（出國類別：參加國際會議）

亞洲醫療器材法規調和會

第 20 屆年會系列會議

(AHWP Workshop、AHWP TC Meeting & AHWP Annual Meeting)

服務機關：衛生福利部食品藥物管理署
姓名職稱：朱玉如副組長、蔡文偉技正、
張嘉玲副審查員

派赴國家：泰國

出國期間：104 年 11 月 2 日至 104 年 11 月 6 日

報告日期：105 年 2 月 3 日

摘要：

亞洲醫療器材法規調和會(Asia Harmonization Working Party, AHWP)第 20 屆年會系列會議於泰國曼谷舉辦，系列會議包括為期 3 天的 Workshop、第 19 屆 AHWP Technical Committee (TC) Meeting 及第 20 屆 AHWP Annual Meeting。本會參與人員來自 30 個不同國家，超過 250 名各界醫療器材領域專業人士共襄盛舉。本署由朱玉如副組長率同擔任 AHWP TC 轄下體外診斷醫療器材工作小組((WG2 - Premarket: IVDD)主席蔡文偉科技正等一行 3 人代表與會。

AHWP 大會首兩日安排以 AHWP PLAYBOOK 內容為基礎之延伸課程。第三天安排歐盟、日本等非會員國代表，簡介其醫療器材管理近期發展及未來重點、醫療器材面臨新興議題(如 MDSAP)專題演講及與 DITTA 合辦醫用軟體專題討論。

第四天係第 19 屆 AHWP TC Meeting，由 AHWP TC 現任主席沙烏地阿拉伯 Mr. Ali Al Dalaan 代表致詞後，接續由 TC 及各 WG 的主席，報告其新任期未來規劃及年度工作進度。本署蔡文偉技正代表 AHWP WG2 於會中說明將提次日 AHWP 大會進行採認之體外診斷醫療器材國際基準文件、 104 年 8 月份在台北召開工作小組之會議成果及未來研究方向。

第五天舉行第 20 屆 AHWP Annual Meeting，由 AHWP 大會現任主席韓國 Dr. Jeong Hee-kyo 主持，邀請國際醫療器材規管理論壇 (IMDRF)等重要國際組織，以及各會員國代表，說明近期醫療器材管理重點及未來規劃。隨後大會表決通過蒙古及哈薩克成為 AHWP 第 25 及 26 個會員國，並計有 10 項以上文件通過採認，最後宣布 2016 年 AHWP 年會將於菲律賓舉行。

關鍵字（Keyword）：亞洲醫療器材法規調和會 (Asian Harmonization Working Party, AHWP) 、國際醫療器材官方論壇 (International Medical Device Regulators Forum, IMDRF)、醫材單一稽查計畫(Medical Device Single Audit Program, MDSAP)、體外診斷(IVD) 醫療器材

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一、目的：

AHWP（Asian Harmonization Working Party）係 1999 年由我國、新加坡、馬來西亞、南韓、中國大陸、香港、菲律賓、印尼、泰國及印度等 10 個亞洲經濟體之官方衛生單位成立，近年持續蓬勃發展，目前共有 26 個會員經濟體（Member Economy），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)、坦桑尼亞 (Tanzania)、泰國 (Thailand)、越南(Vietnam)、葉門(Yemen)、蒙古(Mongolia)、哈薩克 (Republic of Kazakhstan) 以及我國 (Chinese Taipei)等 26 個會員經濟體，會員體橫跨亞洲、南美洲、非洲。該組織致力於研究並推動醫療器材法規調和，除定期召開研討會，提供各國官方醫療器材法規機關及醫療器材業者一分享交流平台，同時積極與「國際醫療器材官方論壇 (International Medical Device Regulators Forum, IMDRF)」、亞太經合組織 (APEC)及世界衛生組織 (WHO)等國際組織合作，以建立全球醫療器材法規要求、程序與標準之調和。此次會議，本署除代表體外診斷醫療器材工作小組更新工作進展外，亦與 WHO 代表會面商討初步合作方向，即時掌握各先進國家與代表性國際組織最新管理重點及未來規劃，促進我國醫療器材法規與國際趨勢調和，提升我國國際影響力與國內醫療器材相關產業競爭力。

二、過程：

(一)、會議日程總表：

日期	地點	時間	議題
11 月 2 日 (一)	曼谷	09:00~ 18:00	AHWP Playbook Workshops
11 月 3 日 (二)	曼谷	09:00~ 18:00	AHWP Playbook and other Workshops
11 月 4 日 (三)	曼谷	09:00~ 18:00	AHWP Workshop
11 月 5 日 (四)	曼谷	10:00~ 17:30	The 19th AHWP Technical Committee (TC) Meeting
11 月 6 日 (五)	曼谷	09:00~ 17:30	The 20th AHWP Annual Meeting

(二)、會議日程表：

Day-1： AHWP Playbook Workshop

08:30-09:00	Registration	
09:00 - 09:10	Welcome Address by TC Chair	Mr Ali M. Al-Dalaan Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
09:10 - 09:20	Opening Address of Capacity Building Project & Proposed Training Programs	Ms Tran Quan Vice President, Regulatory Affairs and Quality Assurance, APAC and Greater China, GE Healthcare Pte Ltd, Singapore
09:20 - 09:50	Key Note Address	TBC
09:50 - 10:20	Academia's view point on Healthcare Regulations and its Impact on Business	Prof Jasmy Yanus Dean, Faculty of Biosciences and Medical Engineering, University of Technology of Malaysia, Malaysia
10:20 - 10:50	In an Emerging Economy, how can the 'CAB' play a balanced role and support prudent regulations for medical devices	Ms Catherine Derrien Director Quality Systems, APAC, Middle East & Africa, Boston Scientific, Singapore

10:50 - 11:10	TEA BREAK	
11:10 -11:50	Introduction & Objective of the Playbook Scope an Proposed Training Program	Ms Joanna Koh Consultant, Singapore
11:50 -12:40	Development of Legislative Controls	Mr Sanjay Kumar Senior Reg Specialist / Ag DD ofMDB, HSA, Singapore
12:40 -13:40	LUNCH	
13:40 -14:45	Implementation Steps - Phased in Approach Consider Possible Scenarios • Back log syndrome • Controls by other agencies eg customs • Loss of availability of current products	Ms Tan Ming Hao Manager, Regulatory Associates LLP, Singapore
14:45 -15:35	Manpower — What is needed to plan for manpower resources? What funding is required?	Mr Alfred Kwek Regional Director Government Affairs/HME Samsung Electronics Singapore, Singapore
15:35 - 16:00	TEA BREAK	
16:00 - 17:10	Panel - Hidden Challenges in Capacity Building Projects	**Ms Tran Quan** (moderator) Vice President, Regulatory Affairs and Quality Assurance, APAC and Greater China, GE Healthcare Pte Ltd, Singapore **Ibu Ade Indrajit,** Director, Medical Device, MOH, Indonesia **Prof. JASMY, Dean**, Faculty of Biosciences and Medical Engineering, University of Technology of Malaysia **LYE YAN LEV,** Business Development Manager, Cambridge Consultants, Singapore

Day-2: AHWP Playbook and Other Workshops

09:00-09:10	Opening & Recap	Ms. Joanna Kob Consultant, Singapore
09:10 - 09:50	Post Market Considerations to Put in Place - WHY the POST before the PRE	Ms. Chadporn TANAKASEMSUB, Area Head of Regulatory Affairs,

		Asia & Russia, Atcon Laboratories, Inc., Thailand
09:50 - 10:30	Premarket - the WHY of Essential Principles & Prudent Review Policies	Mr Vincent Lam Certification Manager, TU'V SUD Malaysia
10:30 – 11:00	TEA BREAK	
11:00-12:00	Panel - Legislation & A Business Case - A Symbiotic Relationship -What role can industry play in development of legislation ，What and how should the roles be balanced	**Ms Petra Kaars-Wiele** (Moderator) Senior Director International Regulatory, Quality & Labeling, Abbott GmbH & Co KG Germany **Ms Tan Hwee Ee**, Director & Principal Consultant, DH RcgSys Pte Lid Singapore **Mr Scott Sardeson,** RAC-EU/US International Regulator)'Affaire and Quality Compliance Leader, 3M Health Care Business, USA | **Mr Zamane Abd** Rahman, Chief Executive, Medical Device Authority, MOH Malaysia **Mr Alfred Kwek,** Regional Director, Goverment Affairs/HME, 1 Samsung Electronics, Singapore
12:00-13:00	LUNCH	
13:**0**0-13:20	Setting up a globally harmonized UDI system and *its* benefits	Ms Geraldlne Lissalde Bonnet Manager Public Policy, GS1AISBL Belgium
13:20- 14:20	Post Market - Safety Surveillance for Medical Devices	**Mr Eric Woo** Regional Director. ECRJ Institute (Asia Pacific)

14:20-15:20	Panel Preview and Assessment of Post Market Cases		**Mr Scott Sardeson** (Moderator) RAC-EU/US, International Regulatory Affairs and Quality Compliance Leader, 3M Health Care Business, USA **Mr Arthur Brandwood** (Co-Moderator) CEO, Brandwood Biomedical Australia **Ms SasikaU Devi Taangavclu,** Director of Policy, Code and Standard Division, MDA Malaysia **Mr Saujjv Kuraar. Senior Reg** Specialist/Ag DD ofMDB, HSA **Mr Eric Woo,** Regional Director, ECRi Institute (Asia Pacific) **Ms Msvisnne Vap;** Area Regulatory Affairs Manager, Surgical & Vision Care, Asia & Russia, Alcon, Singapore **Mr Hans-Heiner Junker** Manager Certification CRT2, Product Service GmbH, Division, TOV SUD, Germany
15:20-15:55	Clinical Studies for CE Marking of IVD Medical Devices	**Tcro Laolajainen** Head of Clinical Operations, Roche, Diagnostics, Germany	WG6 Training on Quality System Audit Mr Albert Li Manager，Manager,

15:55-16:30	Panel - Clinical Evaluation for General MI) / Good Clinical Practice	**Ms Sumati Randeo** (Moderator) Director Global Strategy, Regulatory Affairs & Advocacy, Abbott Quality and Regulatory, Abbott Laboratories, India **Mr Tcro Laulajainen** Head of Clinical Operations, Roche Diagnostics, Germany **Ms.Yuwadee PATANAWONG** Director of Medical Device Control, Thailand FDA **Mr. Greg Lclanc** Manager, Regulatory Affairs and Quality Systems, Cook (Canada) Inc. **Mr. Aseem Sahu** Deputy Drugs Controller Drugs Standard Control Organization, DGHS, MOH &FW, FDA **Ms. Mie Obama** Clinical Quality Manager APAC Mcdtroiiic Corporate Clinical Quality & Compliance Sydney, Australia	Principal Administration , Center of Measurement Standards, Office of Medical Device Evaluation, ITRI, Chinese Taipei Mr. Vincent Lam Certification Manager, TOV SUD Malaysia
16:30-18:00	ASEAN MDD – Panel Discussion -US Aid Program	**Mr Matthew. Hein** International Trade Specialist, US Department of Commerce, USA **Mr Michael Flood** Consultant, Locus Consulting, AU	

Day-3: AHWP Workshop (Continue)

09:10- 10:00	IMDRF Work Item for Single Audit Program - MDSAP	**Mr. Kondou-Hideyuk**i, IMDRF Representative & Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division, MHLW, Japan

10:00- 11:30	Regulatory Updates from Other Non-member Economy: -EU -Japan -US -Republic of Kazakhstan	**Mr Hans-Heiner Junker** Manager Certification CRT2, Product Service GmbH, Division, TUV SUD, Germany **Mr Kondou-Ilideyuki** IMDRF Representative & Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division, MHLW, Japan **Mr. Scott Sardeson** International Regulatory Atfeirs and Quality Compliance Leader, 3M Health Care Business, USA **Gulmira Mukhamedzhanov** Deputy Director, National Center of Expertize of Drugs and Medical Devices, Ministry of Health and Social, Development. Republic of Kazakhstan
11:30-12:00	Patient Registries	**Mr Michael C. Morton,** Global Medical Technology Alliance (GMTA) Represeniative, Vice President, Corporate Regulatory Affairs, Medtronic, USA
12:00-13:00	LUNCH	

13:00-14:00	A Moment to Pause, A Moment to Regain Our Sanity	Dr Wolff Von Auer Managing Director, Counsellor, Counselling & Hypnotherapy Hub, Singapore
14:00-18:00	Capacity Building Project (Closed Meeting)	Ms Tran Quan (Moderator) Vice President, Regulatory Affairs and Quality Assurance, APAC and Greater China, GE Healthcare
14:00-17:00	WG7 Training on Quality Management System	**Ms. Aldshwaty M.OIayfaal** Principal Assistant Director, Medical Device Authority, Ministry of Health, Malaysia **Mr Ee Bio Licw** Owner and consultant, Access-2-Hcalthcare, Singapore
14:00-18:00	AHWP-DI1TA Joint Session on Software as a Medical Device (SaMD)	
14:00-14:05	Welcome and Introduction	DrSethuraman Rama Deputy Director, MDB, HSA
14:05-14:30	Basic elements on Software as a Medical Device (SaMD) and qualification Relation between health software and Medical software	Mr Frans Jacobs DITTA Member & Sr. Manager Global Regulations & Standards Philips
14:30-15:00	IMDRF SaMD WG Activities	Mr Kondou-Hideyuki, IMDRF Representative & Deputy director, Medical Device and Regenerative Medicine Product Evaluation Division, Ministry of Health, Labour and Welfare (MHLW) Japan
15:00-15:30	International overview on risk classification of SaMD Introduction of IEC 62304 and IEC 82304-1	Mr Frans Jacobs DITTA Member & Sr. Manager Global

		Regulations & Standards Philips
15:30-15:50	TEA BREAK	
15:50-16:20	An overview of software development models - Basics How to manage changes for SaMD in the development lifecycle?	Mr Tony Yip AHWP WG3 Co-chair & Manager, Quality Assurance/ Regulatory Affairs, Far East Region, Elckta Limited, Hong Kong SAR
16:20-16:50	Software Risk Management - Effective measures for safety Software Verification and Validation	TBC
16:50-17:20	Regulatory overview of SaMD including related post-market aspects	Mr. Seil Park Assistant Director, Division of High-Tech Medical Devices, MFDS, Republic of Korea
17:20-17:55	Speakers panel discussion including Q&A	Moderated by **Mr Tony Yip** Manager, Quality Assurance/ Regulatory Affiars, Far East Region. Elekta Limited, Hong Kong SAR **Mr Frans Jacobs** DITTA Member & Sr. Manager Global Regulations & Standards Philips **Mr Sell Park,** Assistant Director, Division of High-Tech Medical Devices, MFDS, Republic of Korea
17:55-18:00	Closing words	Dr. Stfauraman Rama, Deputy Director, MDB, HAS

Day-4: 19th AHWP Technical Committee (TC) Meeting

08:00-09:45	AHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting)	TC & WG Leaders & TC Advisors
10:00 - 10:10	Welcome Speech	Ms.Yuwadee Patanawong Director of Medical Device Control, Thailand FDA

10:10-11:10	Opening of Meeting Adoption of Agenda Roll Call Highlight of TC	**Mr.Ali AI Dalaan** Chair, AHWP TC, Executive Director, Medical Devices Sector, Saudi FDA
11:10-12:00	Work Group Updates: WG1 - Pre-market: General MD WG2 - Pre-market: IVDD	**Mr Essam Mohammed AI Mohandi**s Executive Director, Surveillance and Biometrics, Saudi FDA **Ms Ming Hao TAN** Manager, Regulatory Associates LLP, Singapore **Mr Wen-wei TSAI** Technical Specialist Division of Medical Devices and Cosmetics, TFDA, Department of Health, Chinese Taipei **Mr Albert POON** Consultant, Freelance Hospital and Medical Device Consultancy, Hong Kong SAR
1200-1300	Lunch	
13:00-16:30	Work Group Updates (Continued): WG3 - Pre-market: Software as a Medical Device WG4 - Post-Market WG5 - Clinical Performance & Safety WG6-QMS: Audit & Assessment WG7 - QMS: Operation & Implementation WG8 - Standards STG-(U&N) -UDI & Nomenclature	**Dr SETHUR-AMAN Rama** Deputy Director, MDB, HSA. **Mr Tony YIP** Manager, Quality Assurance/ Regulatory Affairs, Far East Region, Elekta Limited, Hong Kong SAR **Ms Jennifer MAK** Senior Electronics

	Work Group Updates (Continued): WG3 - Pre-market: Software as a Medical Device WG4 - Post-Market WG5 - Clinical Performance & Safety WG6-QMS: Audit & Assessment WG7 - QMS: Operation & Implementation WG8 - Standards STG-(U&N) -UDI & Nomenclature	Engineer, Medical Device Control Office Department of Health, Hong Kong SAR **Ms Kitty MAO** RA Director, ASEAN & APAC RA Operation, GE Healthcare **Ms Yuwadee PATANAWONG** Director of Medical Device Control, Thailand FDA **Ms Sumati Randeo** Director Global Strategy, Regulatory Affairs & Advocacy, Abbott Quality and Regulatory, Abbott Laboratories, India **Mr Abdullah AL RASHEED** Compliance & Enforcrmmt Exec. Director, Saudi FDA **Ms Shirley SUM** Senior Director, Johnsons & Johnsons Regulatory Compliance (Asia Pacific), Johnson &Johnson **Ms Aidahwaty M.OIaybal** Principal Assistant Director, Medical Device Authority, MOH Malaysia **Mr Ee Bin Liew** Owner and Consultant, Access-2-Healthcarc, Singapore **Ms Maria Cecilia MATIENZO**

		Division Chief, Medical Non-radiation Device Regulation Division, Bureau of Health Devices & Technology. Philippines **Mr Tony LOW** BS-P Medical South East Asia, TUV Rhincland, Malaysia **Mr YANG Lian Chun** Director of Registration 11 Division, China FDA **Ms Carol YAN** Senior Director, Johnson & Johnson, China
16:30- 16:50	Speech by TC Advisors Representative	**Mr Scott Sardeson** International Regulatory Affairs and Quality Compliance Leader, 3M Health Care Business, USA
16:50 17:20	Highlight of AHWP Playbook Topics	**Ms Joanna KOH** Consultant, Singapore
17:20 17:30	Closing Remarks	**Dr Jcong-Rim LEE** Co-chair, AHWP TC Director, Cardiovascular Devices Division, MFDS, Republic of Korea

Day-5: 20th AHWP Annual Meeting

09:00 - 09:30	Opening Ceremony -Welcome Address Opening Speech - Group Photo	Dr. Boonchai Somboonsuk Secretary General, Thai-FDA Dr. Jeong Hee-kyo Chair, AHWP. Director General, Medical Device

		Evaluation Department, MFDS, Republic of Korea
09:30-13:00	Updates By: AHWP AHWPTC IMDRF APEC WHO ASEAN TEC PAHWP	**Ms. Tran Quan** vice-chair, AHWP Vice President, Regulatory Affairs and Quality Assurance, APAC and Greater China, GH Healthcare **Mr. Ali M. Al-Dalaan,** Chair, AHWPTC Executive Director, Medical Devices Sector. Saudi FDA **Mr. Kondou-Hideyukj** IMDRF Representative, Deputy Director, Medical Device and RegeneraUve Medicine Product Evaluation Division, MHLW, Japan **Dr.AriantiAnftya** APEC Representative, Director of Medical Device Production and Distribution Service, MOH, Indonesia **Ms. Irena Prat** Group Lead, Diagnostics Assessment, WHO **Mr. Zamane Abdul Rahman** ASEAN Representaiive, MDA, MOH Malaysia **Mr. Dennis Chew** Regional Director, A PRC, IEC, Singapore **Ms. Agnes Kijo**

		PAHWP Representative，Tanzania FDA
	Liaison Member Updates by: GS1: Lessons learned from UDI implementation and UDI development across the world DITTA	**Ms. Gerald]ae Lissaldc-Bonnet** Manager Public Policy, GS1 AISBL, Belgium **Mr. Susuma Uchiyaraa** DITTA representative, Chairman, International Coinmitlee, JIRA/TOSHIBA, Japan
13:00-14:00	Lunch	
14:00 - 16:30	Regulatory Updates from Member Economy: Thailand China India Korea Pakistan Tanzania	**Ms Yuwadee PATANAWONG** Director of Medical Device Control, Thailand FDA **Mr Gso Guobiao** Deputy Director General, Medical Device Registration Department, CFDA. People's Republic of China **Mr Aseem Sihe** Deputy Director , Central Drugs Standard Conlroi Organization, FDA Bhawan, India

	Regulatory Updates from Member Economy: Thailand China India Korea Pakistan Tanzania	**MrSeil Park** Assistant Director, Division of High-Tech Medical Devices, MFDS, Republic of Korea **Dr Noor Muhammad Shah** Director Medical Device Division, Drug Regulatory Authority of Pakistan **Ms.Agnes Sitfa Kijo** Manager, Medical Devices & Diagnostics Registration, FDA,Tanzania.
16:30-17:10	Resolutions: Application for Joining AHWP Member Economy WG1-Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device -White paper on Regulation of Combination Products - A Review of International Practice WG2 & WG1-Definition of the Terms Medical Device and In Vitro Diagnostic (IVD) Medical Device WG3-Guidance Document on Medical Device Software Qualification and Classification WG4- Adverse Event Reporting Guidance for Medical Device Manufacturer or its Authorized Representative WG5- Clinical Evaluation WG5-Clinical Evidence for Medical Device - Key definitions and Concepts WG5-Clinical Evidence for IVD Medical Device Key Defini lions and Concepts WG5-Clinical Evidence for IVD Medical Device - Scientific Validity Determination and Performance Evaluation WG6-Distributor Auditing Checklist WG6-Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies WG6-Regulatory Audit report Guidance Document STG-Guidance for Medical Device Naming Rule	**Dr. Hee-kyo Jeong** Chair, AHWP Director General, Medical Device Evaluation Department, MFDS, Republic of Korea **Mr Bryan So** (Moderator) Executive Deputy Secretary General, Principal Consultant. Hong Kong Productivity Council, Hong Kong SAR
17:10- 17:40	Report by Secretariat -Report by AHWP Secretariat from 2014 to 2015 -Report on Financial Statement for 2014/2015 -Proposal for Budget 2015/2016	Mr Bryan So Executive Deputy Secretary General, Principal Consuhanl, Hong Kcng Productivity Council, Hong Kong SAR

17:40-17:50	Announcement of 21th AHWP Annual Meeting Host	Dr Hee-kyo Jeong Chair, AHWP Director General. Medical Device Evaluation Department. MFDS, Korea
17:50-18:00	Closing Remarks	Dr Hee-kyo Jeong Director General. Medical Device Evaluation Department, MFDS, Korea
18:00-18:30	The 4th AHWP ASL Annual General Meeting (AGM)	(Open to AHWP Member Hconomy Only)

(三)、2015AHWP 系列會議內容摘要：

1. 本屆大會有別於以往，安排了為期 3 天的 Workshop。**11 月 2 至 3 日**課程內容係根據 2014 年 AHWP 技術委員會發布之 PLAYBOOK 內容沿伸之議題，主要由東南亞國家協會（The Association of Southeast Asian Nations, **ASEAN**）學、業界人士分享之專題演講與討論。

   其中對於 Mr. Eric Woo (Regional Director. ECRJ Institute (Asia Pacific) 講述醫療器材上市後安全監視議題(Post Market - Safety Surveillance for Medical Devices)，印象最為深刻。講者提到醫護人員在加護病房內執行之醫療行為(Action)，每日約計有 178 項，假設每日僅有１％的失誤發生，便足以讓每位病患遭受 2 項醫療疏失 (Medical Error)。講者建議衛生主管機關應與醫療照護者及製造業者，建立持續性溝通管道，以增進病患安全及不良事件通報 (Adverse Event Report) 機制；另對於創新醫療器材必須有適切的技術性評估程序 (Technology Assessment Program)。最後，講者以撥放 Josie King[註] 紀錄影片結尾，期望藉此早逝的生命故事，提醒大眾防範醫療疏失的重要性。

註：Josie King,一位年紀不足 2 歲的小女孩，在 2001 年由於美國霍普金斯醫院一連串的醫療疏失，於就醫不久後死亡，事後家人化悲憤為力量，成立基金會，致力推廣並維護病患安全。

圖 1:Josie King Case

2. 由於本屆 AHWP 系列會議有多位 AHWP TC 轄下體外診斷醫療器材工作小組((WG2 - Premarket: IVDD) 工作小組顧問 (Advisors)及成員(Members)參加，機會難得，本署代表特於 11 月 2 日舉辦第 2 次面對面工作會議 (FTF Meeting)，討論 IVD 醫療器材國際基準相關工作。會議地點由 AHWP TC 顧問 Dr. Petra KAARS-WIELE 及 WG2 組員 Ms. YoungSook Park 協助安排，假亞培公司(Abbott Laboratories Ltd.)曼谷總部會議室召開。本次會議參加者分別來自 7 個國家，共 8 位 (詳如表 1)。會中討論將於本屆 AHWP 大會採認之國際基準文件「Definition of medical device and IVD medical devices」，參考外界回饋意見，完成最後定稿。另由 Ms. Shelley TANG 說明各國體外診斷醫療器材相關管理法規現況之調查結果，並彙整製作「Survey of IVD medical device regulatory status」參考文件初稿。另就 WG2 預訂研擬「Common template for Submission dossier for IVD medical device」國際基準內容進行討論，惟礙於場地時間限制，將另擇期繼續未完成工作。

項次	姓名	身分介紹
1	蔡文偉技正	我國 TFDA:WG2 主席
2	Mr. Albert Ka-Fat POON	香港:WG2 副主席
3	Dr. Petra KAARS-WIELE	德國 Abbott 公司:AHWP TC 顧問
4	Ms. Shelley TANG	澳洲前 TGA 退休官員:WG2 顧問
5	Mr. Sanoj PRABHAKARAN	沙烏地阿拉伯聯合大公國 BD 公司:WG2 成員
6	Ms. Samara ZHU	中國 Alere 公司:WG2 成員
7	Mr. Christopher CHAN	我國工業技術研究院:WG2 成員
8	Ms. YoungSook Park	韓國 Abbott 公司:WG2 成員

表 1；AHWP-WG2 2ND FTF Meeting 與會人員

3. **11 月 4 日**大會安排歐盟、日本等非會員國的代表，簡介其醫療器材上市前審查相關法規更新，接續進行「醫療器材單一稽核計畫 (Medical Device Single Audit Program, MDSAP)」、Patient Registries 及 AHWP 與全球影像診斷、智慧醫療技術和放射治療貿易協會(Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association, DITTA)合辦之醫用軟體 Joint Session 等專題演講與討論。內容摘要如下：

1) **歐盟**代表德國 TUV SUD Mr. Hans-Heiner Junker (Manager Certification CRT2, Product Service GmbH, Division, TUV SUD, Germany)提到歐盟將有重大法規變革，原「90/385/EEC 主動植入式醫療器材指令」、「93/42/EEC 醫療器材指令」及「98/79/EC 體外診斷醫療器材指令」等 3 項現行指令將被「一般醫療器材法規 (Regulation on medical devices, MDR)」及「體外診斷醫療器材法規 (Regulation on in-vitro diagnostic medical devices(IVD), IVDR)取代，預估一般醫材及 IVD 醫材之新舊制過渡期分別為 3 年及 5 年。現有的認證機構(Notified Bodies)資格將無法延續至新制，須重新取得認證資格，且目前核發之 CE 證書(EC-certificates)亦將於新舊制過渡期之後自動失效。另歐盟規劃建置「醫療器材資料庫」

(EUDAMED)，其內容雖不及 US FDA 官網資料完整，但將考量開放不同層次之內容予各國主管機關及認證機構，以達資訊流通。

2) 日本代表厚生勞動省 Mr. Hideyuki Kondo (Deputy Director, MHLW, Japan)介紹近期日本醫療器材管理更新：包括 2015 年 2 月份在醫藥品醫療機器綜合機構 (PMDA) 舉辦第二屆對外國醫療器材法規人員法規訓練課程，包括上市前審查、QMS 、上市後監督 (Postmarket Surveillance, PMS) 及製造廠實地觀摩等；日本官方 (MHLW & PMDA) 於 2015 年 6 月 23 日宣布正式加入醫療器材單一稽核計畫 (Medical Device Single Audit Program, MDSAP)，繼澳洲 TGA、巴西 ANVISA、加拿大衛生部及美國 FDA 之後，正式成為第 5 名聯盟成員；另介紹日本藥物快速審查機制(Sakigake Strategy)，符合特定條件的藥物 (如治療重症疾病或全球首創新藥等)，即可採用此機制，增進審查時效，縮短上市時程。

厚生労働省

Press Release

平成 27 年 6 月 23 日
【照会先】
医薬食品局医療機器・再生医療等製品担当参事官室
参事官　機部　総一郎（内線 2911）
調整官　近藤　英幸　（内線 2787）
（代表電話）　03(5253)1111
（直通電話）　03(3595)2419

Medical Device Single Audit Program Pilot に正式参加します

～国際協力の下、医療機器の品質確保を推進～

医療機器の品質確保に関する国際協力活動として、2014年1月から米国、カナダ、オーストラリア及びブラジルにより「MDSAP（Medical Device Single Audit Program（医療機器単一調査プログラム））Pilot」が試行的に運用されています。本日、米国ワシントンDCで行われるMDSAPフォーラムの場で、日本も正式メンバーとして本プログラムに参加することを表明します。今後とも本活動の下で、より一層の医療機器の品質確保を徹底してまいります。

圖 2:日本正式加入 MDSAP 官方聲明

3) 日本 Mr. Hideyuki Kondo (Deputy Director, MHLW, Japan)講授醫療器材單一稽核計畫 (Medical Device Single Audit Program, **MDSAP**)專題演講：

- 2012 年 11 月份澳洲、巴西、加拿大及美國等 4 國醫療器材主管機關於巴西簽署合作宣言，成立醫療器材單一稽核計畫國際聯盟 (MDSAP Pilot International Consortium)，規劃 3 年試行期(2014-2016)，並於 2017 年正式實行。目前聯盟成員除前述創始國家外，2015 年加入新進會員日本。

- 該計畫期以單一稽核涵蓋包括 ISO 13485:2003、 巴西 GMP、日本 QMS 及美國(21 CFR Part 820)等醫療器材品質管理系統要求規定。目前只有加拿大衛生部 (CMDCAS)認可之稽核單位，方能執行 MDSAP 稽核工作，而醫療器材業者則係採自願性報名接受稽核。
- 另 IMDRF 管理委員會於 2015 年 9 月份批准 MDSAP 評鑑指引 (IMDRF/MDSAP WG/N8 FINAL:2015-Regulatory Authority Assessment Method Guidance)、MDSAP 稽核報告(IMDRF/MDSAP WG/N24 – MDSAP Audit Report Guidance)等兩份指引文件。

4) **AHWP 與 DITTA** 合辦的醫用軟體訓練及專題討論 (AHWP-DITTA Joint Session on SaMD)：議題包含醫用軟體的分類、標準、風險管理、生命週期及上市後管理等。

圖 3：現任 AHWP TC 主席 Mr. Ali AI Dalaan 致歡迎詞

4. **11 月 5 日**召開第 19 屆 AHWP Technical Committee (TC) Meeting，由現任 AHWP TC 主席沙烏地阿拉伯 Ali AI Dalaan (Executive Director, Medical Devices Sector, SFDA) 開幕致詞並報告技術委員會未來展望後，由 AHWP TC 轄下各工作小組(WG)依序報告工作進度與未來規劃。內容摘要如下：

1) WG1 (Pre-Market: General MD)報告現階段主要工作項目醫療器材共同提交技術文件範本 (Common Submission Dossier Template, CSDT) 基準文件及複合性產品比較研究 (White paper on summary of combination products guidelines in AHWP and IMDRF jurisdiction)等 2 份文件已完成定稿，將

提次日大會進行採認。未來將研擬醫療器材產品群組(Grouping)及與 STG 合作單一識別追溯系統(Unique Device Identification, UDI)等相關基準文件。

2) WG2 (Pre-market: IVDD)工作小組主席為本署蔡文偉技正，於會中說明體外診斷醫療器材相關國際基準文件 (Definition of the Terms Medical Device and In Vitro Diagnostic (IVD) Medical Device)定稿，將提次日大會進行採認。另提及 WG2 於 2015 年 8 月份在台北召開第 1 次面對面工作小組會議 (FTF Meeting)，計有 3 位 AHWP 顧問及 11 名組員與會。未來將持續研擬體外診斷醫療器材相關基準文件，如符合性評鑑 (Conformity assessment)、分級 (Classification)及產品標示(Labelling)等，並積極爭取代表 AHWP 參加國際組織活動 (如 ISO/TC 212 技術委員會)。
3) WG3 (Pre-market: Software as a Medical Device)報告現階段主要工作項目醫用軟體相關基準文件 (Guidance document on Medical Device Software – Qualification and Classification) 已完成定稿，將於次日大會進行採認。未來將研擬醫用軟體之風險分級 (Risk Classification)基準。
4) WG4 (Post-Market)於會中說明醫療器材不良事件通報基準 (Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative)定稿已完成，將提次日大會進行採認。未來規劃聚焦於特定醫療器材(如人工水晶體及人工關節)之不良事件通報。
5) WG5 (Clinical Performance & Safety)報告完成醫療器材/體外診斷醫療器材之臨床評估(Clinical evaluation)及臨床證據(Clinical evidence)等相關 4 項指引文件，將於次日大會進行採認。另將持續代表 AHWP 參與 ISO 14155 修訂相關活動，未來將進行全球臨床試驗法規更新及臨床試驗查核相關研究。
6) WG6 (Quality Management System: Audit & Assessment)說明完成醫療器材品質管理系統稽核相關 3 份基準定稿，含稽核策略 (Auditing Strategies)、稽核報告 (Audit Report)及經銷商稽核清單 (Distributor

Auditing Checklist)，將提次日大會進行採認。未來將參與 IMDRF MDSAP 基準文件審查並持續辦理醫療器材品質管理系統稽核訓練課程。

7) WG7 (Quality Management System: Operation & Implementation)報告完成 AHWP 各會員經濟體對於 AHWP WG7 基準文件採認狀況之調查研究及 2015 年 10 月份在馬來西亞吉隆坡舉辦教育訓練，並預告新版 ISO 13485 將對醫療器材進口商 (Importer)及經銷商 (Distributor)有所規範。未來將持續代表 AHWP 參與 ISO 13485 制定相關活動及提供訓練課程。
8) WG8 (Standards)說明該工作小組係於 2013 年新成立，目前刻正進行 AHWP 各會員國之醫療器材審查程序相關標準採認研究(Identify & list AHWP individual member economies Recognized Standards used for medical device regulatory purposes)。
9) STG (Special Task Group on UDI & Nomenclature) 說明完成醫療器材命名規則 (Guidance for Medical Device Naming Rule)，將於次日大會進行採認。由中國主導的醫療器材命名(Nomenclature)及醫療器材單一識別系統(UDI)已積極與 IMDRF 合作中，並於中國舉辦醫療器材監督管理國際論壇 (China International Medical Device Regulatory; CIMDR)，未來將持續掌握國際醫療器材命名規則及單一識別系統發展並參與法規調和工作。

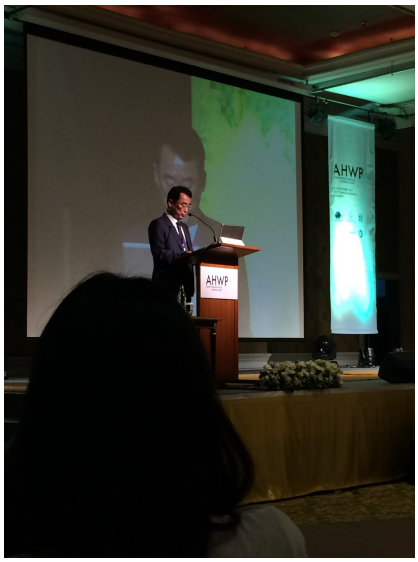


圖 4：現任 AHWP 主席 Dr. Hee-Kyo Jeong 開幕致詞

4.**11 月 6 日**召開第 20 屆 AHWP Annual Meeting，由現任 AHWP 主席韓國 Dr. Hee-Kyo Jeong (Director General, Medical Device Evaluation Department, MFDS)開幕致詞並報告大會未來展望後，接續由國際醫療器材規管理論壇(International Medical Device Regulation Forum, IMDRF)、東南亞國家協會(The Association of Southeast Asian Nations, ASEAN)及泛非洲醫療器材法規調和會 (Pan Africa Harmonization Working Party, PAHWP)等國際組織，以及中國大陸、韓國等會員國代表，簡介近期醫療器材管理重點及未來規劃。內容摘要如下：

(1) 國際醫療器材規管理論壇 (**IMDRF**)由日本 Mr. Hideyuki Kondo (Deputy Director, MHLW, Japan)代表報告：

- IMDRF 起源於 2011 年 10 月，係一國際醫療器材法規人員組成之自發性團體，延續全球醫療器材法規調和會 (Global Harmonization Task Force, GHTF) 建立之醫療器材法規調和工作基礎，以論壇方式建立平台，旨在加速國際間醫療器材法規調和。目前會員國包含澳洲、巴西、加拿大、中國大陸、歐盟、日本、俄羅斯及美國等 8 個國家，世界衛生組織 (WHO)及亞太經合組織轄下法規協和指導委員會(APEC,RHSC)列為官方觀察員，亞洲醫療器材法規調和會 (AHWP)及泛美衛生組織 (PAHO)則受邀為國際組織觀察員。
- IMDRF 在 2016 年至 2020 年間之首要任務，係強化上市後監督、增進上市前審查效能及持續與相關國際組織合作。另主管機關警訊報告交換系統 (National Competent Authority Report, NCAR) 預計在 2016 年 4 月份試行階段結束後正式實施 。
- 有關醫療器材送件格式 (Regulated Product Submission, RPS)，共同資料元素 (Common Data Elements)文件已完成外界意見蒐集，刻正研擬最終定稿。另醫療器材不良事件命名及編碼原則 (AE Terminology and Coding)文件，刻正進行研擬，並積極尋求與

ISO/TC 210 醫療器材品質管理技術委員會之合作。

(2) 東南亞國家協會 (**ASEAN,** 簡稱東協) 由印度 Mr. Aseem Sahu (Director General of Health Services, Ministry of Health & Family Welfare, India)代表報告：東協於 1967 年 8 月份在曼谷成立，創始會員國為印尼、馬來西亞、菲律賓、新加坡及泰國，其後加入汶萊、越南、寮國和緬甸，柬埔寨，組成東協 10 國持續至今。講者提及 2015 年 8 月份東協 10 國已完成醫療器材指令 (ASEAN Medical Device Directive，AMDD)簽署，該協會未來工作方向將著重於成立東協醫療器材委員會及協助各會員國 AMDD 之立法調和程序。

(3) 泛非洲醫療器材法規調和會 (**PAHWP**)由坦尚尼亞 Ms. Agnes Kijo (Tanzania, FDA)代表報告：講者介紹 2012 年 PAHWP 於開普敦正式成立，目前有 15 會員國。現任主席國為坦尚尼亞 (Tanzania)， 副主席為尼日利亞(Nigeria)，秘書處為南非 (South Africa)。該調和會目前首要任務係發展體外診斷醫療器材，以杜絕傳染疾病散播並拯救生命。未來工作重點在非洲地區上市前審查文件、製造廠品質系統稽核及臨床試驗等面向之法規調和。

(4) 接著由**中國大陸**國家食品藥品監督管理局 (China Food and Drug Administration, CFDA)的高國標副司長報告中國近期的醫療器材法規更新：

- 中國大陸於 2014 年 3 月份修訂“醫療器械監督管理條例”，並於同年 6 月 1 日生效；自 2014 年 2 月份實施創新醫療器材審查程序至今，審查 30 件醫療器材， 其中已有 8 件醫療器材核准上市，如 Proton Heavy Ion Treatment System, 2nd Generation PMGTM 等。
- 2015 年 5 月份公布醫療器材臨床評估規範，簡化部分第二、三等級醫療器材臨床試驗規定；醫療器材分類原則 (Medical Device Classification Rules)於 2015 年 7 月份正式公布；另大陸 UDI 系統正進行研擬，規劃以植入性醫療器材為優先實施品項.；醫療器材

命名原則 (Medical Device Naming Rules)目前刻正公開徵求外界意見。

(5) **韓國**食品藥品安全部(Assistant Director, Division of High-Tech Medical Devices, MFDS) 的 Mr. Seil Park 代表報告韓國近期醫療器材管理更新：醫療器材依其風險程度低至高，分為 Class I- IV 等 4 個等級，其中半數為第 II 等級醫療器材。MFDS 為強化高風險醫療器材審查能量，將部分低風險醫療器材(Class I & 部分 Class II)之上市前審查工作委由其附屬單位 MDITAC(Medical Device Information and Technology Assistance Center)審理，另醫療器材製造廠改採群組管理 (Company List)，同一製造廠之分公司無須再個別登記，前述新制皆於 2015 年 7 月份正式生效。醫療器材製造廠須於產品核准上市「前」符合製造廠品質系統(GMP)之相關規定，將於 2016 年 1 月份全面實施。

(6) 隨後由秘書處逐一宣讀預計於 AHWP 大會採認文件，並徵求最後意見。由於所有文件皆已事先經過 TC,WG 內部代表審核及對外公開徵求意見，故會員如未有其它意見，即完成採認程序。本屆年會成果豐碩，超過 10 份文件完成採認，涵蓋上市前審查、上市後通報、臨床評估、醫用軟體及醫療器材品質系統管理等領域，文件名稱詳列如下：(全文內容請參閱 AHWP 官方網頁 *http://www.ahwp.info/index.php?q=node/558*)

- Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device Product Submission.
- White Paper on Regulation of Combination Products – a Review of International Practice.
- Guidance document on Qualification of Medical Device Software.
- Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative 2 Resolution towards Endorsement WG documents.
- Clinical Evaluation.

- Clinical Evidence for Medical Device – Key Definitions and Concepts.
- Clinical Evidence for IVD Medical Device – Key Definitions and Concept.
- Clinical Evidence for IVD Medical Device – Scientific Validity Determination and Performance Evaluation.
- Distributor Auditing Checklist.
- Guidance on Regulatory Auditing of Quality Management System of Medical Device Distributions: Auditing Strategies.
- Regulatory Audit Report Guidance Document.
- Guidance for Medical Device Naming Rule.

(7) 大會尾聲，在秘書處進行事務性報告更新後，陸續掌聲表決通過蒙古(Mongolia)及哈薩克 (Republic of Kazakhstan)成為 AHWP 的第 25 及第 26 個會員國，最後主席宣布 2016 年 AHWP Annual Meeting 將在菲律賓舉辦，細節俟確認後將另行公布於 AHWP 官網，本會圓滿結束。

5. 由於世界衛生組織(World Health Organization, WHO)診斷器材預先認證小組(Prequalification Team) 刻正積極推動體外診斷醫療器材預先認證計畫(Prequalification Program for IVD)，本署代表特於 11 月 6 日利用會議空檔，與該小組領導(Lead) Irena Prat 女士安排會面，會中雙方同意先就 WHO 及 AHWP WG2 組織間活動資訊交流、專家/專業知識交流及共同研擬國際文件等，作為未來初步合作方向。

三、心得與建議事項：

1. 持續主動參加相關國際研討會，加速我國醫療器材管理與國際調和

本屆 AHWP 會議內容涵蓋「醫療器材單一稽核計畫(Medical Device Single Audit Program, MDSAP)」、「醫療器材軟體(Software as a Medical Device, SaMD)品質管理系統要求」等新興議題，以及歐盟、日本等先進國家醫療器材法規更新進展，加上各工作小組發表最新研究成果及指引文件，如經銷商之稽核策略(Strategy)及稽核清單(Check List)，議題多元豐富。建議持續主動參與相關國際研討會，借鏡國外醫療器材管理經驗，做為我國未來醫療器材法規修訂或政策推動之參考，加速我國醫療器材管理與國際調和。

2. 持續參與國際組織相關事務， 提升我國國際能見度與影響力

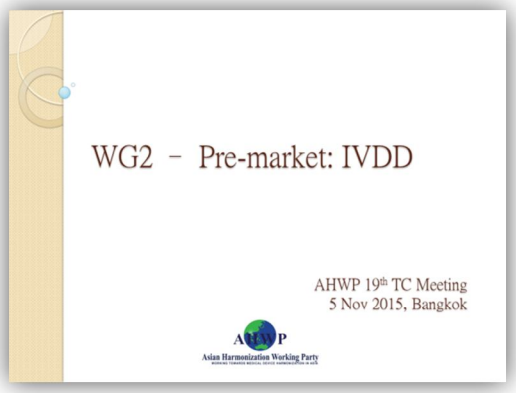
我國自亞洲醫療器材法規調和會 (Asian Harmonization Working Party, AHWP) 創始之初，便擔任許多重要職務。近年我國於醫療器材法規國際調和之努力與貢獻，已備受 AHWP 大會及各國的肯定，如 2012 年我國在台北成功主辦 AHWP 第 17 屆年會暨系列會議，迄今仍為人津津樂道。建議持續積極參與國際組織 (如 AHWP 及 IMDRF) 相關事務，以提升我國於國際組織之能見度及影響力，並增進外國與我國合作互惠之意願。

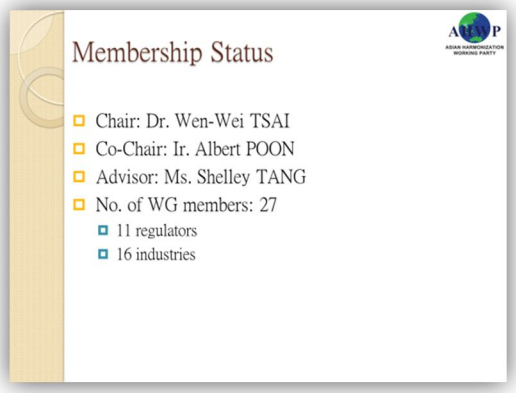
3. 持續舉辦國際法規研討會，提升我國產業競爭力

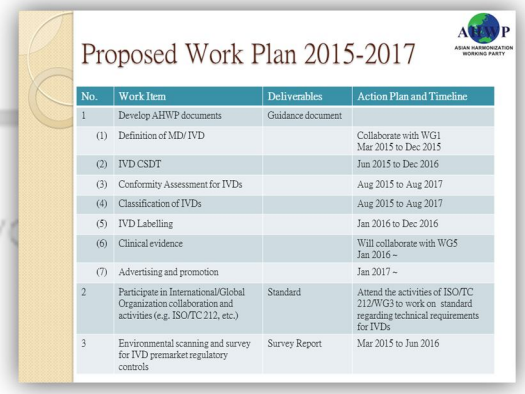
國際醫療器材相關法規研究，須投入大量資源，惟對於國內普遍中小規模之醫療器材產業而言，相對困難。建議持續舉辦國際型醫療器材法規研討會或訓練課程，邀請國際醫療器材官方代表及業界專家，來台說明各國醫療器材法規要求最新現況，藉提供面對面交流學習機會，有助於國產醫療器材業者即時了解國際法規趨勢，並從中發掘合作契機，提升我國產業競爭力。

四、附件：

1. AHWP WG2 簡報內容

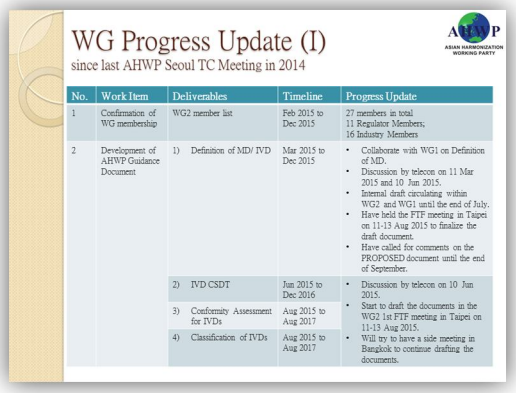






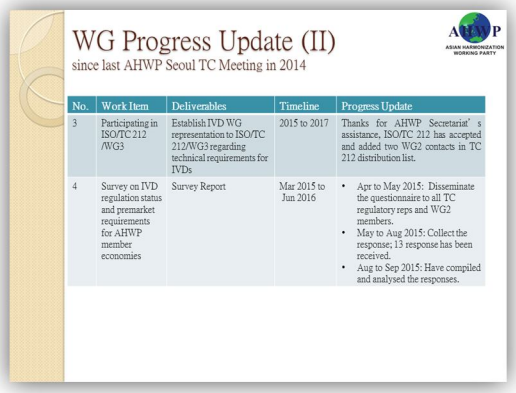
Proposed Work Plan 2015-2017

No.	Work Item	Deliverables	Action Plan and Timeline
1	Develop AHWP documents	Guidance document	
(1)	Definition of MD/ IVD		Collaborate with WG1 Mar 2015 to Dec 2015
(2)	IVD CSDT		Jun 2015 to Dec 2016
(3)	Conformity Assessment for IVDs		Aug 2015 to Aug 2017
(4)	Classification of IVDs		Aug 2015 to Aug 2017
(5)	IVD Labelling		Jan 2016 to Dec 2016
(6)	Clinical evidence		Will collaborate with WG5 Jan 2016 ~
(7)	Advertising and promotion		Jan 2017 ~
2	Participate in International/Global Organization collaboration and activities (e.g. ISO/TC 212, etc.)	Standard	Attend the activities of ISO/TC 212/WG3 to work on standard regarding technical requirements for IVDs
3	Environmental scanning and survey for IVD premarket regulatory controls	Survey Report	Mar 2015 to Jun 2016



WG Progress Update (I)
since last AHWP Seoul TC Meeting in 2014

No.	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	Feb 2015 to Dec 2015	27 members in total 11 Regulator Members; 16 Industry Members
2	Development of AHWP Guidance Document	1) Definition of MD/ IVD	Mar 2015 to Dec 2015	• Collaborate with WG1 on Definition of MD. • Discussion by telecon on 11 Mar 2015 and 10 Jun 2015. • Internal draft circulating within WG2 and WG1 until the end of July. • Have held the FTF meeting in Taipei on 11-13 Aug 2015 to finalize the draft document. • Have called for comments on the PROPOSED document until the end of September.
		2) IVD CSDT	Jun 2015 to Dec 2016	• Discussion by telecon on 10 Jun 2015. • Start to draft the documents in the WG2 1st FTF meeting in Taipei on 11-13 Aug 2015.
		3) Conformity Assessment for IVDs	Aug 2015 to Aug 2017	
		4) Classification of IVDs	Aug 2015 to Aug 2017	• Will try to have a side meeting in Bangkok to continue drafting the documents.



WG Progress Update (II)
since last AHWP Seoul TC Meeting in 2014

No.	Work Item	Deliverables	Timeline	Progress Update
3	Participating in ISO/TC 212 /WG3	Establish IVD WG representation to ISO/TC 212/WG3 regarding technical requirements for IVDs	2015 to 2017	Thanks for AHWP Secretariat' s assistance, ISO/TC 212 has accepted and added two WG2 contacts in TC 212 distribution list.
4	Survey on IVD regulation status and premarket requirements for AHWP member economies	Survey Report	Mar 2015 to Jun 2016	• Apr to May 2015: Disseminate the questionnaire to all TC regulatory reps and WG2 members. • May to Aug 2015: Collect the response; 13 response has been received. • Aug to Sep 2015: Have compiled and analysed the responses.

AHWP WG2 Working Meeting, 11-13 Aug 2015

- The meeting was held in Taipei and was attended by 3 AHWP advisors and 11 members
- Achievements:
  - Discussion on AHWP Proposed Documents
    - AHWP/WG2-WG1/P001:2015 – Definition of medical device and IVD medical devices
  - Discussion on the survey of IVD medical device regulatory status
    - The survey was circulated in the WG2 and forwarded to all TC regulatory representatives of 24 member economies, and had 13 respondents
  - Discussion on AHWP WG2 work items
    - Guidance document on Common template for Submission dossier for IVD medical device

AHWP/WG2-WG1/P001:2015 – Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'

- Scope of paper:
  - This document applies to all products that fall within the definition of medical device and In Vitro Diagnostic (IVD) Medical Device.
- Objective of paper:
  - To provide harmonized definitions of the terms 'medical device' and 'In Vitro Diagnostic (IVD) medical device'.
- Summary:
  - The present guidance serves as guidance for Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry on the definitions for the terms 'medical device', and an 'In Vitro Diagnostic medical device'.
  - The document contains the definition of the terms 'medical Device', 'In Vitro Diagnostic (IVD) medical device', 'accessory to a medical device' and 'accessory to an IVD medical device'.

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Survey on IVD Medical Device Regulations

- Conducted during May – June 2015
- Questions on
  - Set up of Regulatory Authority for IVD MD
  - Definition and Classification of IVD MD
  - Conformity Assessment requirements
  - Post-market surveillance requirements
- Subsequent report by Co-Chair Albert Poon

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Survey on IVD Medical Device Regulations

- Survey conducted during May – June 2015
- Sent to 24 member economies
- 13 respondents
- Questions on
  - Set up of Regulatory Authority
  - Definition of IVD medical device
  - Classification
  - Conformity Assessment requirements
  - Post-market surveillance requirements

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Survey on IVD Medical Device Regulations

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

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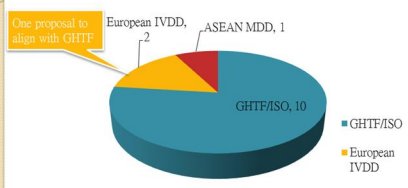
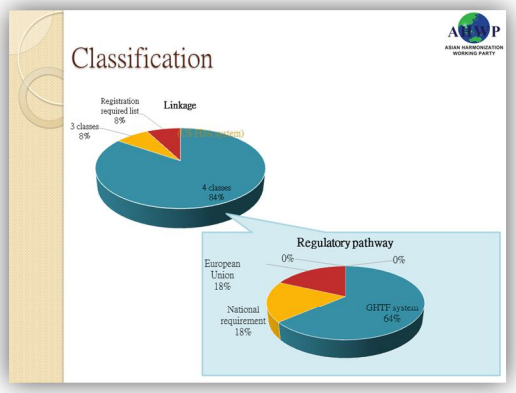
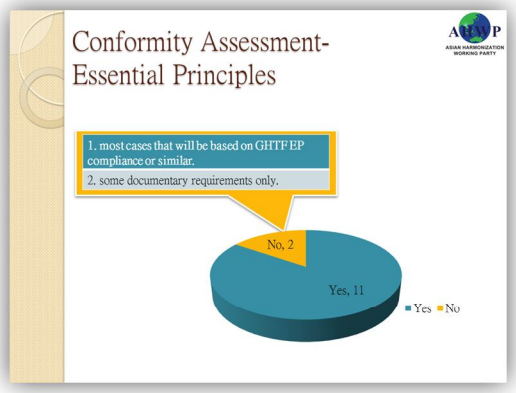
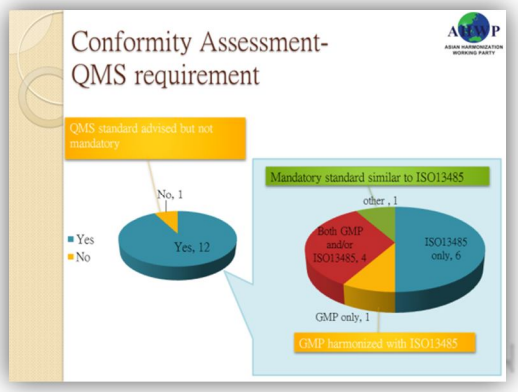
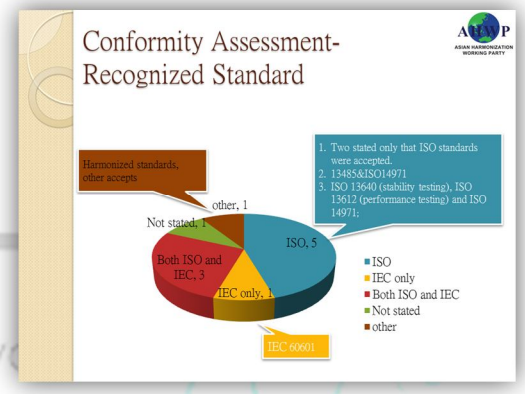
Definition of IVD

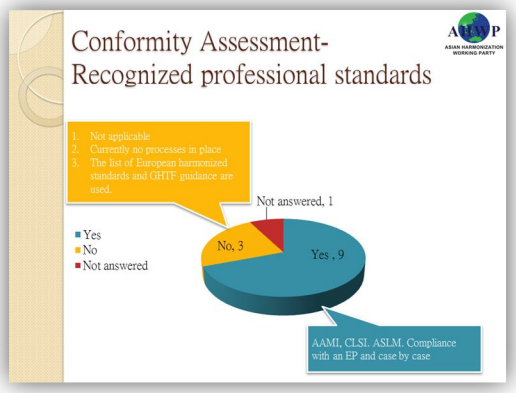


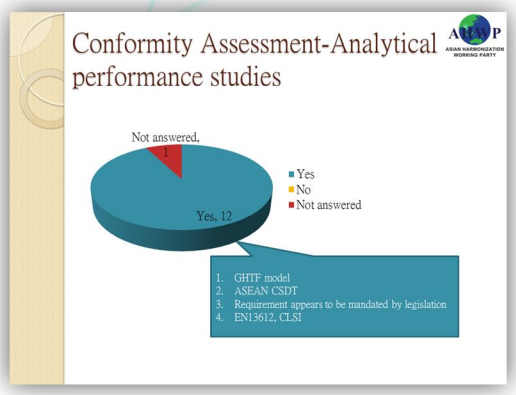

Classification
Registration required list 8%
Linkage
3 classes 8%
4 classes 84%
Regulatory pathway
European Union 18%
0%
0%
National requirement 18%
GHTF system 64%

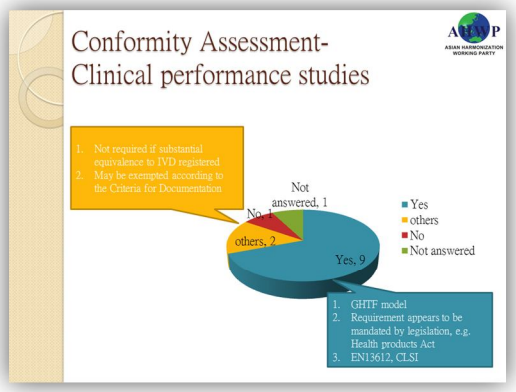

Conformity Assessment- Essential Principles
1. most cases that will be based on GHTF EP compliance or similar.
2. some documentary requirements only.
No, 2
Yes, 11
Yes
No

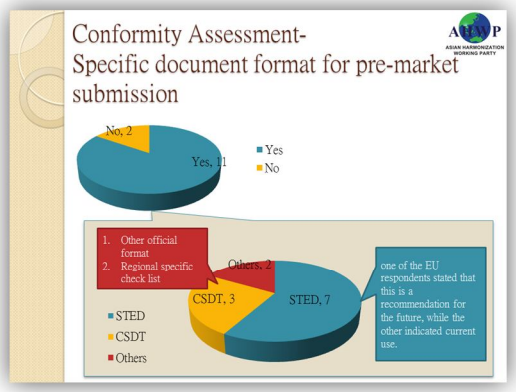

Conformity Assessment- QMS requirement
QMS standard advised but not mandatory
No, 1
Yes
No
Yes, 12
Mandatory standard similar to ISO13485
other , 1
Both GMP and/or ISO13485, 4
ISO13485 only, 6
GMP only, 1
GMP harmonized with ISO13485

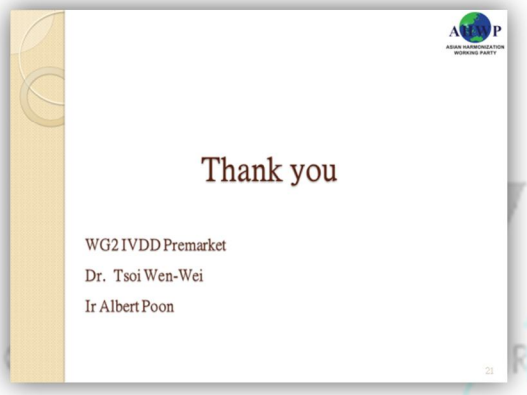

Conformity Assessment- Recognized Standard
Harmonized standards, other accepts
1. Two stated only that ISO standards were accepted.
2. 13485&ISO14971
3. ISO 13640 (stability testing), ISO 13612 (performance testing) and ISO 14971;
other, 1
Not stated, 1
ISO, 5
Both ISO and IEC, 3
IEC only, 1
IEC 60601
ISO
IEC only
Both ISO and IEC
Not stated
other


Conformity Assessment- Recognized professional standards
1. Not applicable
2. Currently no processes in place
3. The list of European harmonized standards and GHTF guidance are used.
Not answered, 1
Yes
No
Not answered
No, 3
Yes , 9
AAMI, CLSI. ASLM. Compliance with an EP and case by case


Conformity Assessment-Analytical performance studies
Not answered, 1
Yes
No
Not answered
Yes, 12
1. GHTF model
2. ASEAN CSDT
3. Requirement appears to be mandated by legislation
4. EN13612, CLSI







2. 20th AHWP 與會人員大合照