出國報告（出國類別：參加國際會議）

參加 2014 年亞洲醫療器材法規調和會系列會議

(AHC-AHWP Joint 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：杜培文組長、許蒨文研究員、吳正寧科長、蔡文偉技正
派赴國家：韓國
出國期間：103 年 11 月 17 日至 103 年 11 月 22 日
報告日期：104 年 2 月 5 日

摘要：

此次於韓國首爾舉辦的 2014 年亞洲醫療器材法規調和會(Asia Harmonization Working Party, AHWP)系列會議，包括 2 天的 AHC-AHWP Joint Workshop、第 18 屆 AHWP Technical Committee (TC) Meeting 及第 19 屆 AHWP Annual Meeting。由於本署醫療器材及化粧品組杜培文組長係為 AHWP 大會副主席，本次第 19 屆年度會議即將選舉新一任 2015-2017 年的大會主席、副主席，以及 TC、各工作小組(Work Group, WG)等之主席、副主席等職位。為爭取我國於國際會議之能見度，故由本署杜培文組長率同擔任 AHWP TC 轄下體外診斷醫療器材工作小組(WG1a-IVDD)主席之吳正寧科長等一行 4 人與會。

於 2014 AHC-AHWP Joint Workshop 中，除由包括日本、中國大陸、韓國、新加坡、美國、墨西哥、沙烏地阿拉伯等國的代表，簡介各國醫療器材上市前審查相關法規與要求外，並就目前醫療器材面臨的新興議題，包括醫材單一稽查計畫(Medical Device Single Audit Program, MDSAP)、醫材單一識別系統(Unique Device Identification, UDI)、醫療用軟體(Medical Software)及醫材翻新(Medical Device Refurbishment)等專題進行演講與討論。

第三天的第 18 屆 AHWP TC Meeting，由 AHWP TC 及各 WG 先進行閉門會議，接著由 TC 及各 WG 的主席，報告工作進度與進展。本署吳正寧科長代表 WG2(亦即為原先的 WG1a)進行報告，包括產出 3 份 IVD 產品管理相關的文件以及辦理 1 場 Training Workshop 等。

第四天的第 19 屆 AHWP Annual Meeting 進行新一任的領袖選舉，結果由韓國的 Jeong Hee-kyo (Director General, Department of Medical Device Evaluation)擔任 AHWP 大會主席，馬來西亞的 Zamane Bin Abdul Rahman (Chief Executive, Medical Device Authority, MOH)擔任官方代表副主席，由沙烏地阿拉伯 Ali Al Dalaan 擔任 TC 的主席，韓國的 Lee Jeong-Rim 擔任 TC 的官方代表副主席。

關鍵字(Keyword)：亞洲醫療器材法規調和會(Asian Harmonization Working Party, AHWP) 、(APEC Harmonization Center, AHC)、亞洲太平洋經濟合作會議(APEC)、醫材單一稽查計畫(Medical Device Single Audit Program, MDSAP)、醫材單一識別系統(Unique Device Identification, UDI)、醫療用軟體(Medical Software)、醫材維修(Medical Device Refurbishment)

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一、目的：

AHWP（Asian Harmonization Working Party）係 1999 年由我國、南韓、中國大陸、香港、新加坡、菲律賓、馬來西亞、印尼、泰國及印度 10 個亞洲經濟體之衛生單位成立，目前共有 23 個會員經濟體（Member Economy），包括 Abu Dhabi, Brunei Darussalam, Cambodia, Chile, Chinese Taipei, Hong Kong SAR/China, India, Indonesia, Jordan, Kingdom of Saudi Arabia, Laos PDR, Malaysia, Myanmar, Pakistan, People's Republic of China, Philippines, Republic of Korea, Singapore, South Africa, State of Kuwait, Thailand, Vietnam, Yemen，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之調和，並定期召開研討會，由各國官方醫療器材法規機關及醫療器材業者共同參與。AHWP 與「全球醫療器材法規調和會」（Global Harmonization Task Force, GHTF）、APEC 及 WHO 等組織合作，以期建立全球醫療器材法規要求、程序與標準之調和。此次於韓國首爾舉辦之會議，包括了 2 天的 2014 AHC-AHWP Joint Workshop、第 18 屆 AHWP TC Meeting 及第 19 屆 AHWP Annual Meeting。

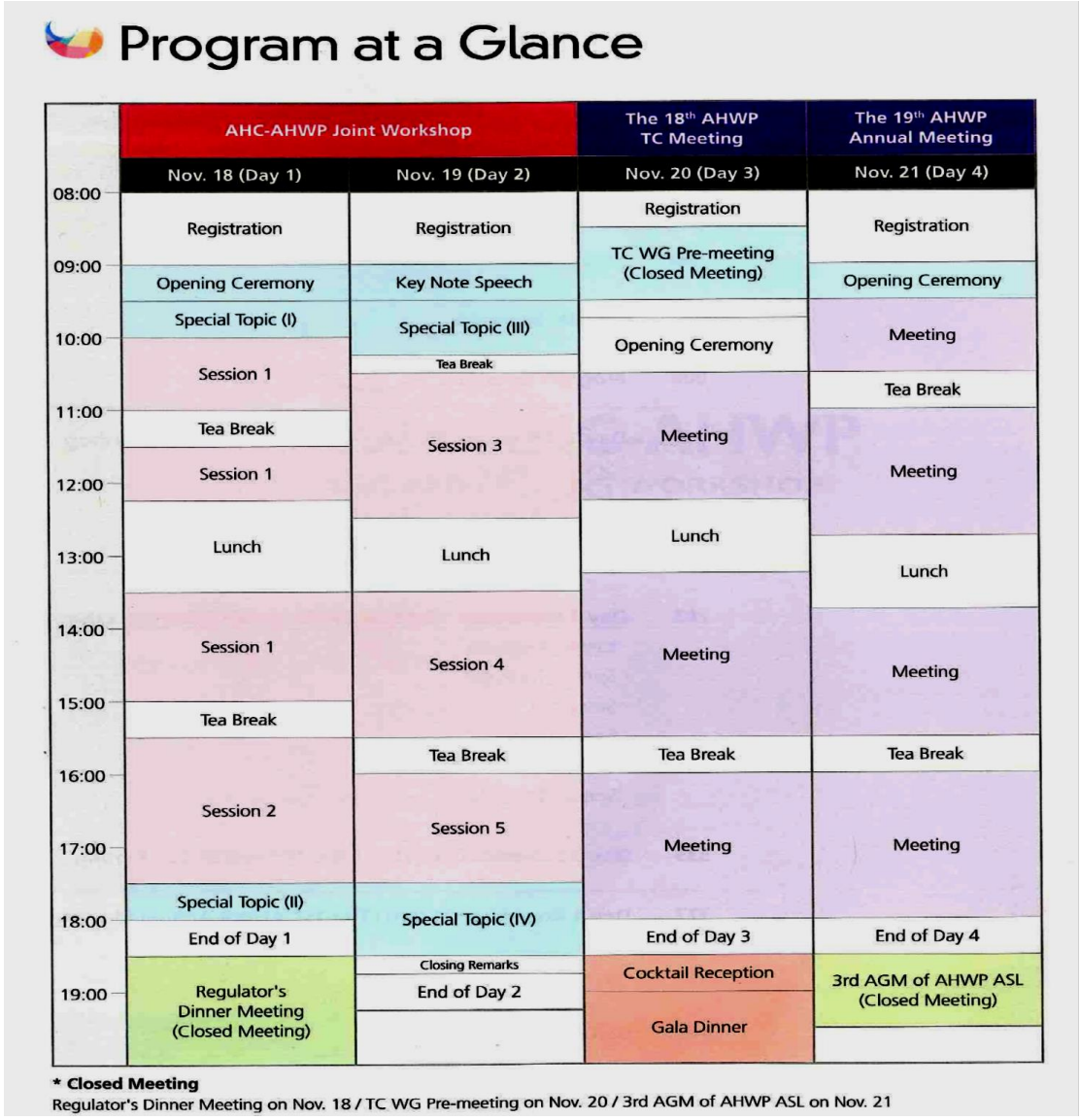
在此次 AHC-AHWP Joint Workshop 中，第一天先邀請日本、中國大陸、韓國、新加坡、美國、墨西哥、沙烏地阿拉伯等國的代表，介紹各國醫療器材上市前審查相關法規與要求，尤其是近期許多國家陸續修訂了醫療器材相關管理法規，也在此次會議一併說明。第二天則是針對多項醫療器材議題，包括醫材單一稽查計畫（Medical Device Single Audit Program, MDSAP）、醫材單一識別系統（Unique Device Identification, UDI）、醫療用軟體（Medical Software）及醫材翻新（Medical Device Refurbishment）等專題進行演講與討論。

第三天的第 18 屆 AHWP TC meeting 中，宣布了即將進行新一任領袖的選舉規則。並由 TC 顧問團(TC Advisors)代表，說明對於 AHWP 的觀察與建議。接著由 TC 各 WG 陸續報告其工作進展與未來目標。第四天緊接著召開 AHWP 第 19 屆年度會議，會中邀請 IMDRF 會員國日本 MHLW 官員 Hideyuki Kondo 報告 IMDRF 近期狀態；以及 APEC RHSC 代表 Lindsay Tao 報告 APEC 法規協調的現況。現任大會主席 Saleh S. AL-Tayyar 頒發給各會員國、各 WG 的主席、各 TC 顧問等各一本"Playbook for Implementation of a Medical Device Regulatory Framework"。此次會議亦表決接受 Tanzania 成為 AHWP 第 24 個會員國，接著的是進行新一任(2015-2017)領袖選舉。選後則由 TC 報告文件採認情形，以及預算

經費等事務性事宜。

二、過程：

(一)、會議日程總表：



Program at a Glance

	AHC-AHWP Joint Workshop		The 18th AHWP TC Meeting	The 19th AHWP Annual Meeting
	Nov. 18 (Day 1)	Nov. 19 (Day 2)	Nov. 20 (Day 3)	Nov. 21 (Day 4)
08:00	Registration	Registration	Registration	Registration
09:00	Opening Ceremony	Key Note Speech	TC WG Pre-meeting (Closed Meeting)	Opening Ceremony
10:00	Special Topic (I)	Special Topic (III)	Opening Ceremony	Meeting
	Session 1	Tea Break		Tea Break
11:00	Tea Break	Session 3	Meeting	Meeting
12:00	Session 1		Lunch	
13:00	Lunch	Lunch		Lunch
14:00	Session 1	Session 4	Meeting	Meeting
15:00	Tea Break			
16:00	Session 2	Tea Break	Tea Break	Tea Break
17:00		Session 5	Meeting	Meeting
18:00	Special Topic (II)	Special Topic (IV)	End of Day 3	End of Day 4
	End of Day 1	Closing Remarks	Cocktail Reception	3rd AGM of AHWP ASL (Closed Meeting)
19:00	Regulator's Dinner Meeting (Closed Meeting)	End of Day 2	Gala Dinner	

*** Closed Meeting**
Regulator's Dinner Meeting on Nov. 18 / TC WG Pre-meeting on Nov. 20 / 3rd AGM of AHWP ASL on Nov. 21

第一天(11/18)會議議程表：		
2014-11-18 (Day 1) AHC-AHWP Joint Workshop		**Speaker/Moderator**
08:00 - 09:00	registration	
09:00 – 09:30	Opening ceremony	
	Welcome speech	Jang Byung-Won
	Opening speech	Saleh S. Al-Tayyar
	Opening speech	Jin-Ho Wang
	Group photo & short break	
09:30 – 10:00	The AHWP Playbook – Now what? Thoughts on implementation	Michael Gropp
Session 1	Regulatory Status of Premarket Submission and Approval Requirements in AHWP and APEC Region	
	Session Chair: Jennifer Mak (Regulator), Sumati Randeo (Industry)	
10:00 – 15:00	Premarket Submission and Approval Requirements in AHWP & APEC Member Economies	
	i) Japan (PMDA)	Madoka Murakami
	ii) China (CFDA)	大陸國家藥品食品監督總局高國標
	iii) Korea (MFDS)	Jeong Rim Lee
	iv) The ASEAN Picture of Harmonized Controls for Medical Devices (HSA)	Joanna Koh
	v) USA (Industry)	Donna-Bea Tillman
	vi) Mexico (COFEPRIS)	Gretel Rueda Almanza
	vii) Saudi Arabia (SFDA)	Ali M. Al-Dalaan
	Overall Q&A of Session 1	
Session 2	Experiences of Industry on Premarket Submission and Approval Requirements	
	Session Chairs: Yuwadee Patanawong (Regulator), Eun-Hee Cho (Industry)	
15:30 – 17:30	Premarket Registration Requirements in Multiple Markets across Korea, USA, Japan, EU, AHWP Members	Kyungyoon Kang
	Analyzing Approval Process of Substantial Equivalence Devices based on Previously Approved Devices across Korea, USA, Japan, EU, AHWP Members	
	Specific Topic on Clinical Data Requirements (Comparison by Nations)	Michael C. Morton
	Performance Evaluation of In Vitro Diagnostics in EU, America, China	Hubert Bayer
	Overall Q&A of Session 2	
17:30 – 18:00	Strategy for Commercialization in Korea	Tran Quan (Moderator) Myung-Soon Chung
18:30~	Regulators' meeting (closed meeting)	

第二天(11/19)會議議程表：		
2014-11-19 (Day 2) AHC-AHWP Joint Workshop		**Speaker/Moderator**
09:00 – 09:45	Keynote speech	Sherry Keramidas
09:45 – 10:15	Regulatory Intelligence	Petra Kaars-Wiele
Session 3	Special Topics on Medical Devices (I)	
	Session Chairs: Emily Wu (Regulator), Lindsay Tao (Industry)	
10:30 – 12:30	Medical Devices Single Audit Program (MDSAP)	Scott Sardeson
	Blending UDI with Good Distribution Practice for Medical Devices	Philippe Auchair
	Global Standards for a Safer and More Efficient Medical Devices Supply Chain	Geraldine Lissalde Bonnet
Session 4	Special Topics on Medical devices (II)	
	Session Chairs: Abdullah Al Rasheed (Regulator), Tony Low (Industry)	
13:30 – 15:55	Medical Software 1 – Medical Software Guidance and Recent Update in USA	Donna-Bea Tillman
	Medical Software 2 – Medical Software and Recent Update in Japan	Naoki Morooka
	Medical Software 3 – Standalone Medical Software and Mobile Applications – Present and Future	
	Overall Q&A on Session 4	
Session 5	Special Topics on Medical Devices (III)	
	Session Chairs: Lupi Trilaksono (Regulator), Alfred Kwek (Industry)	
15:10 – 17:40	Medical Device Refurbishment – Safeguards for Safety, Performance and Quality	Jeroen Gruben
	Refurbished Medical Devices: What is the Risk-Benefit	Wu Liqing
	The EU Medical Device Regulations	Rainer Voelkson
	Overall Q&A on Session 5	
	What's new on MD horizon: Can surgery be better?	Seungwan Sohn
17:40 – 18:00	Closing Remarks	

第三天(11/20)會議議程表：		
2014-11-20 The 18th AHWP Technical Committee Meeting		**Speaker/Moderator**
08:30 - 09:30	TC WG Pre-meeting	
09:30 – 09:50	Opening ceremony	
	Welcome speech	Kim Young-Gyuen
	Opening speech	Saleh S. Al-Tayyar
09:50 – 10:15	Roll Call	Bryan So
	Adoption of Agenda	Joanna Koh
	Announcement of the Election Arrangement of Office Bearers of AHWP TC & AHWP Working Groups	Bryan So
10:15 – 10:45	Tea break & Distribution of Election Form	
10:45 – 11:45	Report and Overview of AHWP TC of the Past Term	
	i) Key Milestones	Joanna Koh
	ii) SWOT Analysis – New Streamline Proposal of the TC Structure	Alfred Kwek
11:45 – 12:15	Short speech by TC Advisors Representative	TC Advisor Representative
13: 30 – 14:15	Short speech by TC Advisors Representative	Joanna Koh Tan Ming Hao
14: 15 – 17:50	WG Updates	
	Session Chair: Chadporn Tanakasemsub	
	Update by WG1: Pre-Market – General MD	Alfred Kwek
	Update by WG2: Pre-Market – IVDD	Emily Wu
	Update by WG4: Post-Market	Jennifer Mak
	Update by WG5: Clinical Performance & Safety	Yuwadee Patanawong
	Update by WG6: Quality Management System – Audit & Assessment	Abdullah Al Rasheed
	Update by WG7: Quality Management System – Operation & Implementation	Ali M. Al-Dalaan
	Update by WG8: Standards	Lupi Trilaksono
	Update by WG9: Training	Jack Wong
	Update by STG – Medical Device UDI & Nomenclature	Carol Yan
17:50 – 18:00	Closing Remarks by AHWP TC Chair	Joanna Koh

第四天(11/21)會議議程表：		
2014-11-21 The 19th AHWP Annual Meeting		**Speaker/Moderator**
08:30 – 09:10	Opening Ceremony	
	Welcome speech	Chung Seung
	Opening speech	Saleh S. Al-Tayyar
	Souvenirs to Host, Honorable Guests and Sponsors	
09:10 – 11:30	Keynote Speech	
	IMDRF Status updates	Hideyuki Kondo
	APEC Status Updates	APEC Representative
11:30 – 12:30	Adoption of Agenda	Saleh S. Al-Tayyar
	Roll Call (Only Official Members)	
	Confirmation on Minutes of the 18th AHWP Meeting held in Malaysia in 2013	Lindsay Tao
	AHWP Status Updates	
	Announcement of Election Arrangement for Office Bearers of AHWP	Bryan So
12:30 – 13:30	Lunch & Distribution of Election Forms	
13:30 – 17:40	Country Updates	AHWP ME Representatives
	Report Highlights – by AHWP TC	Joanna Koh Ali M. Al-Dalaan
	Report by Secretariat	Ali M. Al-Dalaan Bryan So
	Resolution toward Endorsement	Ali M. Al-Dalaan Bryan So
	Election of AHWP Leadership 2015 ~ 2017	Bryan So
17:40 – 17:50	Speech by Newly Elected Chair of AHWP	
17:50 – 18:00	Closing Remarks by Outgoing Chair of AHWP	Saleh S. Al-Tayyar

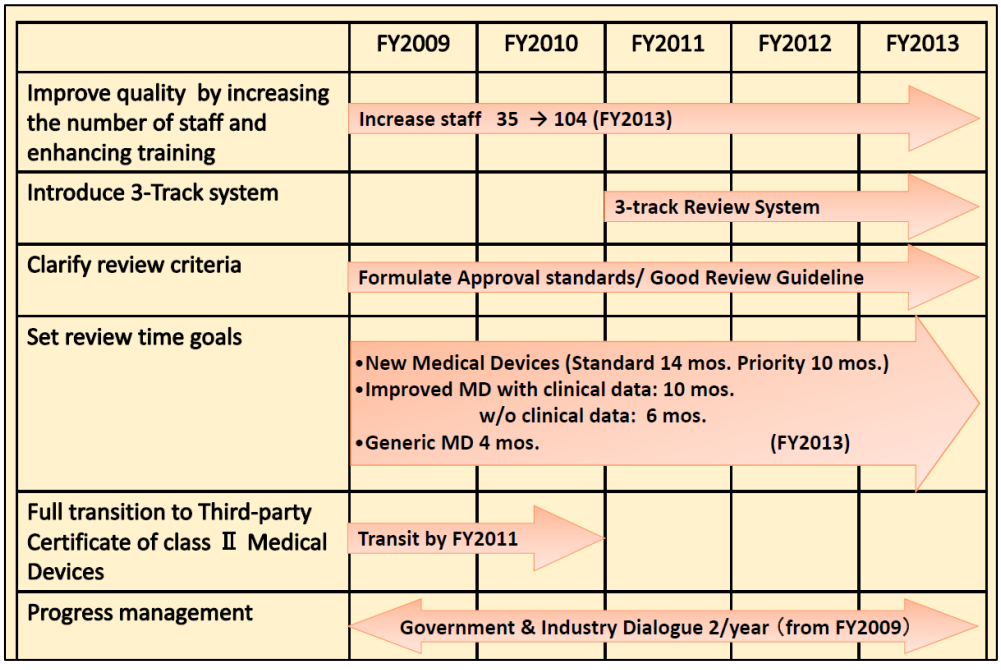
(二)、11 月 18-19 日是由 APEC AHC 與 AHWP 合辦的醫療器材訓練課程：

Day-1

1. 首先由美國的 Michael Gropp 介紹有關 AHWP Playbook，為了讓 AHWP 會員國，得以執行 AHWP 所制定的 Guidance，並建構醫療器材管理架構。AHWP 依據原 GHTF 制定之草案，修訂成為" Playbook for Implementation of a Medical Device Regulatory Framework"，以供會員國遵循。
2. 接著由日本、中國大陸、韓國、新加坡、美國、墨西哥、沙烏地阿拉伯等國的代表，簡介各國醫療器材上市前審查相關法規與要求外。摘要如下：

(1) 由日本行政法人醫藥品醫療機器總合機構(Pharmaceutical and Medical Devices Agency, PMDA)的 Madoka Murakami 介紹日本醫療器材上市前審查需求：

日本是依據風險將醫療器材分為四級管理。2008 年日本提出一行動計畫(如下圖)，以加速醫療器材上市審查。



2014 年審查人員已增加至 104 人，審查時間改善了 44.8-75%，諮詢服務案件增加至 169 件。並設定 2018 年達成下列審查時效目標：

New MD：

Standard items： 12 months (原來是 14 months)

Priority items： 9 months (原來是 10 months)

Improved MD：

With clinical data： 9 months (原來是 10 months)

Without clinical data： 7 months (原來是 6 months)

Generic MD：

New application： 5 months

Partial change application： 4 months

(2) 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：

2014 年 3 月 31 日中國大陸新修訂了"醫療器械監督管理條例"，並於同年 6 月 1 日生效。基於風險管控原則，將醫療器械分為三個等級加以管理。

A. Pre-marketing：

Class I MD(第一類醫療器械)： filing (備案)

Class II and III(第二類及第三類醫療器械)： registration(註冊)

B. Post-marketing：

Class I MD(第一類醫療器械) ：製造廠 filing (備案)

Class II (第二類醫療器械)： 製造廠 certification，經銷商 filing

Class III (第三類醫療器械)： 製造廠 certification，經銷商 certification

新法規加重了醫療器材製造廠、經銷商、使用單位的責任，並重新定義醫療器材、鼓勵創新研發及強化臨床試驗管理。

CFDA 並已陸續公布了 5 個相關子法規，並自 2014 年 10 月 1 日起實施。接著即將發布 GCP(Good Clinical Practice for Medical Device Products)及 GSP(Good Supply Practice For Medical Device Products)等規範。

(3) 由韓國食品藥品安全部(Ministry of Food And Drug Safety, MFDS)的 Jeong-Rim Lee 報告其醫療器材管理：

韓國依據風險將醫療器材分為四個等級，管理涉及 MFDS 的 9 個部門及 8 個區域辦公室。

Class IV MD 自 2014 年 1 月 1 日起，送審文件須符合 STED。Quality Management System 是依據 ISO13485，且分為四種查核：

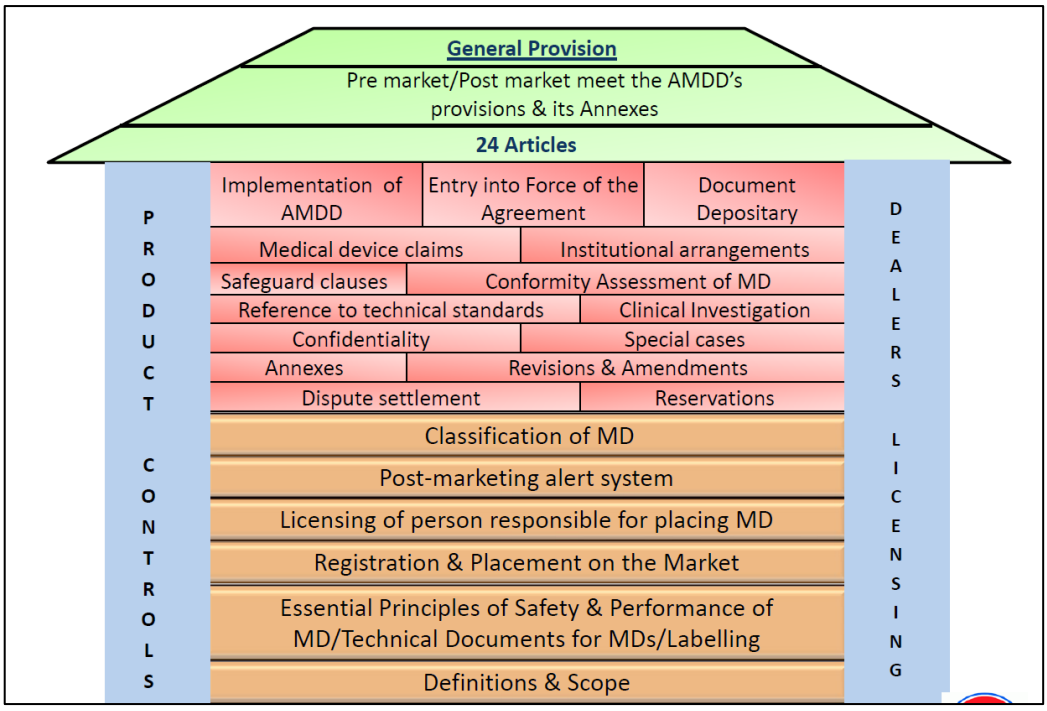
A. Initial Inspection： for the 1st manufactured MD
B. Additional Inspection： to add new product group
C. Modified Inspection： for change manufacturing site
D. Periodic Inspection： for re-certification within 3-year period

近期的法規更新包括：

A. 原先以藥品管理的體外診斷醫療器材(IVDD)，自 2014 年 11 月 10 日起以醫療器材管理。
B. 原料如汞、石棉和塑化劑(DEHP、DBP、BBP)等的限量，將列入 IV administration set 的審查項目。
C. IEC 60601-1(3rd ed.)已經納入審查程序，但實施日期依 MD 等級略有不同。

(4) 由新加坡衛生科學局(Health Sciences Authority, HAS)的 Joanna Koh 報告東南亞國協(Association of Southeast Asian Nations, ASEAN)醫療器材管理協合情況：

ASEAN 架構下 MDPWG (Medical Devices Product Working Group)所制定的 ASEAN Medical Devices Directive (AMDD)，已於 2014 年 8 月經東協部長會議(ASEAN E Economic Minister Meeting, AEM)簽署，並將於 2015 年 1 月起生效。



對於業界而言，AMDD 有對於 MD 的定義相同、相同的分類分級、技術標準協和、相同的送審文件及上市後通報文件之優點。

(5) 美國的部分則是由 Biological Consulting Group 的資深顧問 Donna-Bea Tillman 來講解 FDA 分類分級、510K 及 PMA 等之規定及審查流程。

(6) 由墨西哥衛生部(Ministry of Health, MOH)聯邦預防衛生風險委員會(COFEPRIS)的醫材審查員 Gretel Rueda 說明墨西哥的醫材管理：

由於墨西哥與美國、加拿大及日本簽署有 Equivalence Agreement，故對於此三國已審查通過的醫療器材有簡化措施。但因美國醫療器材分三級，加拿大分為四級，所以加拿大的 Class I 不包含在此協議中。

對美國的簡化措施如下：

FDA Class I ： CFG + EIR + FDA Approval

FDA Class II and III ： CFG + EIR + FDA Approval (ER&L, 510(K), PMA) + Techno-Vigilance Report

對加拿大的簡化措施如下：

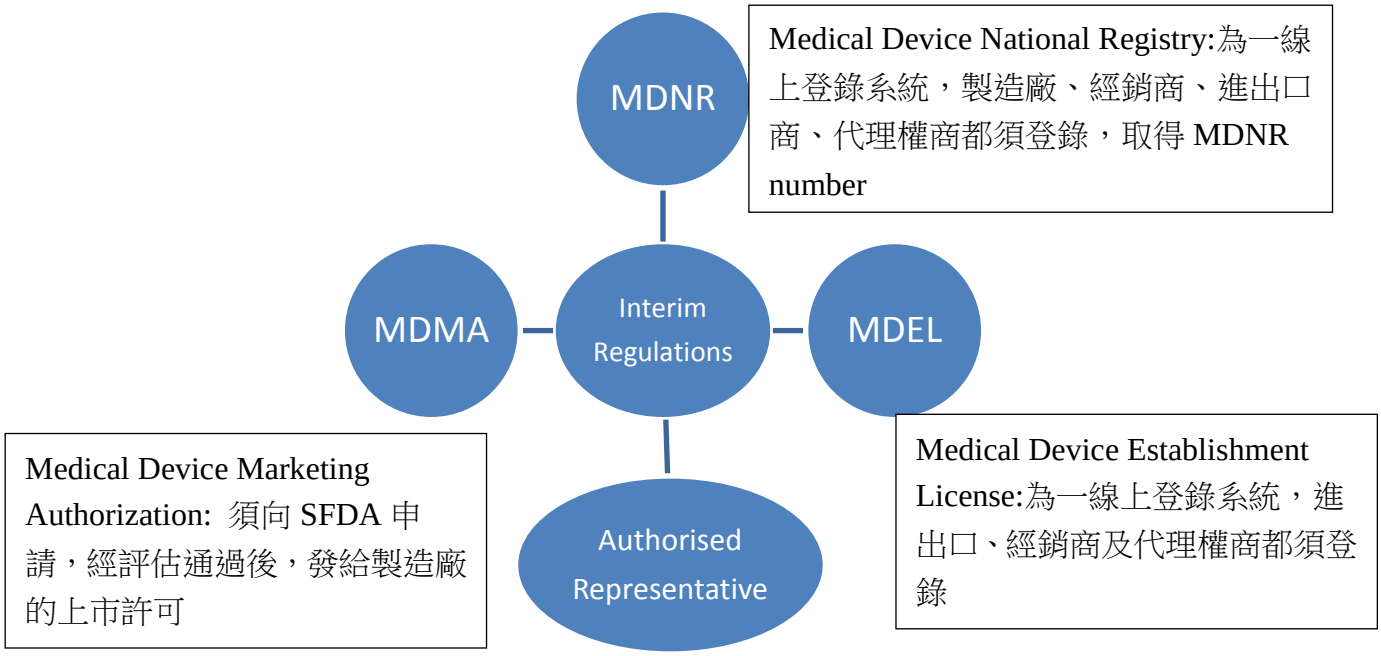
Health Canada Class II、III、IV： MD License + ISO 13485：2003 Certificate + ISO17021 + Authorization (Authorized Third)

對日本的簡化措施如下：

Letter of Approval issued by the MHLW + Export Notification + CFS + Letter of Representation

(7) 由沙烏地阿拉伯 SFDA 的 Ali AI Dalaan 報告沙烏地阿拉伯的醫療器材管理：

要在沙烏地阿拉伯販售醫療器材需具備下列要求：



(8) 接著由幾位產業界代表分享在不同國家申請醫療器材上市的分析比較：

韓國及日本上市前審查程序及要求比較如下：

Comparison of Korea & Japan Regulatory Requirements

MD Classification		Regulatory Path		Review Party			Requirement	
Korea	Japan	Korea	Japan	Korea		Japan	Korea	Japan
Class I	General MD	Notification	Self-Certification	MFDS: 0 Months		PMDA: 0 Months	Device Description, Non-Approval Process	
Class II	Controlled MD	Technical Document Review	Nin-Sho Certification: Products Compliant with Certification Standards	SE/Modified Devices: MFDS Authorized 3rd Party Institute: 25 Days	Approval-MFDS Regional Office: 10 Days	Recognized Certification Body: 3-6 Months	−Recognized SE Device: Test Report for Safety & Performance −SE/Modified Device: Test Report for Safety & Performance, Comparison Data	Recognized Certification Body Assesses Conformity to the Certification Standards and QMS. The Certification Standards Comprise the Nomenclature

								and HS as Technical Standards.
Class III Class IV	Specifically Controlled MD	Technical Document Review STED Format	Shonin Approval From MHLW	−New: MFDS Medical Device Evaluation Dept: 55 Days −Medical Device Evaluation Dept: 70 Days −Clinical Study Plan Approval: 30 Days	Approval-MFDS Headquarter Office: 10 Days	PMDA: 8-16 months	New Device: Aforementioned Data+ Additional Safety, Performance Data, Origin, Development Process, Clinical Data, Oversea Usage Status	Submit Application Documents to Prove that Device Safety and Effectiveness have been Demonstrated per Article 40, Paragraph 1 of PAL. Enforcement Regulations

在臨床試驗方面，依據目前管理趨勢為：鼓勵創新、聰明管理及相互接受臨床試驗數據。美國 FDA 與日本 PMDA 正進行一項 Pilot Program，朝向一個臨床試驗即可符合此兩個法規單位的要求，並研擬心血管醫療器材全球臨床試驗之標準。羅氏公司則報告各國對於體外診斷試劑之臨床評估要求。

(9) 最後介紹 Commercialization in Korea (Pricing, Distributorships and Compliance)

3. 另外，本署吳正寧科長以 AHWP TC WG2 主席身分，受倫敦衛生與熱帶醫學院(London School of Hygiene and Tropical Medicine; LSHTM)邀請參加 Ad Hoc Meeting of the 'Affordable Access, In-Vitro Diagnostics (AAIVD) Project'，於會中說明 WG2 工作進度及討論未來工作內容。AAIVD 計畫主要係為促進非洲等發展中國家可取得具品質之體外診斷醫材，以降低傳染性疾病擴散的情況為目標。本次會議參加人員包括 LSHTM 的 Prof. Rosanna Peeling 與 Mr. Albert Poon、本署吳正寧科長與蔡文偉技正及 Ms. Sheryl Hsiao、Mr. Benny Ons (TC 顧問)、Mr. Jack Wong (AHWP Training WG 的副主席)，以及新加入 AHWP 的 Tanzania FDA 代表 Mr. Sillo, Hiiti (Director General)及 Ms. Agnes Sita Kijo (Medical devices assessment and enforcement manager)。會中 Prof. Peeling 亦代表泛非洲醫療器材法規調和會(Pan Africa Harmonization Working Party; PAHWP)報告 AAIVD 計畫的執行現況及工作進度。本次會議除討論 WG2 所

研擬之文件內容外，Prof. Peeling 亦提出建立體外診斷醫材管理相關之遠距教育平台構想，以提供 PAHWP 等發展中國家快速取得相關法規標準等資訊，提升其對體外診斷醫材之管理能量。因由比爾蓋茲基金會(Gates Foundation)及加拿大衛生部(Health Canada)支持倫敦大學的 AAIVD 計畫已結束(2012-2014 年)，Prof. Peeling 正積尋求其他基金支援。

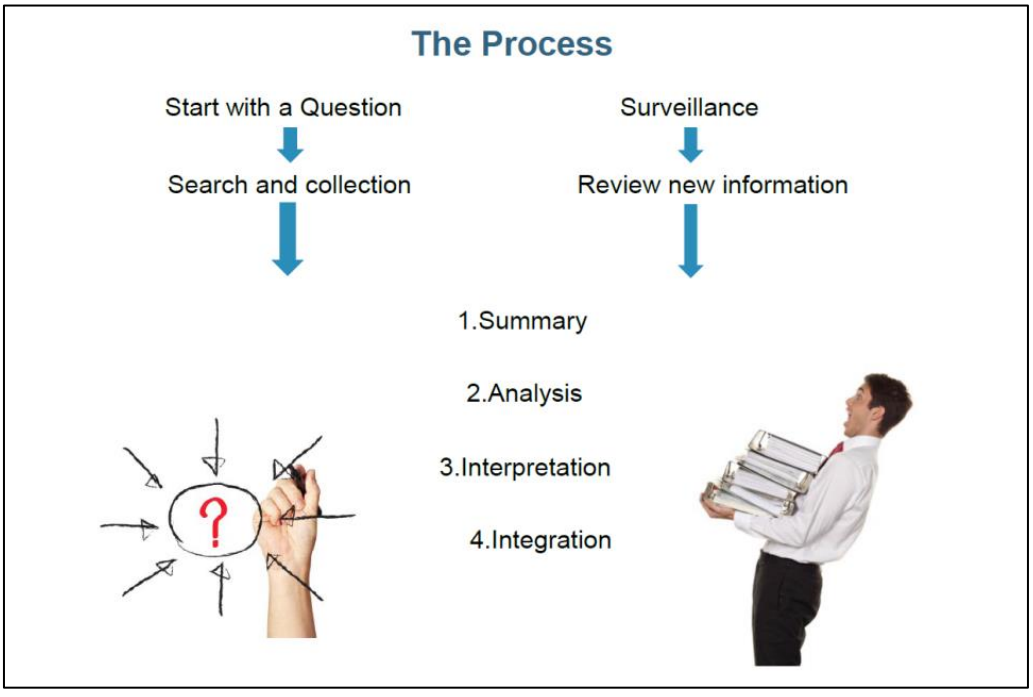
Day-2

1. 首先由美國醫療法規學會(Regulatory Affairs Professionals Society, RAPS)的 Dr. Sherry Keramidas 報告對於各國醫療器材管理部門的調查分析：

   Dr. Sherry 認為好的管理專業應具備對科學、技術的理解，有能力與整個產品生命週期中所涉及的其他專家溝通，如科學、臨床操作、法規、政策或業務等專業人員，另有組織和溝通能力及具備分析與批判性思維能力。

2. Abbott 公司的 Dr. Petra Kaars-Wiele 講題為"Regulatory Intelligence"：

   她定義"Regulatory Intelligence"為：處理多個來源的訊息和數據，並加以分析數據及其相關的內容，產生出有意義的輸出，例如監管策略的風險和機會等。這個過程是由需求驅動的並與決定和行動連結。隨著管理環境的不斷變更，此活動不會停止。其程序略如下圖：

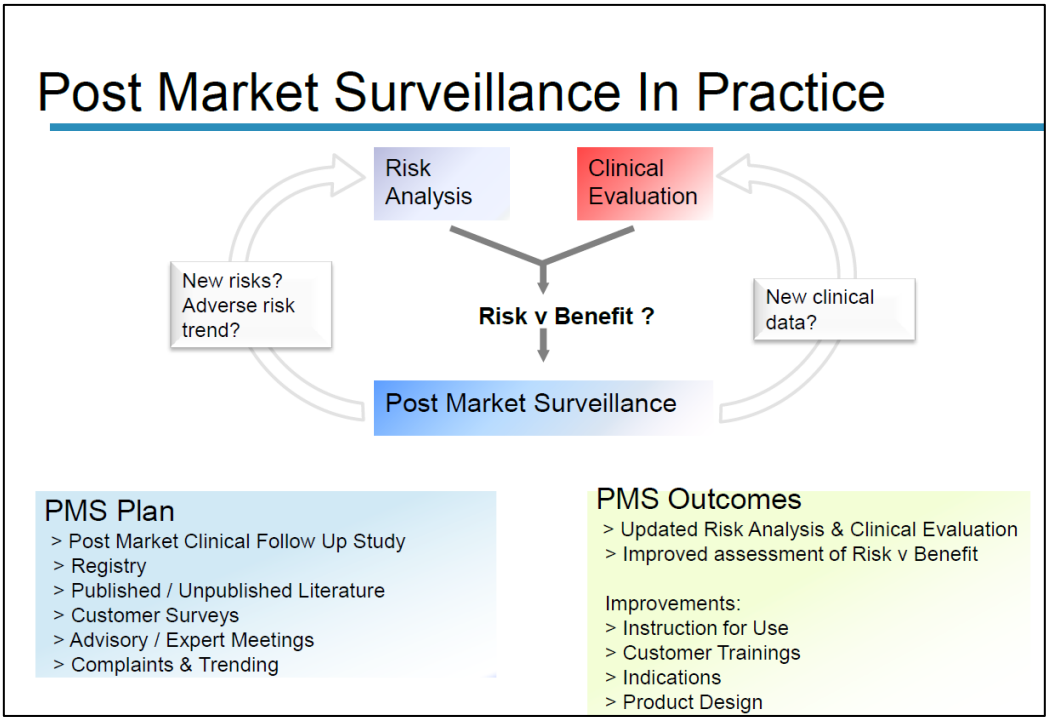


Dr. Petra 更提供了許多獲取有效醫療器材管理及科技資訊的方法與途徑。

3. 接著由 3M 公司的 Scott Sardeson 報告 MDSAP 的情形：

Medical Device Single Audit Program (MDSAP)是由澳洲、巴西、加拿大及美國於 2012 年 11 月簽署合作宣言，並自 2014 年 1 月開始的 pilot program。IMDRF 亦有 MDSAP WG，並已完成幾分相關的指引文件。包括對於 Auditing Organization (AO)認可程序等。目前能參加的 AO 僅限於有加入 Health Canada CMDCAS Program 的 AO，醫材製造廠則可主動提出申請加入。

4. Abbott 公司 Philippe Auclair 說明 UDI 使用在上市後監控：



使用 UDI 可以達到改善事件通報、提升不安全產品回收效率、促進主管機關對於醫材上市後的管理、降低不當使用醫療器材造成的醫療過失等目的，更可促進病患安全、改善上市後監控、促進全球貿易。為達成這些目標，全球管理單位應該合作，建立全球協和的 UDI System。

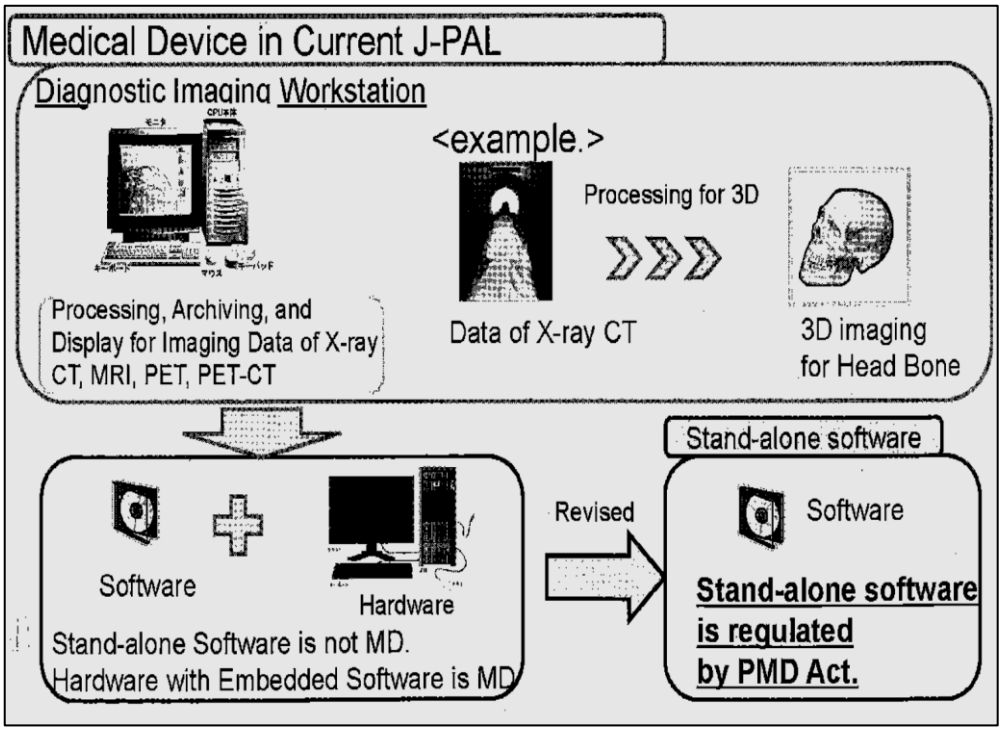
5. 接著是來自美國、日本及韓國的業界代表，說明 USFDA、日本及 AHWP 對於醫用轉體的管理，摘述如下：

(1). US FDA Regulation of Standalone Software： 2014 update：美國發布有相關指引包括： Mobile Medical App Guidance、Guidance on Software in

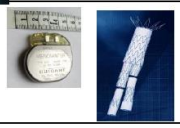
Premarket Submissions´Cybersecurity Guidance´Wireless Guidance.

目前 USFDA 對於 Mobile Medical Apps，只管理作為醫療器材附件的 App，以及改造行動介面成為醫療器材的 App。對於部分 Mobile Medical Apps 雖略符合醫療器材定義，但以"Enforcement Discretion"，暫時不予管理，2014 年 6 月 14 日 FDA 發布的指引，FDA 即運用" Enforcement Discretion"，對於 MDDS、Medical Image Storage Devicesedical Image Communication Devices 等將不以醫療器材管理。2014 年 10 月 12 日 FDA 發布的"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"，FDA 期望個製造廠於醫材研發階段時，將電腦防護納入，以維護醫材的功能性及安全。故在上市前審查時，即應提供相關文件。

(2). 日本於 2013 年 11 月 27 日修訂 Parmaceutical Affairs Law (PAL)為 PMD Act，並自 2014 年 11 月 25 日施行，2014 年 6 月 27 日發布"Medical Device Development Promotion Act"。新法中即將原先不管的 Stand-alone Diagnostic Software 納入醫療器材管理。如下圖所示：

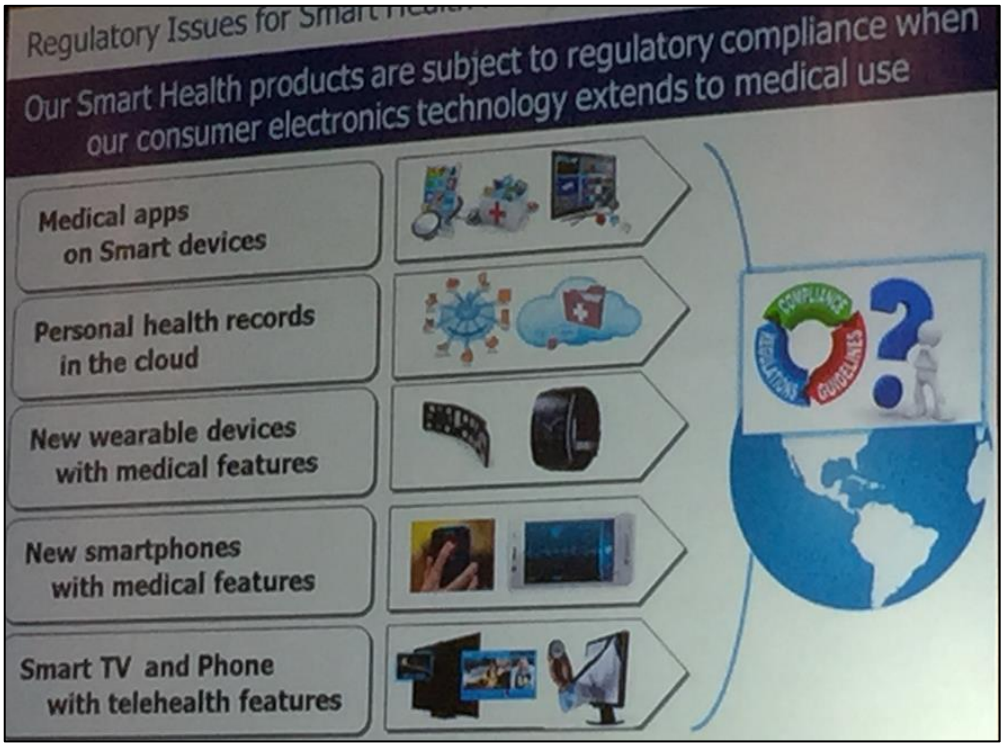


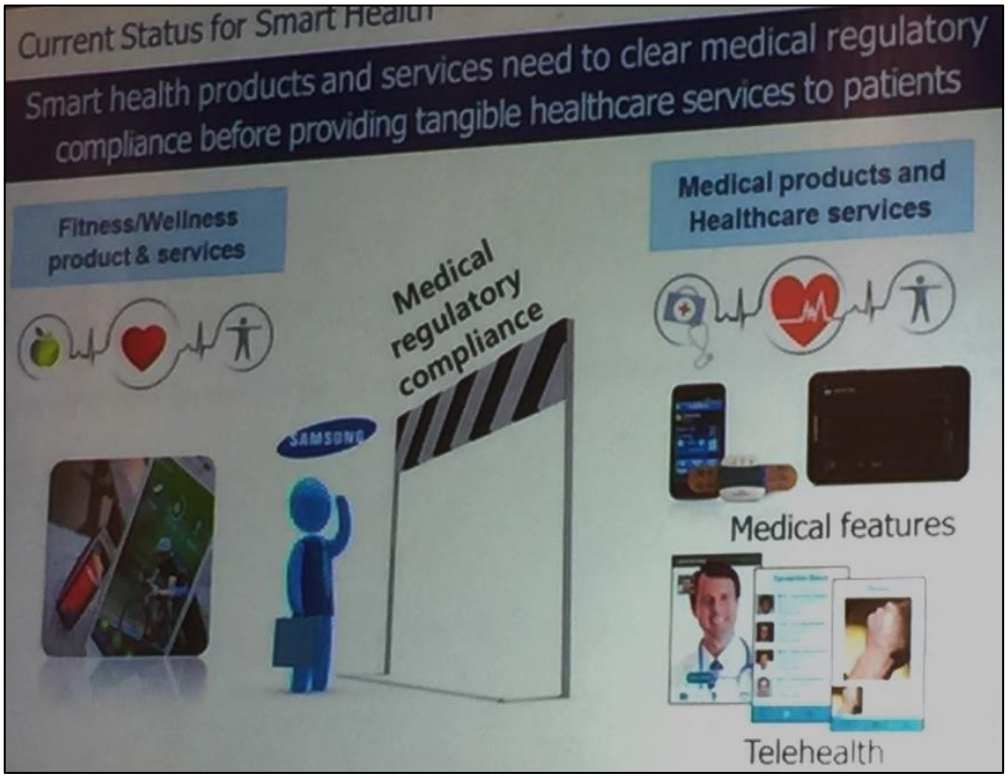
並且擴張運用 Third Parties 進行某些高風險醫材的登記。如下圖所示：

GHTF Classes	Risk-based Classification	Pre-market	
		Class	Approval /Certification
Class A	Extremely Low Risk (X-Ray films, Surgical Instruments) 	"General" **(Class I)**	**Self-declaration (notify to PMDA)**
Class B	Low Risk (MRI, digestive catheters Ultrasound Diagnostic Devices) 	"Controlled" **(class II)**	**Registered Certification Body Certification**
Class C	Medium Risk (artificial bones, dialyzer) 	"Specially Controlled" **(class III & IV)**	**MHLW's Approval**
Class D	High Risk (pacemaker, artificial heart valves) 		

Extended to Part of Class C

(3). 接著是由 Samsung Electronics 代表 Peter Rhee 講述 Smart Health：Peter 介紹了許多 Samsung 所生產的智慧醫療的產品包括行動電話、Apps、穿戴裝置等，如下圖所示項目，即有可能列為醫療器材管理，故以產業界的立場而言，國際應制定一致的要求與標準，以促進 Smart Health 產業發展。



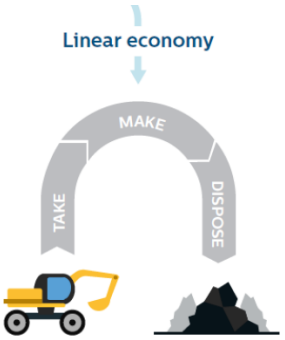


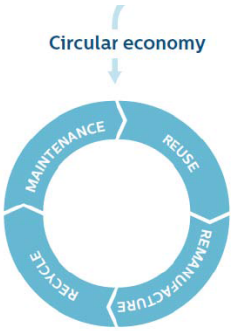
6. 接著也是由飛利浦、西門子等醫材產業代表，報告有關醫療器材翻新(Medical Device Refurbishment)現況，以及 Swiss Federal Office of Public Health 代表說明歐盟管理法規，摘要如下：

(1). Philips Health 是全球影像診斷、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)的成員之一，Jeroen Gruben 擔任 DITTA GRP (Good Refurbishment Practice) taskforce 的 Vice-chair。依據 DITTA 對於"Refurbishment of Used Medical System"是指："The process to restore used equipment or systems into a condition of safety and effectiveness comparable to when new. This includes actions such as repair, rework, update and replacement of worn parts with original parts. All actions are performed in a manner consistent with product specifications and Service procedures defined by the manufacturer for that equipment or system without significantly changing the equipment's or system's performance,

safety specifications and/or changing intended use as in its original registration”

隨著人年人口增加，醫療照護需求增加，新科技發展迅速，醫療照護消費持續增長。須從 Linear economy 轉變為 Circular economy，才能善用資源。





A circular economy aims to decouple economic growth from the use of natural resources by using those resources more effectively.

For a sustainable world, the transition form a linear to a circular economy is a necessary boundary condition.

Product refurbishment, improving reusability and new business models away from product ownership, will help us in the right direction.

以 Refurbished Medical Imaging Equipment 為例，具有下列優點：

Economy Solution: Typically 70-80% of new price

High Performance: Previous or current generation products

Risk Free Investment: Same as new warranty、service back-up

所以醫療器材翻新是一個全球性增長的概念，包含提供控制醫療照護成本的解決方法與具備合理性，並亟待國際法規調和。

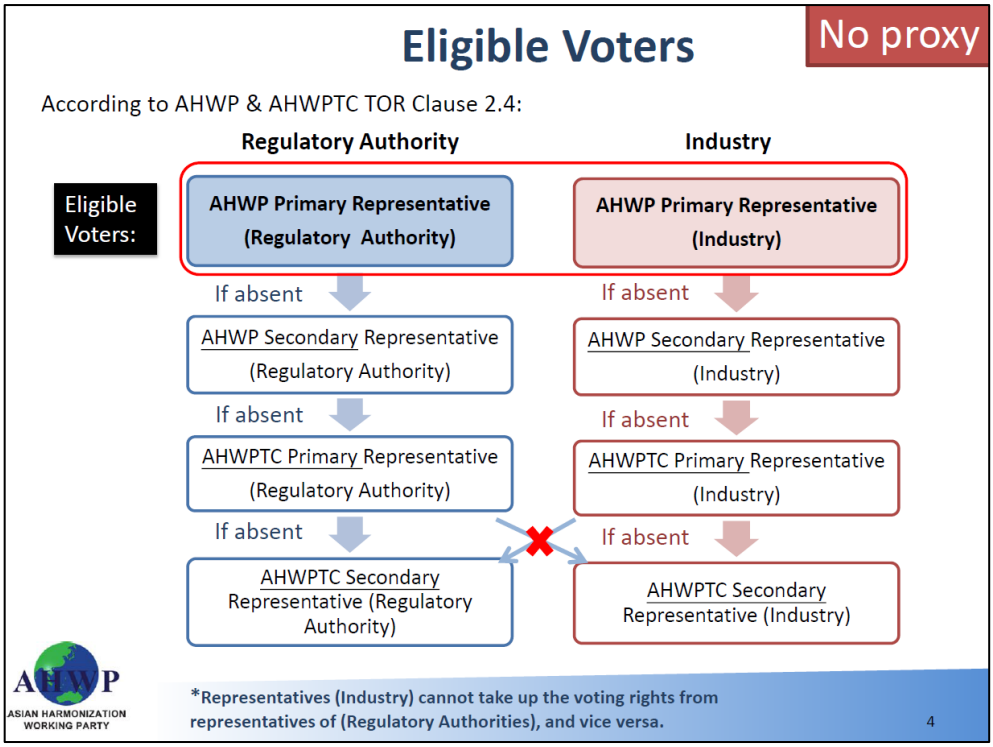
(2). Siemen Healthcare 也是 DITTA 的成員之一，Wu Liquing 也是 DITTA GRP Taskforce 的一員。Siemen 建立了一個 ecolin-Siemen refurbished systems，已有十年的歷史。雖然 DITTA 的 GRP 尚未成為一國際標準，但該公司已依據此標準來進行。醫材翻新可以降低二氧化碳排放，達到環境保護目的。

(3). 最後由 Rainer Voelksen 說明歐盟對於醫材翻新的管理：目前歐盟對此並無一致的法規，目前僅有製造廠的維修責任，尚無全面檢查大整修後重新販售的規定。Single-use 就僅是單次使用，Re-use 通常是指由使用者或送回製造廠，經清潔或消毒滅菌後使用。各會員國對於 re-use 的規範不一，有些會員國不允許由合約的第三方去進行消毒滅菌。

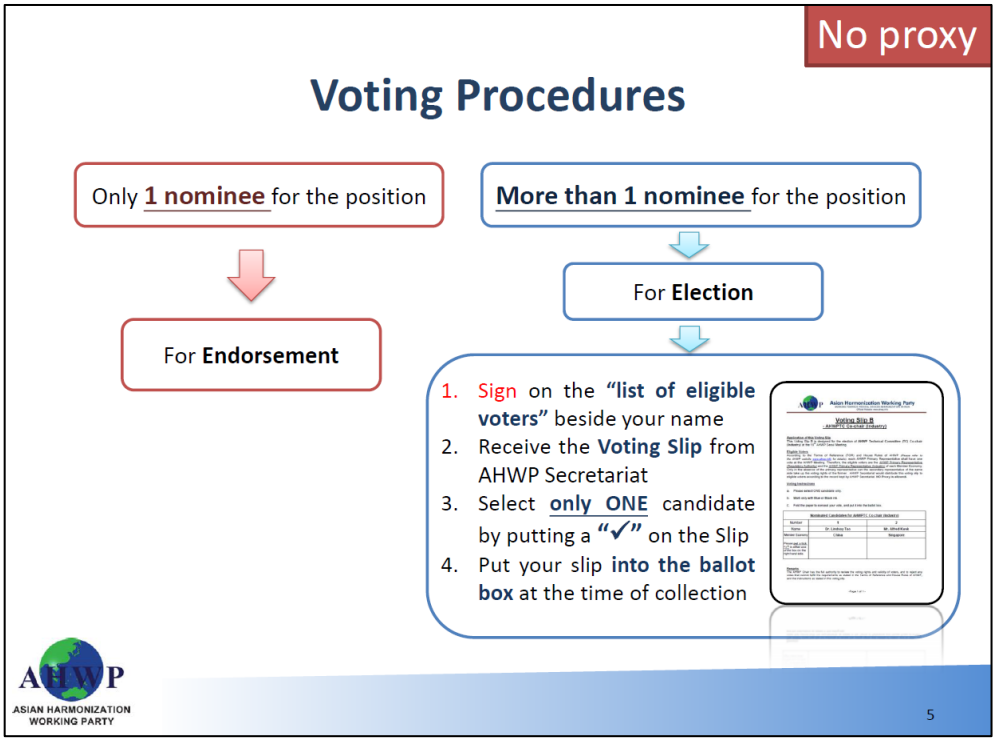
7. 最後是由韓國 Intuitive Surgical Korea 的 Seungwan Sohnu 演講"What's New on the Medical Device Horizon?"：他提到目前健康照護面臨的問題，包括人口老化(所以面對疾病與手術挑戰更長，也需要效期更長的產品)、醫療照護花費提高(因為住院時間拉長、併發症、二次手術、再住院、復原期等因素)，人類追求的不僅是生活,而是生活的品質。他以 MIS (Minimally Invasive Surgery) 為例，為了提升手術品質，故有了 Robotic Surgeon 的發展。以機器手臂輔助醫師進行手術，可以縮小傷口、降低併發症、再住院率及死亡率，所以此種手術方式已逐漸運用在更多科別的手術。

(三)、11 月 20 日為第 18 屆 AHWP TC Meeting，又地主國韓國 Hee-Kyo Jeong (Director General, Medical Device Evaluation Department; MFDS)以及現任 AHWP 主席 Dr. Saleh S. Al-Tayyar 致詞後，由大會秘書處再次說明新任領袖選舉規則與安排。選舉規則摘要如下：

1. 會員國具備投票權代表之優先順序如下圖。
2. 不能由下圖各優先順序代表以外之代理人參加投票。
3. 下圖官方代表與業界代表不能互為代理人參加投票。

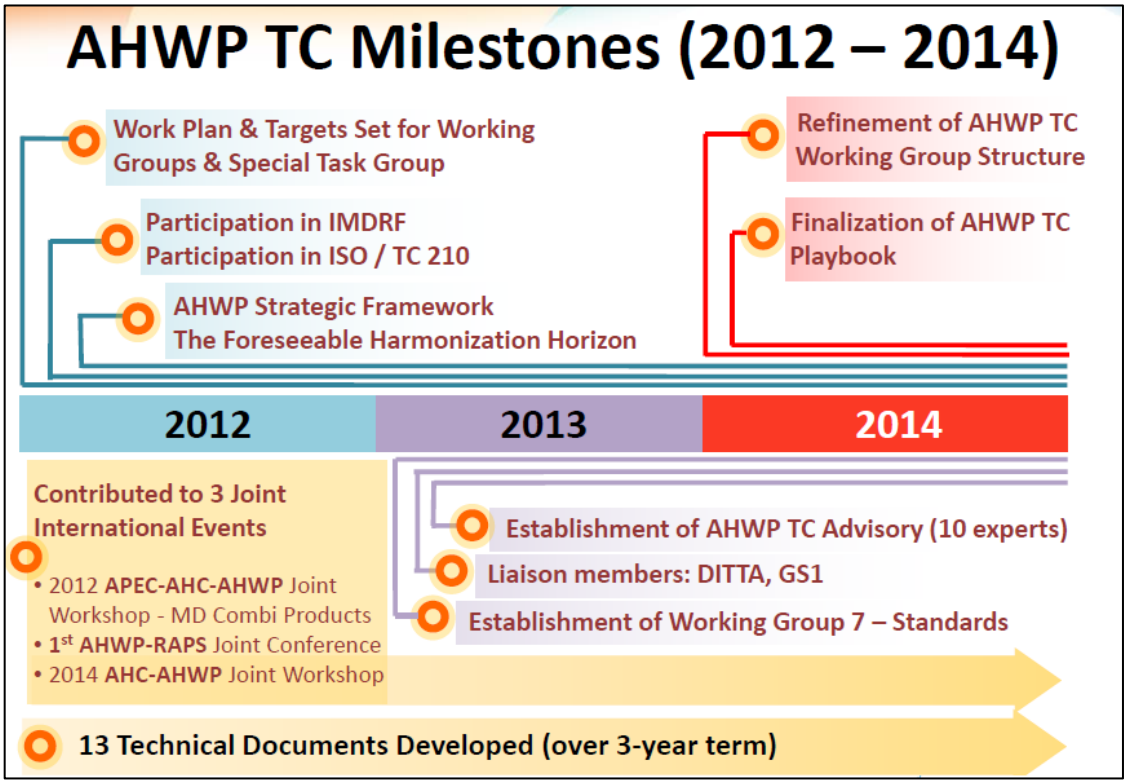


如果參與該項職位之競選者僅有一位時，直接由大會同意。如有兩位競選者時，將採不記名投票。



接著由 Ms. Joanna Koh 報告 AHWP TC 於即將結束的任期內(2012-2014 年)所完成各項突破之里程碑，包括參與國際醫療器材法規管理論壇(International Medical

Device Regulatory Forum; IMDRF)及國際標準組織(International Standard Organization; ISO)等重要國際組織之活動、擬定 AHWP 至 2020 年之策略架構(Asian Harmonization Working Party Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon")、新建立「標準」工作小組(Work Group 7 - Standard)、完成"Playbook for Implementation of a Medical Device Regulatory Framework"等重要工作，並於此任期中共完成了 13 件技術文件，其中 5 件為我國領導之體外診斷醫療器材工作小組所完成。此外，於此任期結束前，重整 TC 工作小組架構，期能促進各工作小組間橫向聯繫，因應醫療器材產品與管理複雜且多變的現況。另外，Ms. Joanna Koh 亦說明此任期內有關 AHWP Annual Meeting 的辦理方式有較大的改變，皆係採與其它法規訓練與調和相關國際組織合作，曾合作之國際組織包括 APEC、美國醫療法規學會(Regulatory Affairs Professionals Society; RAPS)及 AHC 等，由其規劃併 AHWP Annual Meeting 辦理法規訓練課程研討會，提升醫療器材相關各主管機關及業者參與 AHWP TC Meeting 及 AHWP Annual Meeting 之意願。



接著，由 AHWP 各 WG 報告其工作進度與未來規劃，報告內容摘要如下：

1. WG1 (Pre-Market: General MD)說明現階段主要工作項目為醫療軟體、複合式產品(Combination Product)及醫療器材群組化(Medical Device Grouping)等三項，其中複合式產品已於2013年發表白皮書草稿供各界參考，暫無更新進度。有關醫療軟體，已完成全球多國對醫療軟體認定實務的調查，接續將研擬醫用軟體認定為醫療器材之白皮書文件。有關醫療器材群組化部分，已完成推動群組化醫療器材國家之相關法規現況調查，調查國家包括美國、歐盟、加拿大、新加坡、沙烏地阿拉伯及馬來西亞。
2. WG2 (Pre-market: IVDD)工作小組主席為本署吳正寧科長，於會中說明已完成體外診斷醫療器材管理相關之文件，包括 STED (Summary Technical Documentation)及 CSDT (Common Submission Dossier Template)國際上主要技術文件摘要格式比較、醫材評估時標準之定位，以及具品質之傳染性疾病體外診斷醫材取得合宜性之管理架構等 3 項文件，其中前兩項將於次日 AHWP Annual Meeting 中進行採認程序，成果豐碩。另亦說明於 2014 年間辦理 1 場體外診斷醫材法規國際會議及 2 場面對面 WG2 工作會議，提供 WG2 成員及 PAHWP 代表交流學習之平台。
3. WG3 (Pre-market: Software as a Medical Device)為將成立之工作小組，尚無組織成員及相關工作進度。
4. WG4 (Post-Market)於會中說明已於 2014 年 5 月升級線上安全警示發布系統(Safety Alert Dissemination System; SADS)之安全性，供 AHWP SADS 官方成員使用；並以研擬完成不良事件報告格式與回報時間表建議基準("Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorized Representative")，並將於次日 AHWP Annual Meeting 中進行採認程序。WG2 未來工作方向暫規劃以研擬醫材不良事件或抱怨後處理之建議基準。
5. WG5 (Clinical Performance & Safety)說明已完成 ISO 14155 的 2003 年版、2011

年版及 ICH GCP 比較分析報告，並積極參與 ISO/TC 194 之標準討論會議，未來工作重點將討論採用 GCP 相關標準及規劃研擬適用於 AHWP 會員經濟體之基準文件。由報告中可知，該工作小組應暫無具體成果。

6. WG6 (Quality Management System: Audit & Assessment)說明正研擬供輸入者(Importers)及經銷商(Distributors)參考之醫材稽查基準，該文件初稿已完成，現正徵求意見中。該 WG 亦藉由此次 AHWP 系列會議之機會，於 11 月 19 日上午舉辦 Training on Quality System and Audit 訓練會議，落實稽核人員之訓練，該訓練模式亦可作為 WG2 未來參考。WG2 規劃未來工作重點，考量不同公司規模適用之稽核流程亦不同，故將針對中小企業稽核流程研擬相關基準，並注意 IMDRF 中 MDSAP 計畫之發展，並適時參與 IMDRF 相關活動。
7. WG7 (Quality Management System: Operation & Implementation)說明已完成對經銷商應符合要求之醫材品質管理系統基準("Guidance on Medical Device Quality Management System - Requirements for Distributors")草案，並將於次日 AHWP Annual Meeting 中進行採認程序。未來工作重點將為提供該 WG 所研擬基準文件使用之教育訓練，以利該文件得以施行於 AHWP 各會員經濟體。
8. WG8 (Standards)說明該工作小組於 2013 年底吉隆坡會議方成立，2014 年度與 WG2 合作完成“Role of Standards in the Assessment of medical device”基準文件，並將於次日 AHWP Annual Meeting 中進行採認程序。該工作小組亦說明未來 2 年工作重點將於選擇代表性標準作為標準認知與使用訓練之先導計畫，並規劃研擬相關評估指標，具體量化對於善用標準對於醫材監管機構的幫助。
9. WG9 (Training)工作小組於 2014 年度無具體成果，並於 TC Meeting 前之 TC Leaders Meeting 閉門會議討論該 WG 之任務，近似 AHWP 秘書處之工作，故 TC 主席裁示該工作小組於本次 Annual Meeting 暫不選主席與副主席，相關工作亦暫轉由秘書處處理。
10. STG (Special Task Group on UDI & Nomenclature)說明由中國主導的醫材命名

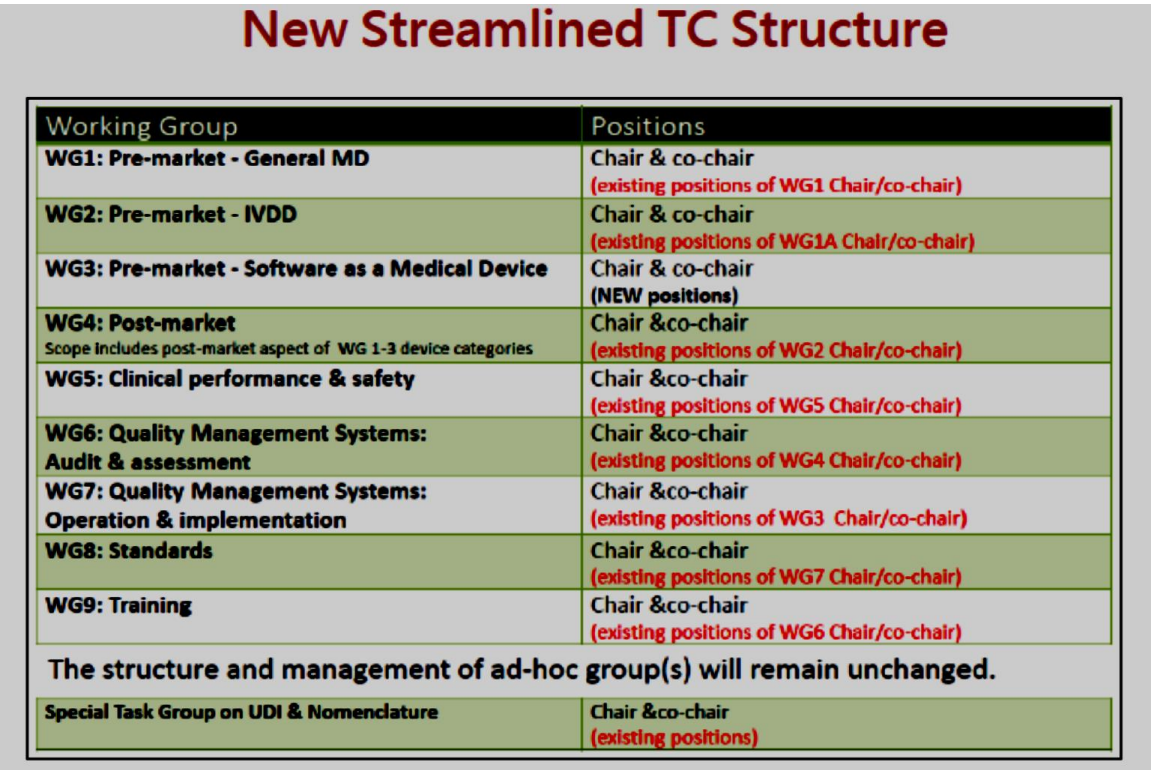
(Medical Device Nomenclature)及醫材單一識別系統(UDI)已積極與 IMDRF 合作中，並於中國舉辦之醫療器材監督管理國際論壇(China International Medical Device Regulatory; CIMDR)規劃特定議題之討論與訓練課程，未來工作重點將係分享中國 UDI 先導計畫之經驗並研擬相關基準供各界參考。。

(四)、11 月 21 日舉辦第 19 屆 AHWP Annual Meeting：此次會議邀請 IMDRF 會員國之一的日本代表 Hideyuki Kondo (Deputy Director, MHLW)演講”IMDRF Status Updates”，以及 APEC RHSC 代表 Lindsay Tao(Johnson & Johnson, China)演講”Update of APEC Regulatory Harmonization”。

接著由秘書處逐一宣讀預計於會上受 AHWP 採認之文件，並徵求最後意見，由於各文件先前皆已經過 WG 內部、TC 內部、ME 各代表及公開意見徵求，故於該採認程序所列文件未有其它意見，完成採認程序。前述文件包括：

1. "Comparison between the Common Submission Dossier Template (CSDT) format and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices"。
2. "Role of Standards in the Assessment of Medical Devices"。
3. "Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorized Representative"。
4. "Guidance on Medical Device Quality Management System - Requirements for Distributors"。
5. "White Paper on Medical Device Software Regulation - Software Qualification and Classification"。

接著即由 AHWP 秘書處進行事務性報告及各國狀態簡要更新，AHWP TC 及秘書處已將各 WG 組織架構重組，安排如下：



接著大會表決通過坦桑尼亞(Tanzania)成為 AHWP 的第 24 個會員國，秘書處也重申選舉規則及此次領袖選舉競選情形後，即進行各領袖職位之同意及選舉。最終 2015-2017 年領袖選舉結果如下表，並於最後，大會宣布 2015 年 AHWP Annual Meeting 將在泰國舉辦。

Position	Name	Organization	Economy
AHWP Chair	Dr. Hee-Kyo Jeong	MFDS	Korea
AHWP Vice Chair (Regulator)	Mr. Zamane Abd Rahman	MDA, MOH	Malaysia
AHWP Vice Chair (Industry)	Ms. Quan Tran	GE Healthcare	Singapore
AHWP TC Chair	Mr. Ali M. Al-Dalaan	Saudi FDA	KSA
AHWP Co-chair (Regulator)	Dr. Jeong-Rim Lee	MFDS	Korea
AHWP Co chair (Industry)	Mr. Alfred Kwek	Samsung Electronics	Singapore
WG1 Premarket: General MD	Mr. Essam Mohammed Al Mohandis	Saudi-FDA	KSA
	Ms. Tan Minghao	Regulatory Associates	Singapore

		LLP	
WG2 Premarket: IVD	Mr. Wen-Wei Tsai	TFDA	Taiwan
	Mr. Albert Poon	Freelance	Hong Kong
WG3 Premarket: Software as a MD	Dr. Rama Sethuraman	HSA	Singapore
	Mr. Tony Yip	Elekta	Hong Kong
WG4 Postmarket	Ms. Jennifer Mak	MDCS, DOH	Hong Kong
	Ms. Kitty Mao	GE Healthcare	Singapore
WG5 Clinical Performance & Safety	Ms. Yuwadee Patanawong	Thai FDA	Thailand
	Ms. Sumati Randeo	Abbott	India
WG6 QMS: Auditing & Assessment	Mr. Abdullah Al Rasheed	Saudi FDA	KSA
	Ms. Shirley Sum	J&J	Singapore
WG7 QMS Operation & Implementation	Mr. Aldawaty M. Olaybal	MDA/MOH	Malaysia
	Mr. Ee-Bin Liew	Access-2 Healthcare	Singapore
WG8 Standards	Ms. Maria Cecilla Matienzo	Bureau of Health Devices & Technology	Philippines
	Mr. Tony Low	TUV Rheinland	Malaysia
WG 9 Training	N/A	N/A	N/A
STG UDI & Nomenclature	Mr. Lianchun Yang	China FDA	China
	Ms. Carol Yan	J&J	China

三、心得與建議事項：

(一) 建議TFDA持續積極參與AHWP國際組織相關事務

我國屬 AHWP 組織創始國之一，亦曾於 AHWP 組織中擔任重要職務，且於該組織中，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。由於另一重要國際醫療器材法規論壇 IMDRF 組織，主要工作項目與政策方向僅限會員國且法規主管機關人員得以參加，現況會員國少，已形成一較為封閉的法規研定組織團體。因此，較為開放的 AHWP 組織已漸受各國重視且具國際影響力，故如 TFDA 持續參與 AHWP 相關活動並擔任要角，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。

(二) 鼓勵國內醫療器材產業參與相關國際法規調和組織

全球醫療器材之管理已逐漸趨向國際調和化，醫療器材法規調和國際組織(如 AHWP、IMDRF 等)之地位日漸重要，此類組織所制訂之基準與規範，可作為各國醫療器材管理之參考，進而達成醫療器材國際調和之目標。建議鼓勵國內廠商多參與或瞭解此類組織及其所訂定之國際規範，以瞭解醫療器材管理最新國際趨勢，且可藉由參加此類國際會議之機會，增進國內廠商與各國主管機關代表接觸之機會，有助於國內廠商之對外發展。

(三) 加強新興科技相關人才培訓課程，以提升我國醫療器材管理能量

隨新興科技持續進步，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，例如 3D 列印、複合式產品等管理方式，對主管機關及廠商皆係一大挑戰。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，亦建議同時重視醫療器材管理需延攬具新興科技背景之人才，期可提升我國因應醫療器材產業快速發展之現況，增進我國醫療器材產業之國際競爭力。

附件

WG2: Pre-market – IVDD

(formerly WG1a- IVDD)

- Chair: Ms. Emily Wu
- Acting Co-Chair: Ms. Sheryl Hsiao
- Secretary: Dr. Wen-Wei Tsai

- No. of WG members: 23

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

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

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 | **1 Training Workshop**

- *AHWP/WG1a/PD005-007 have been drafted*
- *1 international conferences on IVD medical devices regulations*

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

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

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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.

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

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.

Thank you!