party, AHWP)體外診斷醫療器材工作小組(WG1a - IVDD)於 2014 年之工作規劃及執行進度，並討論未來各國際組織分工合作之模式。其中，WG1a 工作小組於 2014 年間，預計將有 3 件體外診斷醫療器材國際基準完成，且將依正式程序使該文件受採認為 AHWP 文件，另外，將於我國舉辦 1 場大型國際法規訓練會議，預計邀請美國、歐洲、澳洲等各國醫療器材主管機關官員或業界代表與會，提供各國法規更新之現況。另外，於本次會議中，已擬訂 AHWP、PAHWP 及 ALADDIV 於 2014-2016 年之工作計畫。此外，藉由參加本次會議之機會，拜訪位於香港生產力局之 AHWP 秘書處，並瞭解與討論 AHWP 本年度將於首爾舉辦年度大會及領袖改選相關細節與規定，及討論 AHWP WG1a 工作小組於 2014 年預定工作項目之執行程序，藉此機會面對面討論澄清相關細節，有利於本年首爾 AHWP 年度大會之參會規劃及 WG1a 年度工作之執行。

目　次

壹、目的

為加強傳染性疾病早期診斷及預防的需求，英國倫敦大學衛生及熱帶醫學院(London School of Hygiene & Tropical Medicine, LSHTM)接受比爾蓋茲基金會(Bill & Melinda Gates Foundation)及加拿大國際衛生組織 Grand Challenges Canada 委託，邀請亞洲醫療器材法規調和會(Asian Harmonization Working Party, AHWP)體外診斷醫療器材工作小組(WG1a - IVDD)，共同研擬有關體外診斷醫療器材價格取得合宜性(Affordable Access to In-vitro Diagnostics, AAIVD)之計畫，期能藉由建立完善的體外診斷醫療器材管理體制，以促進發展中國家人民之健康水準。

於前揭 AAIVD 計畫中，為提升發展中國家醫療器材主管機關對 IVD 產品管理的能力，並瞭解當地官方及產業界於產品上市所面臨的問題，本次會議邀集亞洲 AHWP、非洲醫療器材法規調和會(Pan-African Harmonization Working Party, PAHWP)及拉丁美洲體外診斷醫療器材協會(Latin America IVD Association, ALADDIV)等區域性國際組織代表，於香港召開體外診斷醫療器材價格取得合宜性計畫之特設會議(Ad Hoc Meeting of the AAIVD Project)，研擬 IVD 產品管理之跨國/跨區合作模式及可行方案，以改善發展中國家傳染性疾病普遍之現況。

由於現任 AHWP WG1a 之主席係由我國食品藥物管理署吳科長正寧擔任，故於本次會議中，由吳科長正寧及蔡技正文偉出席與會，本次會議除可促成我國與其它區域性國際組織合作之契機外，亦有助於提升我國體外診斷醫療器材管理之國際影響力與國際形象。本次會議主要目的包括：(1)相互瞭解各區域性體外診斷醫療器材法規調和國際組織之現況;(2)共同研商擬訂未來 AAIVD 計畫之跨國合作模式及可行方案。

另外，由於 LSHTM 安排本次會議地點係在香港生產力局(Hong Kong Productivity Council, HKPC)之會議室，故亦藉由本次會議之行程，安排拜訪 AHWP 秘書處，並瞭解與討論 AHWP 本年度將於首爾舉辦年度大會及領袖改選相關規定，及 AHWP WG1a 工作小組於 2014 年預定工作項目的執行程序。

貳、議程

本次會議共有兩天議程，第一天(5 月 19 日)主要係由各醫療器材法規調和國際組織(AHWP WG1a、PAHWP 及 ALADDIV)說明其組織法規調和與更新現況，並討論 AHWP 醫療器材法規管理架構更新，及 AAIVD 計畫中臨床試驗、品質系統與上市後監控之執行進度更新。第二天(5 月 20 日)主要係由各區域性醫療器材法規調和國際組織共同討論未來於 AAIVD 計畫中之工作重點與分工，會議議程詳如下：

DAY 1: Monday 19 May, 2014

Chair*: Rosanna Peeling

13:00 –13.15	Welcome and introductions	
13.15 – 13.45	The Affordable Access to IVDs project: Updates, Meeting objectives and expected outcomes	Rosanna Peeling
13.45 – 14:30	Updates from: - The Asia Harmonization Working Party - The Pan-African Harmonization Working Party - The Latin America IVD Initiative (ALADDIV)	AHWP rep Wellington Oyibo Carlos Gouvea
14:30 – 15:00	Break	
15:00 – 16:00	The AHWP IVD Regulatory Framework Discussion	Benny Ons All
16:00 – 16:30	The South Africa Medical Device IVD regulation draft document	Shabir Banoo
16:30 – 17:00	Updates on Clinical Performance Studies	Rosanna Peeling
17:00 – 17:30	Updates on Quality Audits and Post-marketing Surveillance	

DAY 2: Tuesday 20 May, 2014

Chair: Albert Poon

09:00 – 09:15	Recap of first day	Rosanna Peeling
09:15 – 10:30	Piloting harmonized approaches: 1. Common Registration File 2. Quality audit	All
10:30 – 11:00	Break	
11:00 – 12:30	Piloting harmonized approaches: 3. Joint review of data from clinical performance studies 4. Post-marketing surveillance	All
12:30 – 14:00	Lunch	
14:00 – 15:00	Moving forward: 1. Synergies across regions 2. Inter-regional Workplan 3. Timelines and milestones	All
15:00 – 15:30	Break & Visit AHWP Secretariat	
15:30 – 16:00	Meeting summary and next steps for moving forward	All
16:00	Close of Meeting	

參、會議內容及心得

亞洲醫療器材法規調和會(Asian Harmonization Working Party，簡稱 AHWP)係由亞洲及南美洲各國醫療器材法規主管機關與業者共同組成，為亞太地區推動醫療器材法規調和之重要組織，目前該組織會員國包括阿布達比(Abu Dhabi)、汶萊(Brunei Darussalam)、柬埔寨(Cambodia)、智利(Chile)、香港(Hong Kong SAR, China)、印度(India)、印尼(Indonesia)、約旦(Jordan)、沙烏地阿拉伯(Kingdom of Saudi Arabia)、韓國(Korea)、寮國(Laos)、馬來西亞(Malaysia)、緬甸(Myanmar)、巴基斯坦(Pakistan)、中國大陸(People's Republic of China)、菲律賓(Philippines)、新加坡(Singapore)、南非(South Africa)、科威特(State of Kuwait)、泰國(Thailand)、越南(Vietnam)、葉門(Yemen)以及我國(Chinese Taipei)等 23 個國家，且會員國尚持續增加中。

AHWP 大會轄下設有秘書處及技術委員會，技術委員會共包含 8 個工作小組(Working Group, WG)及 1 個特殊任務小組(Special Task Group, STG)，分別為 WG1 Pre-Market Submission and CSDT、WG1a IVDD、WG2 Post-Market Surveillance and Vigilance、WG3 Quality Management System、WG4 Quality System Audit、WG5 Clinical Safety/Performance、WG6 Capacity Building and Regulatory Training、新成立的 WG7 Standards 以及 STG (N) Medical Device Nomenclature 等小組，我國食品藥物管理署醫療器材及化粧品組官員於 AHWP 組織內擔任之職務，包括杜組長培文擔任 AHWP 大會副主席及吳科長正寧擔任 AHWP 技術委員會轄下體外診斷醫療器材工作小組(WG1a-IVDD)主席。AHWP 之主要任務係建立醫療器材產品安全性及有效性評估，以及品質系統稽核等要項的國際共同基準規範，以協助各國醫療器材主管機關建立共識，採用相同醫療器材管理模式，奠定國際間相互承認之基礎，以促進國際貿易之推動。

為加強開發中國家感染性疾病早期預防、診斷與治療的需求，英國倫敦大學衛生及熱帶醫學院(LSHTM)接受比爾蓋茲基金會(Bill & Melinda Gates Foundation)及加拿大國際衛生組織(GCC)委託，邀請亞洲醫療器材法規調和會(AHWP)體外診斷醫療器材工作小組(WG1a)，共同研擬有關體外診斷醫療器材價格取得合宜性(AAIVD)之

計畫，期能藉由建立完善的體外診斷醫療器材管理體制，以促進發展中國家人民之健康水。食品藥物管理署過去於體外診斷醫療器材法規國際調和上的努力與成果，備受各國及 LSHTM 肯定，故本次會議吳科長正寧及蔡技正文偉受邀與會，本次會議與會者詳如表 1。

表 1、與會者清單

項次	姓名	職稱/單位
1	Rosanna Peeling	Professor and Chair of Diagnostics Research, London School of Hygiene and Tropical Medicine
2	Albert Poon	Consultant, Retired Senior Electronics Engineer, Elect & Mech Services Dept., Hong Kong SAR Government
3	Cheng-ning Emily Wu	Chair of AHWP WG1a Section Chief, Division of Medical Devices and Cosmetics, Food and Drug Administration, Ministry of Health and Welfare, Taiwan (R.O.C.)
4	Wen-Wei Tsai	Secretary of AHWP WG1a Technical Specialist, Division of Medical Devices and Cosmetics, Food and Drug Administration, Ministry of Health and Welfare, Taiwan (R.O.C.)
5	Christopher Chan	Office of Medical Device Evaluation, Center for Measurement Standards, Industrial Technology Research Institute, Taiwan (R.O.C.)
6	Benny Ons	Advisor of AHWP TC BD Europe
7	Carlos Gouvea	ALADDIV Board
8	Shabir Banoo	Head: Pharmaceutical Policy, Research and Services Support Unit Right to Care — Treating AIDS Seriously University of the Witwatersrand and Helen Joseph Hospital

本次會議中，先由 WG1a 代表簡報本年度之工作規劃及進度(簡報詳如附件 1)，包括預定完成 3 件體外診斷醫療器材相關基準文件，並將依照「4-steps procedure of AHWP document endorsement」AHWP 文件採認程序(詳如圖 1)，預計於本年度首爾舉辦之年度大會中被採認為 AHWP 文件。前述 3 件體外診斷醫療器材相關基準文件包括：

1. 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。

2. Strategies for Implementing a Regulatory Framework for Affordable Access to IVD Medical Devices for Infectious Diseases。

3. Role of Standards in the Assessment of Medical Devices。

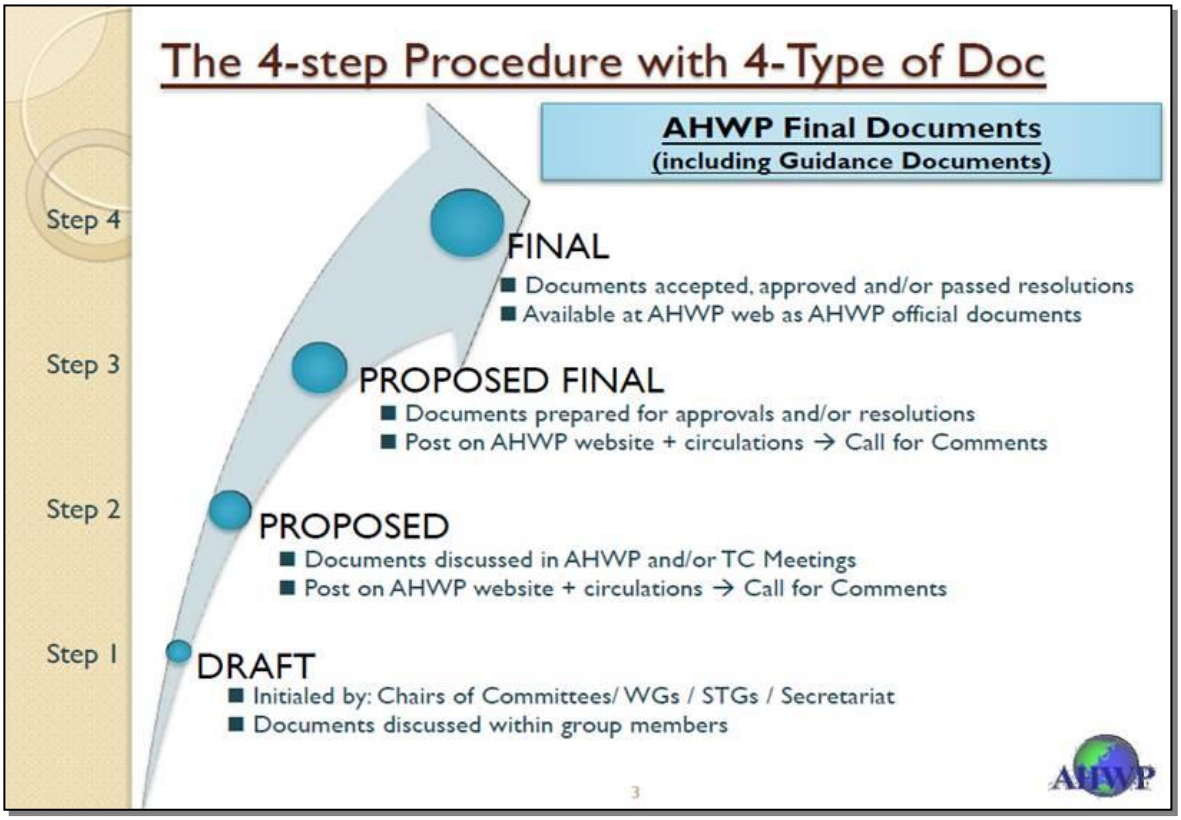


圖 1、4-steps procedure of AHWP document endorsement

另外，WG1a 規劃本年度 9 月於台北舉辦 1 場 IVD 法規訓練國際研討會，邀請與會者共襄盛舉，研討會暫訂議題包括各國(地區)法規更新、IVD 產品安全性及效能評估、國際法規調和趨勢等。此外，由來自南非的 Shabir Banoo 說明近期由南非衛生部(DEPARTMENT OF HEALTH)公布之醫材(含 IVD)管理法規 General Regulations Relating to Medical Devices and In-vitro Diagnostic Medical Devices (IVDs)，內容包括定義、產品分類、查驗登記、上市後監控及罰則等章節，顯示南非已開始重視 IVD 產品之管理，以解決非洲地區傳染性疾病普遍的問題。接著，由 Benny Ons 介紹 AHWP 之法規管理策略架構，供非洲及拉丁美洲代表參考。

接著，由全體與會者共同擬定 2014-2016 年有關 AAIVD 之工作規劃，由於全球醫療器材法規調和會(Global Harmonization Task Force, GHTF)已於 2012 年底結束，該組織已完成數十件醫療器材管理相關基準，可能出現維護與更新的問題。我國於醫療器材法規管理經驗上，較 ALADDIV 和 PAHWP 兩組織內各會員經濟體豐富，故將由 WG1a 工作小組挑選 GHTF 完成之 IVD 產品相關基準文件，進行內容審閱與更新，並轉換為 AHWP 採認之基準文件，提供予 PAHWP 及 ALADDIV 組織參考及使用。

Rosanna Peeling 教授表示，期望未來 AAIVD 計畫可協助 2 或 3 項定點照護(Point of Care, POC)使用之表面抗原分化簇 4 受体(Cluster of Differentiation 4 receptors, CD4)檢測試劑產品上市，以提供快速且簡便之人類免疫缺陷病毒(Human Immunodeficiency Virus, HIV)篩檢。另 Rosanna Peeling 教授亦表示 AAIVD 計畫在 ALADDIV 和 PAHWP 地區執行上尚有政府穩定性不佳及官員流動性高等問題，及政府對相關管理法規之立法意向尚不明確，致計畫執行成效有限。AAIVD 計畫資金支持將於本(103)年底結束，現 Rosanna Peeling 教授正積極尋求其它支持經費，以利該計畫得以持續且順利執行。

另外，由於 LSHTM 安排本次會議地點係在香港生產力局(Hong Kong Productivity Council, HKPC)之會議室，故本次會議本署與會人員，於議程第 2 天下午撥空拜訪 AHWP 秘書處，並瞭解與討論 AHWP 本年度將於首爾舉辦年度大會及領袖

改選相關細節與規定，及討論 AHWP WG1a 工作小組於 2014 年預定工作項目的執行程序，藉此機會面對面討論澄清相關細節，有利於本年首爾 AHWP 年度大會之參會規劃及 WG1a 年度工作之執行。

肆、建議事項

1. 持續積極參與國際組織相關事務提升國際形象

   TFDA 現擔任 AHWP Vice-chair 及 AHWP WG1a Chair 職務至 2014 年底，於 AHWP 組織中扮演多個重要角色，且 TFDA 於醫療器材法規國際調和之努力與貢獻，成果備受 AHWP 大會及各國的肯定。AHWP 組織已漸受各國重視且具國際影響力，故如 TFDA 持續於 AHWP 組織中擔任要角，可提升我國醫材管理之國際形象，增進各國與我國合作之意願，且對於我國醫材相關產業亦有所助益，較符合國內醫材產業之期望。

2. 於國內舉辦國際性研討會協助國內醫材產業與國際接軌

   國產醫療器材廠商規模相對較小，故投入資源於國際醫療器材法規相關事務之意願及比例也較低，建議可由 TFDA 主辦國際醫療器材法規訓練課程及研討會，邀請各國醫療器材主管機關代表及國際醫療器材大廠專家，說明各國醫療器材法規管理現況，提供國內廠商參與國際會議之機會，同時，國內廠商亦可推廣我國自行研發的醫療器材，以達到相輔相成的雙贏局面。

3. 加強人才培訓以提升我國醫療器材管理之能量

   隨電子及資訊科技持續進步，醫療器材產品不斷推陳出新，醫療器材產品上市前及上市後等全生命週期管理亦趨複雜，各國已逐漸重視該領域之人才培訓，建議我國除投注資源於生技產業發展外，需同時重視醫療器材管理人才之延攬及培訓，期可提升我國醫療器材管理之品質與效率外，亦可增進我國醫療器材產業之國際競爭力。

4. 透過國際合作分享我國醫材法規管理經驗

   由於 AHWP WG1a 係由我國醫材主管機關官員領導，且我國於 IVD 醫材法規管理之經驗，於 AHWP 組織各國中，屬經驗較豐富之國家，故我國於 IVD 醫材之管理經驗如能分享予其它國家，除可間接促進法規管理之國際調和外，亦可提升我國之國際形象。

附件 1

FDA

Ad Hoc Meeting of the Affordable Access *In-Vitro* Diagnostics (AAIVD) Project

AHWP WG1a IVDD Activity Update

Hong Kong
May 19-20, 2014

FDA

Recent Changes

- New TFDA Director-General
- AHWP Vice Chair:
  - Director Liu transfer to lead Drug division; Director Tu took up Device and Cosmetic Division's leadership and success Director Liu as AHWP vice Chair
- AHWP WG1a
  - Ms. Emily Wu, Section Chief success Director Liu as AHWP WG1a Chair
  - Jeffrey Chern of ITRI resigned from ITRI and WG1a Co-Chair; Ms. Sheryl Hsiao of BD TW/HK just took up Co-Chair recently

FDA

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

FDA

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	Ongoing

To establish a platform of regulations updates and gap analyses for AHWP Member Economies and Other Developing Countries

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	Ongoing
Affordable and Accessible IVD Medical Devices (Collaboration with LSHTM and GHTF)	1/1/2013	30/10/2014	Ongoing

Completed
Ongoing

FDA

2012-2013 Achievements

- 3 GHTF Final Documents
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices
- 3 AHWP guidance documents were developed and endorsed in 2013 (AHWP/WG1a/F001, F002, F004)
- 2 international conferences on IVD medical devices regulations were held in 2012
  - 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"
- Establishing a platform of regulations updates and gap analyses in 2013
  - 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

FDA

2014 Milestones

- Recruitment of experts & professional users as workgroup members to enhance support in evidence based review process
- 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*

FDA

New members

- Recruitment of experts & professional users as workgroup members to enhance support in evidence based review process

Position	Name	Member Economy	Organization	Remark
Member	Dr. Reba Chhabra	India	National Institute of Biologicals, NOIDA	Reg
Member	Dr. Cristina Sandjaja	Indonesia	Prodia Diagnostic Line, PT	Ind
Member	Ms. Jillianne Coles	Australia	Alere	Ind
Member	Ms. Sheng-Wen Hsiao	Chinese Taipei	BD Taiwan/Hong Kong	Ind
Member	**Dr. Yu-Jiun Chan (experts in clinical virology)**	**Chinese Taipei**	**Taipei Veterans General Hospital,**	**Others**
Member *(to be confirmed)*	Mr. Daniel Chang	Chinese Taipei	Giraffes Pharmaceutical Co., Ltd.	Ind

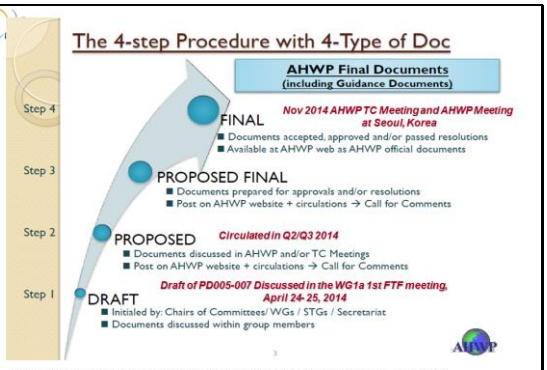
FDA

Development of Regulatory Guidances on IVD Medical Devices

AHWP WG1a Proposed Documents (Draft)

Doc. No.	Title	Status
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	▪ Drafted and discussed on April 24- 25 WG1a 1st FTF meeting ▪ Will be circulated among WG1a members & advisors in Q2/Q3 2014
AHWP/WG1a/PD006D (in collaboration with LSHTM)	Strategies for Implementing a Regulatory Framework for Affordable Access to IVD Medical Devices for Infectious Diseases	▪ Drafted and discussed on April 24- 25 WG1a 1st FTF meeting ▪ Will be circulated among WG1a members & advisors in Q2/Q3 2014
AHWP/WG1a/PD007D	Role of Standards in the Assessment of Medical Devices	▪ Drafted and discussed on April 24- 25 WG1a 1st FTF meeting ▪ Will initiate the collaboration with WG7

The 4-step Procedure with 4-Type of Doc



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

Establishing a platform of regulations updates and gap analyses

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

Proposed Topics of IVD Medical Devices Regulations Conference

- To be held in Sep. 2014
- Proposed Topics
  - Regulations updates (US, EU, Canada, Australia, Malaysia)
  - Safety and performance evaluation
  - Harmonization and regulatory convergence
- Speakers (to be invited)
  - Regulator or Expert from US, Canada, Australia, Malaysia
    - Stephen Lee, Team manager, MHRA, UK
    - Dr Lisa Studdert, Head of Market Authorization Group, TGA
  - Professor Rosanna Peeling (LSHTM, UK)
  - Representative of ISO/TC 212

Affordable Access to IVD Medical Devices

- Guidance document on "Strategies for Implementing a Regulatory Framework for Affordable Access to IVD Medical Devices for Infectious Diseases"
  - Issues raised during TC Leader Meeting, Singapore
- Ad hoc working group meeting to discuss work plan and review work progress on affordable access to IVDs (AAIVD), Hong Kong, May 19-20, 2014.

ISO/TC 212 Collaboration

- Scope of Activities: Standardization and guidance in
  - In Vitro Diagnostic Test Systems
  - Laboratory Medicine
- Applying for participating members or observers of ISO/TC 212
  - 2013/4/13 ISO/TC 212 email to invited AHWP as a Category A liaison

Thank you for your attention!