出國報告（出國類別：參加國際會議）

亞洲醫療器材法規調和會第 18 屆年會暨第 1 屆與美國醫療法規學會聯合會議

(18th AHWP Annual Meeting & 1st AHWP-RAPS Joint Conference)

參會報告

服務機關：衛生福利部食品藥物管理署

姓名職稱：劉麗玲組長、吳正寧科長、蔡文偉薦任技正

派赴國家：馬來西亞

出國期間：102 年 12 月 1 日 – 6 日

報告日期：103 年 3 月 5 日

摘要

本次「亞洲醫療器材法規調和會第 18 屆年會暨第 1 屆與美國醫療法規學會聯合會議」，由我國衛生福利部食品藥物管理署(Food and Drug Administration，簡稱TFDA)劉組長麗玲率隊，吳科長正寧及蔡技正文偉隨同，赴馬來西亞吉隆坡出席與會，會議日期為 102 年 12 月 2 日至 12 月 5 日，我國參會代表於本次會議中報告 WG1a 工作小組於 2013 年之工作進度及未來規劃、AHWP 之策略架構(Strategic Framework)及我國醫療器材法規管理更新等議題。其中，由我國領導之 WG1a 工作小組，於 2013 年間，共有 3 件體外診斷醫療器材國際基準已受 AHWP 採認為該組織之文件，並接受比爾蓋茲基金會(Bill & Melinda Gates Foundation)、加拿大國際衛生組織(Grand Challenges Canada, GCC)與英國倫敦大學衛生暨熱帶醫學院(London School of Hygiene & Tropical Medicine, LSHTM)經費支助，於國內舉辦 1 場大型國際法規訓練會議，共邀請 16 國專家與會，國內外產、學、研界人士共計約有兩百人參加，我國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。

由此次參加 AHWP 年度大會所呈現的成果，我國在醫療器材管理及法規國際調和等方面，於亞洲地區皆屬領導地位，除可促成我國與各國間國際合作之契機外，亦有助於提升我國醫療器材管理之國際影響力與國際形象。

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壹、目的

全球醫療器材產業日漸興盛，使得醫療器材之管理漸受世界各國重視，完善且國際調和的醫療器材管理體制與法規，亦係現今各國醫療器材主管機關最重要的目標之一。有鑒於此，近年來，TFDA 積極參與醫療器材國際調和組織之活動，且自 2012 年起，TFDA 醫療器材主管機關官方代表獲選擔任亞洲醫療器材法規調和組織(Asia Harmonization Working Party, AHWP)副主席及該組織轄下技術委員會體外診斷醫療器材工作小組(WG1a-IVDD)主席，我國即於國際醫療器材法規調和任務中，扮演重要角色。

醫療器材管理國際調和化已成為目前各國醫療器材主管機關所重視議題之一，AHWP 期能藉由建立醫療器材全生命週期(Total Life Cycle)各階段之國際規範，供各國醫療器材主管機關、審查單位及醫療器材相關廠商作為參考；同時，AHWP 亦藉由舉辦各式醫療器材法規管理相關訓練課程，以減少國與國之間、主管機關與廠商之間等對於醫療器材管理法規認知之差異，進而達到各國醫療器材管理模式相互承認之理想；AHWP 亦期能透過有系統的經驗分享，引進醫療器材法規管理相關國際組織(如 IMDRF、GHTF、RAPS 等)之經驗與成果，以縮短 AHWP 建立醫療器材法規管理模型之時程，並期能透過有系統的法規訓練課程，協助醫療器材管理法規較為落後的國家，建立與國際調和之管理制度，以促進亞洲或其他地區國家醫療器材管理制度調和之大會宗旨。

本次出國人員以 AHWP WG1a 工作小組領袖代表及核心成員身分出席，於本次會議中，共有三項議題由我國與會代表負責簡報，包括 WG1a 工作小組年度工作進度及未來規劃、AHWP 之策略架構(Strategic Framework)以及我國醫療器材管理及法規之更新。由此次參加 AHWP 年度大會所呈現的 WG1a 工作小組年度成果，我國在醫療器材管理及法規國際調和等方面，於亞洲地區皆屬領導地位，除可促成我國與各國間國際合作之契機外，亦有助於提升我國醫療器材管理之國際影響力與國際形象。另外，TFDA 赴吉隆坡參會代表團，亦藉由本次會議之機會，於搭機返國前，邀

請 LSHTM 代表 Rosanna Peeling 教授及 WG1a 工作小組成員，轉往馬來西亞衛生部醫療器材管理局召開 WG1a 工作小組會議，擬訂 2014 年之目標，以建立完善體外診斷醫材管理法規與體制為願景，架構國際間法規審查/稽查合作成功模式。

貳、議程

本次會議共可分為 12 月 2 日至 3 日之「第 1 屆亞洲醫療器材法規調和會與美國醫療法規學會聯合研討會(1st AHWP-RAPS Joint Conference)」、12 月 4 日之「第 17 屆 AHWP 技術委員會會議(17th AHWP TC Meeting)」及 12 月 5 日之「第 18 屆 AHWP 年會(18th AHWP Annual Meeting)」三部分，各部分會議議程如下：

12 月 2 日

MONDAY, 2 DECEMBER 2013	
11:00 am–12:00 pm	Registration Check In
12:00–1:00 pm	Lunch
1:00–3:00 pm	● OPENING SESSION ● Welcome and Formal Opening of Conference *Saleh Al Tayyar, PhD, Chair, AHWP, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* *Sherry Keramidas, PhD, Executive Director, Regulatory Affairs Professionals Society* ● Medical Devices: Innovation in Regulatory Approaches *Philippe AuClair, PharmD, PhD FRAPS, Senior Director, Regulatory Strategy & Advocacy, Abbott Quality & Regulatory EMEA, Abbott Laboratories Inc.*
3:00–3:30 pm	Break and Exhibits
3:30–5:00 pm	● Building a Regulatory Framework – The ASEAN Experience *Session Leaders:* *Joanna Koh, Director, Medical Device Branch, Compliance Branch, Health Sciences Authority, Singapore* *Alfred Kwek, Director, Regulatory Affairs, ASEAN, GE Healthcare*
	● Medical Device Single Audit Program (MDSAP) *Session Leader:* *Saleh Al Tayyar, PhD, Chair, AHWP, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* *Speakers:* *William H. Duffell, Jr, Ph.D.* *Medtronic, Corporate Regulatory Affairs* *Hideyuki Kondo* *Office of Medical Device Evaluation, Ministry of Health Labour and Welfare, Japan*

12 月 3 日

TUESDAY, 3 DECEMBER 2013	
8:00–9:00 am	Registration & Breakfast
9:00–10:00 am	● Morning Plenary – Regulatory Convergence *Michael Gropp* *Mike Ward, Co-chair, APEC Regulatory Harmonization Steering Committee at Health Canada*
10:00–10:30 am	Break & Exhibits
10:30 am–12:00 pm	● Building a Regulatory Framework – Essential Elements of Compliance/Surveillance *Rainer Voelksen, Scientific Collaborator, Therapeutic Products Law Section, Directorate Public Health, Switzerland*
	● Unique Device Identification (UDI) *Speaker:* *Géraldine Lissalde-Bonnet, GS1 Global Office* *Kyungja Lee, Regulatory Affairs Manager, Medtronic Korea*
12:00–1:00 pm	Lunch
1:00–3:00 pm	● Market and Postmarket Surveillance: Changing Global Perspective *Session Leaders:* *Saleh Al Tayyar, PhD, Chair, AHWP, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* *Quan Tran, Vice President, QARA, GE Healthcare*
3:00–3:30 pm	Break & Exhibits
3:30–5:30 pm	● CLOSING PLENARY: IMPLEMENTATION AND REGULATORY CAPACITY *Session Leaders* *Saleh Al Tayyar, PhD, Chair, AHWP, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* *Speakers:* *Sherry Keramidas, PhD, Executive Director, Regulatory Affairs Professionals Society* *Dave Klokowski, Product Surveillance Manager, GE Healthcare*

12 月 4 日

17th AHWPTC Meeting

Wednesday, December 4th, 2013
Grand Lagoon Ballroom, Sunway Lagoon Hotel Resort & Spa
Kuala Lumpur, Malaysia

08:00	Registration
08:30 - 09:30	Formal Meeting with AHWP Chair (Close Meeting) ***-TC Leaders & AHWP Chair***
09:30 - 10:00	AHWP TC Working Group Pre-Meeting including discussion of TC Advisory recommendation items with TC Advisors (Close Meeting) ***-WG Chairs/Co-chairs***
10:00 - 10:15	Welcome Address ***Malaysian representative, TBD***
10:15 - 10:30	Opening Speech ***-Dr. Saleh S. Al-Tayyar*** *Chair, AHWP*
10:30 - 10:45	Roll-call ***-AHWP Secretariat*** Adoption of Agenda ***-Mrs. Joanna Koh*** *Chair, AHWP TC* ***-Mr. Ali M. Al-Dalaan*** *Co-Chair, AHWP TC* ***-Ms. Chadaporn Tanakasemsub*** *Co-Chair, AHWP TC*
10:45 - 11:00	Tea Break
11:00 - 11:15	Report and overview of AHWP TC meeting in Taipei & meeting with TC Advisors in Bangkok ***-Mrs. Joanna Koh*** *Chair, AHWP TC*
11:15 - 12:00	Introduction of TC Advisors Short speech by TC Advisors Representative Recommendations made by TC Advisors in TC leaders meeting in Bangkok – some updates ***-Mrs. Joanna Koh*** ***Chair, AHWP TC*** ***-Mr. Ali M. Al-Dalaan*** ***Co-Chair, AHWP TC*** ***-Ms. Chadaporn Tanakasemsub*** ***Co-Chair, AHWP TC*** ***-Mr. Scott Sardeson*** ***TC Advisor, AHWP TC***
12:00 - 13:30	Lunch
13:30 - 15:30	Updates by WG1 ***-Ms. Ming Hao Tan*** *HSA, Singapore* ***-Mr. Alfred Kwek*** *GE Healthcare, Singapore* Updates by WG1a ***-Ms. Li-Ling Liu*** *TFDA, Chinese Taipei* ***-Mr. Jeffrey Chern*** *ITRI, Chinese Taipei* Updates by WG2 ***-Ms. Jennifer Mak*** *DOH, Hong Kong SAR* ***-Dr Kulwant Saini*** *Johnson & Johnson, India* Updates by WG3 ***-Mr. Ali M. Al-Dalaan*** *SFDA, Kingdom of Saudi Arabia* ***-Mr. Ee Bin Liew*** *Philips Healthcare, Singapore* Updates by WG4 ***-Mr. Abdullah Al-Rasheed*** *SFDA, Kingdom of Saudi Arabia* ***Ms. Eun Hee Cho*** *Abbott Vascular, Korea* Updates by WG5 ***-Ms. Yuwadee Patanawong*** *ThaiFDA, Thailand* ***-Ms. Sumati Randeo*** *Abbott Laboratories, India* Updates by WG6 ***-Dr. Rama Sethuraman*** *HSA, Singapore* ***-Mr. Jack Wong*** *Terumo BCT (Asia Pacific), Hong Kong* Updates by STG (N) ***-Mr. Lian Chun Yang*** *CFDA, China* ***-Ms. Carol Yan*** *J&J Medical Asia Pacific, China*
15:30 - 15:45	Tea Break
15:45 - 16:00	Updates from Secretariat ***-Mr. Bryan So*** *HKPC, Hong Kong SAR*
16:00 - 16:30	AHWP TC Meeting Closing Remarks ***-Mrs. Joanna Koh*** *HSA, Singapore*
19:45 – 21:30	**Gala Dinner**

MEETING AGENDA

MINISTRY OF HEALTH MALAYSIA

12 月 5 日

Thursday, December 5, 2013		
Time	Session	Speaker/Moderator
08:00–08:10	Welcome Speech	Mr.Zamane Abdul Rahman Chief Executive Medical Device Authority, Ministry of Health Malaysia
08:10–08:20	Opening Speech	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
08:20–08:50	Keynote Speech	Dr. Sherry Keramidas Executive Director, Regulatory Affairs Professional Society
08:50–09:00	Speech by Honorable Guest	Dr. Hilmi Bin Haji Yahya Deputy Minister of Health, Malaysia
09:00–09:20	Souvenirs to Host, Honorable Guest and Sponsors	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
09:20–09:40	**GROUP PHOTO**	
09:40–10:10	**Tea Break**	
10:10–11:25	AHWP Status Report and Strategic Framework including the Summary on 1st AHWP-RAPS Joint Conference -Adoption of Agenda -Roll Call (Only Official Members)	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
	-Confirmation on Minutes of 17th AHWP Meeting held in Chinese Taipei, 2-6 Nov 2012 -Discussion on the Final Proposed Document ”*AHWP Strategic Framework Towards 2020 -The Foreseeable Harmonization Horizon*”	Ms. Li-Ling Liu Vice Chair, AHWP Director, Division of Medical Devices and Cosmetics, TFDA, Chinese Taipei Ms. Lindsay Tao Vice Chair, AHWP Corporate Director, Global health Policy, Johnson & Johnson, China

	-Summary on 1st AHWP-RAPS Joint Conference	Ms. Quan Tran Advisor to Chair, AHWP Vice President, Quality Assurance & Regulatory Affairs Asia Pacific, GE Healthcare, Singapore
11:25–12:15	Report by AHWPTC	Mrs. Joanna Koh Chair, AHWP TC Director, Medical Device Branch, Health Sciences Authority, Singapore
12:15–13:45	**Lunch**	
13:45–15:15	Country Update • Malaysia • Republic of Korea • Kingdom of Saudi Arabia • Chinese Taipei	Country representatives
15:15–15:25	**Tea Break**	
15:25–15:55	Report by Secretariat -Report by AHWP Secretariat from 2012 to 2013 -Report on Financial Statement for 2012/2013 -Proposal for Budget 2013/2014	Mr. Ali M. Al-Dalaan Secretary General, AHWP Executive Director, Medical Device Sector, SFDA, Kingdom of Saudi Arabia Mr. Bryan So Executive Deputy Secretary General, AHWP Senior Consultant, Hong Kong Productivity Council, Hong Kong SAR
15:55–16:25	ROPOSED FINAL documents for resolutions: 1、AHWP leadership: ”AHWP Strategic Framework Towards 2020 -The Foreseeable Harmonization Horizon” 2、WG1a: “AHWP Regulatory Framework for IVD Medical Devices” 3、WG1a: “Essential Principles of Safety and Performance of IVD Medical Devices” 4、WG1a: “Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices” 5、WG1a: “Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia

	Common Submission Dossier Template (CSDT) format" 6、WG2:"Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative" 7、WG3: "Quality management system –Medical devices –Nonconformity Grading System for Regulatory Purposes and Information Exchange" 8、Secretariat: "Amendment 1 to the GUIDANCE for Member Economy Hosting the Meetings of AHWP or its Technical Committees" 9、Secretariat: "Amendment 2 to the Asian Harmonization Working Party House Rules" 10. Secretariat: "Amendment 3 to the Asian Harmonization Working Party House Rules"	
16:25–16:35	**Tea Break**	
16:35–16:45	Confirmation of Host of the 19th AHWP Meeting	Dr. Saleh S. Al-Tayyar Chair, AHWP Director General, Medical Devices Sector SFDA, Kingdom of Saudi Arabia
16:45–16:55	Closing Remarks	Mr. Zamane Abdul Rahman Chief Executive Medical Device Authority Ministry of Health Malaysia
16:55–18:00	**2nd AGM of AHWP ASL** (Open to Industry and Regulatory Representatives of AHWP Member Economies) -Adoption of Agenda -Admission of New ASL Members -Resolution: Application for tax-exempt charitable status for AHWP ASL under Section 88 of Inland Revenue Ordinance in Hong Kong. -Election of New Directors of the Board	Mr. Ali M. Al-Dalaan President, AHWP ASL Secretary General, AHWP Executive Director, Medical Device Sector SFDA, Kingdom of Saudi Arabia
18:00	**End of the 18th AHWP Main 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、此次會議新成立的 WG7 Standards 以及 STG (N) Medical Device Nomenclature 等小組，TFDA 劉組長麗玲，於本次會議時所擔任 AHWP 之職務，包括 AHWP 大會副主席及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。

AHWP 於每年舉辦 1 場年會(AHWP Annual Meeting)，近年來，年會常與技術委員會會議(AHWP TC Meeting)併辦，兩會議皆屬自由註冊參加之開放式會議(open meeting)。本次會議共可分為三部分，包括 12 月 2 日至 3 日之「第 1 屆亞洲醫療器材法規調和會與美國醫療法規學會聯合研討會(1st AHWP-RAPS Joint Conference)」、12 月 4 日之「第 17 屆 AHWP 技術委員會會議(17th AHWP TC Meeting)」及 12 月 5

日之「第 18 屆 AHWP 年會(18th AHWP Annual Meeting)」。本次會議亦包含 AHWP 組織首次與美國醫療法規學會(Regulatory Affairs Professionals Society, RAPS)合作舉辦之法規訓練研討會，RAPS 之執行長 Dr. Sherry Keramidas 及亞太地區總監 Ms. Susan Tan 皆全程參與本次會議。

本次會議之首日(12 月 2 日)，分別由 AHWP 組織主席 Dr. Saleh Al Tayyar 及 RAPS 執行長 Dr. Sherry Keramidas 開場致詞，接著，由 Dr. Philippe Auclair 簡報創新設計與監管控制應用在醫療器材的概念，並說明醫療器材目前正因醫療技術與一般科學技術的快速發展，促成創新醫療器材的潛在契機，另也因各國人口結構變化與醫療重視等多項因素，對於醫療器材的發展具有推波助瀾作用，現有的法規制度已可能無法提供全面且適當的管理模式，引導出醫療器材相關法規標準，須持續依創新型產品的特性，而能有不斷且快速的因應，製定新規範或酌予調整舊規範的觀念。接著，於醫療器材單一稽核計畫(Medical Devices Single Audit Program, MDSAP)專題中，由 Dr. William H. Duffell 及 Mr. Hideyuki Kondo 分別由產業界及官方兩方面說明 IMDRF 在 MDSAP 之現況，將於 2014 年起，開始 3 年之先導計畫(MDSAP Pilot)。

會議次日(12 月 3 日)，先由兩位 AHWP TC Advisor，Mr. Michael Gropp 及 Mr. Scott Sardeson 以醫療器材法規調和趨勢及上市後監控的重要性講題作為開場。接著由國際條碼標準組織(GS1)代表 Mr. Géraldine Lissalde-Bonnet 及來自韓國業界 Ms. Kyungja Lee 簡報醫療器材單一識別追溯系統(Unique Device Identification, UDI)之現況，現已係國際醫療器材法規管理論壇(International Medical Device Regulators Forum, IMDRF)主要工作項目之一，並將於近期發表 UDI 相關國際基準(該 UDI Guidance 已於 2013 年 12 月 18 日發布於 IMDRF 官方網站)。另外，由 Mr. Dave Klokowski 說明醫療器材領域對全面的上市後監控具有高度期望，且亦敘明所有利害關係人(主管機關、製造商、健康專家、病患、醫療系統服務供應者以及相關專業協會等)皆應具有責任，才能發揮最大效益。

會議第三日(12 月 4 日)為第 17 屆 AHWP 技術委員會會議，當日受邀者之出缺席詳如表 1 所示。首先由馬來西亞官員 Mr. Mohd Amin Yaakob (Senior Principal

Assistant Director, Medical Device Authority, Malaysia)及 AHWP 組織大會主席 Dr. Saleh 歡迎致詞，接著，由表 1 所列出席者輪向現場全體與會者簡要自我介紹。

表 1 第 17 屆 AHWP 技術委員會會議受邀者出缺席名單

No.	Title / Name	Affiliation	Remarks
--Present--			
1	Dr Saleh	SFDA, KSA	AHWP Chair
2	Ms Li-Ling LIU	TFDA, Chinese Taipei	AHWP Vice-chair & WG1a Chair
3	Ms Lindsay TAO	Johnson & Johnson, China	AHWP Vice-chair
4	Mrs Joanna Koh	HSA, Singapore	TC Chair
5	Mr Ali M. AL-DALAAN	SFDA, KSA	TC Co-chair& WG3 Chair
6	Ms Quan TRAN	GH Healthcare, Singapore	Advisor to Chair
7	Ms Tan Ming Hao	HSA, Singapore	WG1 Chair
8	Mr Alfred Kwek	GE Healthcare, Singapore	WG1a Co-chair
9	Mr Jeffrey Chern	ITRI, Chinese Taipei	WG1a Co-chair
10	Ms Jennifer Mak	DOH, HKSAR	WG2 Chair
11	Mr Ee Bin LIEW	Philips Healthcare, Singapore	WG3 Co-chair
12	Mr Abdulah AL-Rasheed	SFDA, Saudi	WG4 Chair
13	Ms Eun Hee CHO	Abbott Vascular, Republic of Korea	WG4 Co-chair
14	Ms Yuwadee PATANAWONG	Thai-FDA, Thailand	WG5 Chair
15	Ms SUMATI Randeo	Abbott Laboratories	WG5 Co-chair
16	Dr Rama SETHURAMAN	SHA, Singapore	WG6 Chair
17	Mr Jack WONG	Terumo BCT, HKSAR	WG6 Co-chair
18	Ms Victoria Qu	J&J, China	STG(N) Secretary
19	Dr Philippe Auclair	Abbott Laboratories	TC Advisor
20	Mr Michael Gropp	independent	TC Advisor
21	Mr LeightonHansel	independent	TC Advisor
22	Dr Eamonn Hoxey	J&J	TC Advisor
23	Mr Greg Leblanc	Cook Medical	TC Advisor
24	Mr Benny Ons	BD Europe	TC Advisor
25	Mr Grant Ramaley	Aseptico Inc	TC Advisor
26	Mr Scott Sardeson	3M Health Care	TC Advisor
27	Mr Bryan SO	Hong Kong Productivity Council, HKSAR	Exe-Deputy Secretary General
28	Ms Carol LIU	Hong Kong Productivity Council, HKSAR	Secretariat
--Apology--			
29	Ms Chadaporn TANAKASEMSUB (Miang)	Zimmer	TC Co-chair
30	Mr YANG Lian-Chun	CFDA, China	STG(N) Chair
31	Ms Carol YAN	Johnson & Johnson, China	STG(N) Co-chair
32	Ms Petra Kaars-Wiele	Abbott	TC Advisor
33	Dr Peter Linders	Philips Healthcare	TC Advisor

接著進入各工作小組報告其年度成果及未來規劃之議程，其中，由我國領導之WG1a 工作小組(簡報內容詳如附件 1)，於 2013 年間，共完成 4 份體外診斷醫療器材國際基準，並將於 AHWP 年會時提報由 AHWP 採認為該組織文件(其中 3 份基準於隔日之 AHWP 大會即通過受 AHWP 採認)，並接受比爾蓋茲基金會、加拿大國際衛生組織(GCC)與英國倫敦大學衛生暨熱帶醫學院(LSHTM)經費支助，於國內舉辦 1 場大型國際法規訓練會議，該會議共邀請 16 國專家與會，國內外產、學、研界人士共計約有兩百人參加，我國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。

會議第四日(12 月 5 日)為第 18 屆 AHWP 年會，分別由馬來西亞衛生主管機關及醫療器材主管機關高層官員 Dr. Hilmi Bin Haji Yahya (Deputy Minister of Health, Malaysia)及 Mr.Zamane Abdul Rahman (Chief Executive, Medical Device Authority, Ministry of Health, Malaysia)歡迎致詞後，由我國劉麗玲組長代表 AHWP 大會，向全體與會者說明 AHWP 之策略架構(AHWP Strategic Framework Towards 2020 -The Foreseeable Harmonization Horizon)，簡報內容詳如附件 2。接著，由馬來西亞、韓國、沙烏地阿拉伯聯合大公國及我國之代表，簡報該國醫療器材法規管理架構之最新狀況(我國部分之簡報內容詳如附件 3)。另外，於此次 AHWP 年會中，共有 10 份組織章程指導文件及法規調和技術文件，提報擬由 AHWP 採認為該組織文件，其中 4 份即為 WG1a 所研擬之技術文件，如下：

1. “AHWP Regulatory Framework for IVD Medical Devices”；
2. “Essential Principles of Safety and Performance of IVD Medical Devices”；
3. “Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices”；
4. “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”。

TFDA 赴吉隆坡參會代表團，於 12 月 6 日搭機返國前，邀請 LSHTM 代表並

邀集 WG1a 工作小組成員，轉往馬來西亞衛生部醫療器材管理局(Medical Device Authority, MDA)召開 WG1a 工作小組會議，擬訂 2014 年之目標，包括將完成 3 件體外診斷醫療器材國際基準、舉辦 1 場體外診斷醫療器材法規訓練國際研討會及施行跨國共同審查先導計畫(Joint Review Pilot Program)。會中 Rosanna Peeling 教授表示，肯定由我國領導的 WG1a 工作小組在 2013 年的努力與成果，亦同意於 2014 年持續提供 WG1a 工作小組經費支助，以建立完善體外診斷醫材管理法規與體制為願景，架構國際間法規審查/稽查合作成功模式，共同為改善發展中或未發展國家人民健康而努力。

肆、建議事項

1. 建議 TFDA 持續積極參與國際組織相關事務

   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. 鼓勵國內醫療器材產業參與相關國際法規調和組織

   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。目前我國 TFDA 已積極參與此類國際組織，建議應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，有助於國內廠商之發展。

3. 於國內舉辦醫療器材法規訓練國際會議及課程

   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 或經濟部相關單位主辦醫療器材法規訓練國際會議及課程，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，提供醫療器材國產業者參與國際會議之機會，進而提升國產產品之競爭力。

4. 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。

附件 1

AHWP WG1a IVDD Update

The 17th AHWP TC Meeting
Kuala Lumpur, Malaysia
Dec 4, 2013

Members of AHWP WG1a

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

Members of AHWP WG1a

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

2012-2014 Missions of AHWP WG1a

- To assist AHWP member economies and other developing countries to implement regulatory framework of IVD medical devices
  - Developing AHWP guidances on IVD medical devices on a TPLC basis
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices
  - Facilitating harmonization and regulatory convergence
- To facilitate capacity building and training activities for AHWP member economies and other developing countries on IVD medical devices regulations
  - Capacity building and training through AHWP as a common platform
  - Regulations updates and gap analyses
  - Experience sharing and case studies on IVD medical devices regulations

AHWP WG1a Projects

To assist AHWP member economies and other developing countries to implement regulatory framework of IVD medical devices

Project	Kick-off (DD/MMM/YY)	Checkpoint (DD/MMM/YY)	Actual Date of Completion (DD/MMM/YY)
Development of GHTF Guidances on IVDs	1/1/2012	2/6/2012	2/6/2012
Revision of GHTF Documents	1/3/2012	13/7/2012	13/7/2012
List of Recognized Standards for IVDs	1/5/2012	30/6/2013	30/9/2012
Best practices for clinical evaluation and investigation	1/5/2012	30/6/2013	30/12/2012
Development of AHWP Guidances on IVD Medical Devices	1/1/2013	30/11/2013	Not yet

To facilitate capacity building and training activities for AHWP member economies and other developing countries on IVD medical devices regulations

Project	Kick-off (DD/MMM/YY)	Checkpoint (DD/MMM/YY)	Actual Date of Completion (DD/MMM/YY)
Training for AHWP Member Economies	30/9/2012	30/10/2014	Not yet
Affordable and Accessible IVD Medical Devices (Collaboration with LSHTM and GHTF)	1/1/2013	30/10/2014	Not yet

Completed
Undergoing

2012 Achievements

- 3 GHTF Final Documents
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices made
- 2 international conferences on IVD medical devices regulations held
  - May 17-18, 2012 "Conference for Convergence on IVD Medical Devices Regulations"
  - Nov 6, 2012 "Conference for Regulatory Convergence on New and Emerging IVD Medical Devices"

2013 Milestones

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

2013 Milestones

6 IVD Regulatory Guidances | 1 Training Workshop

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

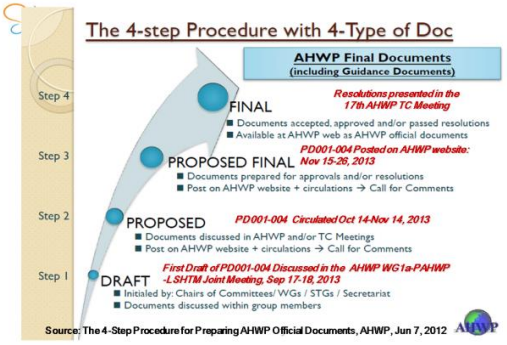
- *AHWP WG1a Working Meeting*
- *The 1st ARFMD & Pre-Forum Workshop*
- *The AHWP WG1a-PAHWP-LSHTM Joint Conference*
- *AHWP WG1a-PAHWP-LSHTM Joint Conference*

Development of Regulatory Guidances on IVD Medical Devices

Development of Regulatory Guidances on IVD Medical Devices

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

The 4-step Procedure with 4-Type of Doc



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

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

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

- AHWP WG1a Working Meeting, May 15-16, 2013
- The 1st African Regulatory Forum for Medical Diagnostics & Pre-Forum Workshop, Jul 24-26, 2013
- The AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations, Sep 16, 2013
- The AHWP WG1a-PAHWP-LSHTM Joint Meeting on POC IVD Medical Devices, Sep 17-18, 2013

AHWP WG1a Working Meeting, May 15-16, 2013

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

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

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

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

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

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

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

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

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

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

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

Thank you for your attention!

附件 2

AHWP
ASIAN HARMONIZATION WORKING PARTY

Asian Harmonization Working Party
Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"

AHWP Strategic Framework

Background and Objective

- **Strategic Objectives:**
  - Continue the momentum built in the past
  - Provide a clear development plan and work targets towards the further enhancement of the capability of AHWP member economies in regulating medical devices, as well as the further strengthening of medical device regulatory harmonization and collaboration activities across the regions
  - Serves as a guiding principles for various AHWP activities

2

AHWP Strategic Framework

Background and Objective (Cont.)

- **Background:**
  - Agreed and decision made by leaders at 16th Annual conference in Bali, Indonesia
  - Draft developed and discussed at February AHWP leaders' meeting
  - Revision based on comments received and circulation for leaders' comments between March to June
  - Draft endorsement by AHWP leaders at AHWP TC meeting in June, 2012
  - Further revision between June to Oct, 2012
  - Final draft posted at AHWP website in Oct 2012 for soliciting AHWP members comments
  - Presented in 17th AHWP meeting in Chinese Taipei
  - Call for comment by all AHWP members by Feb 4, 2013
  - Comments reviewed and incorporated at Secretariat Meeting at KL, May 2013

3

AHWP Strategic Framework

Framework Elements

- **Element One: AHWP Membership Expansion**
  - Welcome any non-AHWP economic members who shows interest in participating
  - Invite current AHWP economic member who has experience and knowledge on medical device regulation to take leadership role at various levels (AHWP, AHWP TC, working groups) at AHWP
  - Secretariat office offer consistent support to member economies

4

AHWP Strategic Framework

- **Element Two: Training and Capacity building**
  - Focus on enhance knowledge on medical device, promote understanding of essential elements of medical device regulation, and promote international best practice
  - AHWP offer support to training and capacity building of members economies, in terms of financial and manpower
  - Identify priorities, partners of NGO, regional/international harmonization organizations (e.g. WHO, APEC, RAPS, MTLI, ARPA, and etc.)
  - Develop curriculum and review periodically
  - Promote utilization of advanced technology on training

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AHWP Strategic Framework

- **Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance**

  Harmonization in important areas based on availability of GHTF global regulatory model and AHWP guidance:
  - Harmonized definition of the term "medical device" (important in determining what and who are subject to regulation);
  - Registration of manufacturers, distributors, and importers and listing of medical devices marketed;
  - Adopt same risk-based classification of medical devices;
  - Single adverse event reporting and post-marketing surveillance system;
  - Single medical device nomenclature system;
  - Single quality management system requirements, and broader acceptance of quality management system audit report by authorized competent authorities ;
  - Acceptance of clinical evidence gathered, and evaluations conducted by, other AHWP/GHTF members ;
  - Acceptance of the same dossier (technical file) template for registration submission (e.g. the CSDT/STED format);
  - Recognition of 'recognized regulatory agencies' registration decisions to expedite evaluation process, etc.

6

AHWP Strategic Framework

- **Element Four: Enhance AHWP's Global Partnership**
  - Proactively approach international/regional organizations (e.g. IMDRF, APEC, ASEAN, WHO)
  - Identify important topics and establish mechanism for effective interaction and networking
    - Process of receiving from and providing feedbacks
    - Membership and representation
    - Joint strategic and roadmap development

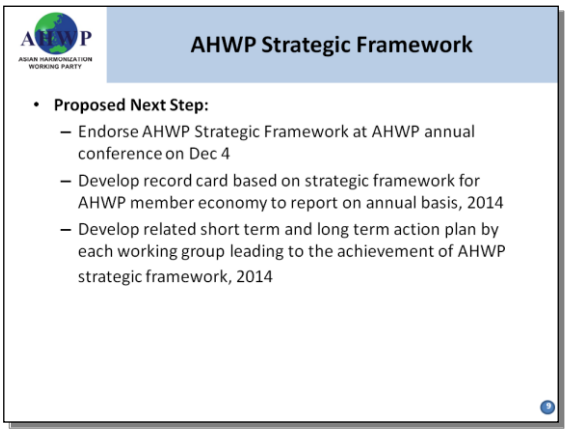
7

AHWP Strategic Framework

Indicator of Success

- Increased inclusiveness of AHWP membership
- Enhanced awareness on the robust and effective medical device regulation in improving access, quality and use of medical device
- Adoption or adaption of the GHTF global regulatory model, AHWP and other harmonized international guidance and standards
- Enhanced collaboration among AHWP members, to improve and promote greater efficiency on regulation and use of resource: nomenclature, single post-market surveillance; multi-acceptance of QMS auditing report
- Enhanced global partnership, AHWP's participation at regional/global forums, and joint activities.

8


AHWP
ASIAN HARMONIZATION WORKING PARTY
AHWP Strategic Framework
• Proposed Next Step:
– Endorse AHWP Strategic Framework at AHWP annual conference on Dec 4
– Develop record card based on strategic framework for AHWP member economy to report on annual basis, 2014
– Develop related short term and long term action plan by each working group leading to the achievement of AHWP strategic framework, 2014


AHWP
ASIAN HARMONIZATION WORKING PARTY
THANK YOU

附件 3

Current Status of Medical Device Administration in Taiwan

Li-Ling Liu, MS, RPh
Director, Division of Medical Devices and Cosmetics
Food and Drug Administration
Chinese Taipei, Taiwan

Dec. 5st, 2013

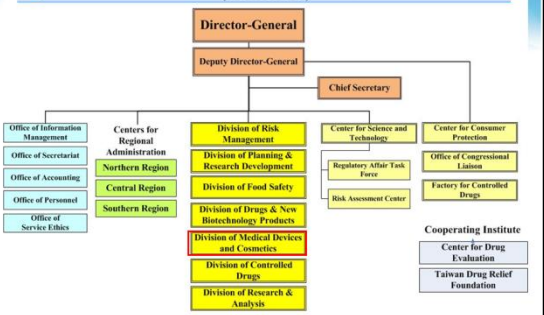
Outline

1. Medical Device Regulatory Framework
2. International Cooperation
3. Future Initiatives

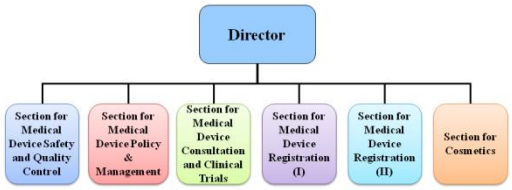
Taiwan Profile

- Area: 36,188 Km²
- Population : 23.22 Millions
- Aging: 10.9% (2011)
- 99% Citizen Covered by NHI
- 17 Medical Centers, 917 Hospitals
- NHE/GDP: 6.6%
- Medical Device Sale Revenue: US$ 4 billion (2012)

Food and Drug Administration, Taiwan (TFDA)

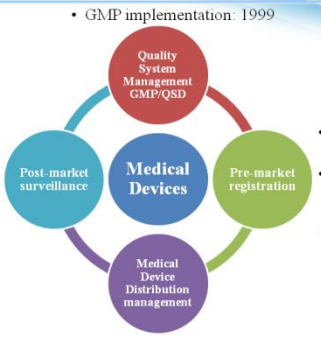


Organization Diagram of Division of Medical Device and Cosmetics



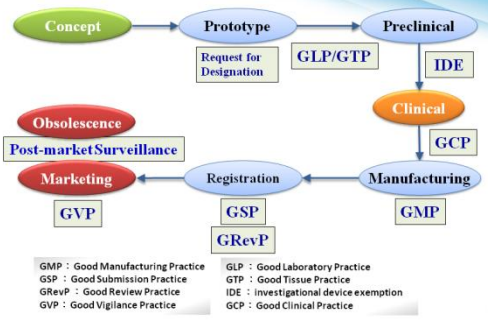
Medical Device Regulatory Framework

- GMP implementation: 1999



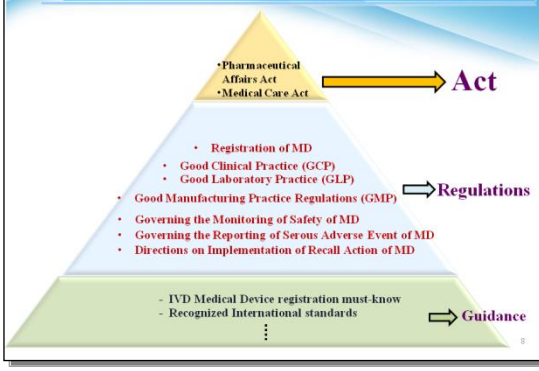
- Beginning of registration：1973
- Number of approved license：32,774 (around 80% imported)

Medical Devices Life Cycle Management



GMP : Good Manufacturing Practice
GSP : Good Submission Practice
GRevP : Good Review Practice
GVP : Good Vigilance Practice
GLP : Good Laboratory Practice
GTP : Good Tissue Practice
IDE : Investigational device exemption
GCP : Good Clinical Practice

Basis of Medical Device Regulation



Amendment on Pharmaceutical Affairs Act

- Article 13 - Definition of Medical Devices
  - The term "medical device", as used in this Act, shall refer to any instruments, machines, apparatus, materials, **software, reagent for in vitro use**, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, **regulating fertility**, or which may affect the body structure or functions of human beings, and **do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body**.

Amended Date: May 8, 2013

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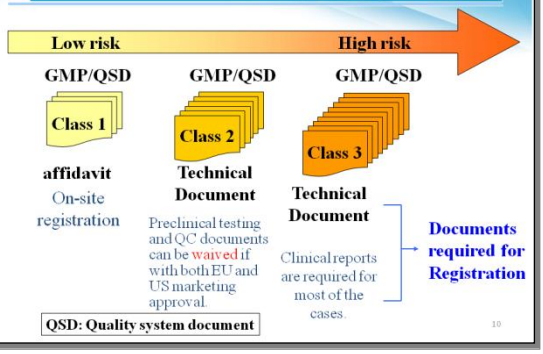
Risk Based Regulation



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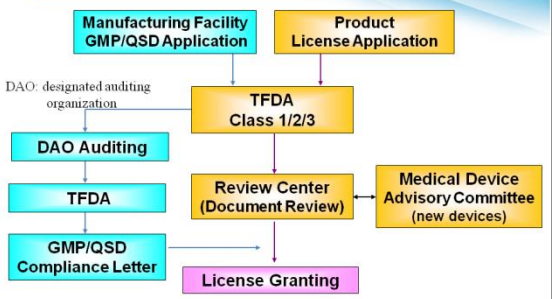
Before Marketing a Medical Device Product in Taiwan



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Review Time and Approval Rate for Medical Device Submissions in 2012

Submission	Proclamation review time (days)	Average review time (days)	Approval rate
New medical devices	220	200	67 %
Substantial Equivalence medical devices (Class 2 and 3)	140	107	79 %
Regular medical devices (Class 1)	On-site registration	–	–

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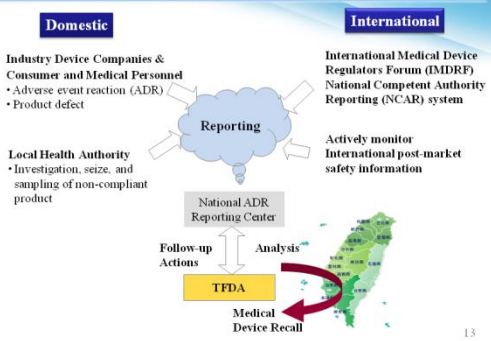
Post-Market Surveillance



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Vigilance Reporting Webpage

- Provide updated safety information to the public
- On-line report an adverse event

http://medwatch.fda.gov.tw

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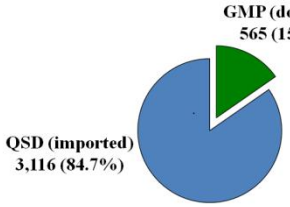
Statistics of GMP/QSD by Domestic and Imported Manufacturers



2013.08.data

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International Cooperation

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International Cooperation

Participation in International Organization

APEC : Member of RHSC

AHWP : Vice-Chair of AHWP, Chair of IVD subgroup

IMDRF, RAPS

Good Review Practices(GRevP) Roadmap

- **Goal**
  - To strengthen the performance, predictability and transparency of regulatory agencies through the implementation or enhancement of Good Review Practices (GRevP) stepwise in each interested APEC economy by 2020
  - To enhance mutual trust for regulatory convergence among economies
- **Specific Activities and Timeframe**
  - Step 1 (2011-2012) : Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation
  - Step 2 (2011-2014) : Planned Solution to Address Gap
  - Step 3 (2012-2015) : Assessing the Impact of GRevP Training and Exchange of Regulatory Information
  - Step 4 (2015-2020) : Reaching the Goal for Achieving Common Regulatory Elements

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Medical Device Combination Products Concept Note

- **Goal**
  - To promote regulatory convergence among member economies for combination products regulated as medical devices throughout the product life cycle
- **Activities Completed**
  - Concept Note: endorsed Aug. 2012
  - Workshop: "2012 APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products" held in Taipei Nov. 2012
  - Gap Analysis Survey among APEC member economies: Completed July 2013
- **Future Activities**
  - round-table discussion among interested APEC economies

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TFDA's Achievements in 2012

- 3 GHTF Final Documents
- Recommendations on the use of recognized standards in safety and performance evaluation of IVD medical devices made
- 2 international conferences on IVD medical devices regulations held
  - May 17-18, 2012 "Conference for Convergence on IVD Medical Devices Regulations"
  - Nov 6, 2012 "Conference for Regulatory Convergence on New and Emerging IVD Medical Devices"

2013 Milestones

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

2013 Milestones

6 IVD Regulatory Guidances

1 Training Workshop

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

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

Development of Regulatory Guidances on IVD Medical Devices

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

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

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

Future Initiatives

- **Enhance quality and effeciency of review**
  Good Review Practice (GRevP)
  Good Submission Practice (GSP)
- **Enhance Post-Marketing Control**
  Unique Device Identification (UDI)
  Good Distribution Practice (GDP)

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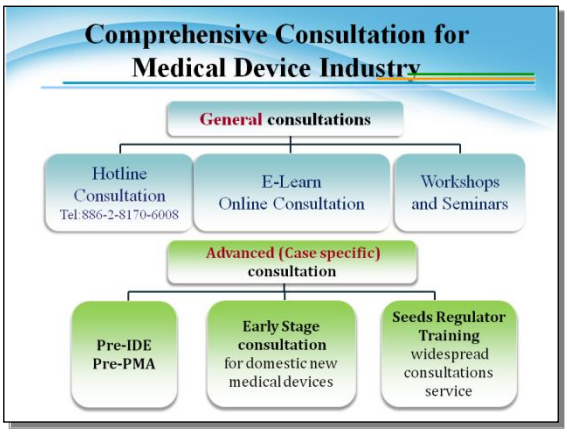
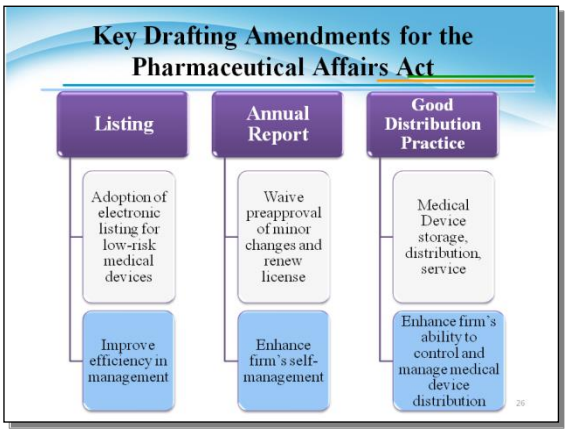
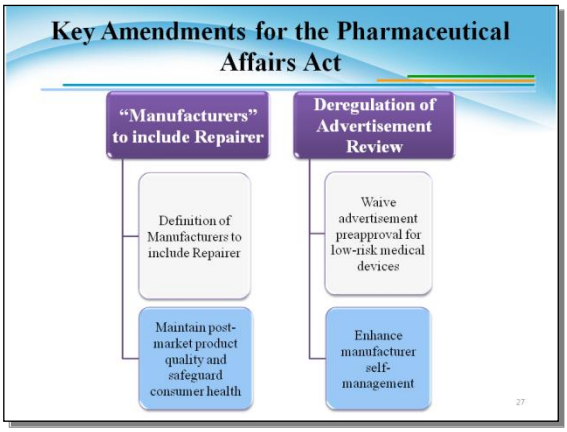

Comprehensive Consultation for Medical Device Industry
General consultations
Hotline Consultation
Tel:886-2-8170-6008
E-Learn Online Consultation
Workshops and Seminars
Advanced (Case specific) consultation
Pre-IDE Pre-PMA
Early Stage consultation for domestic new medical devices
Seeds Regulator Training widespread consultations service


Key Drafting Amendments for the Pharmaceutical Affairs Act
Listing
Annual Report
Good Distribution Practice
Adoption of electronic listing for low-risk medical devices
Improve efficiency in management
Waive preapproval of minor changes and renew license
Enhance firm's self-management
Medical Device storage, distribution, service
Enhance firm's ability to control and manage medical device distribution


Key Amendments for the Pharmaceutical Affairs Act
"Manufacturers" to include Repairer
Deregulation of Advertisement Review
Definition of Manufacturers to include Repairer
Maintain post-market product quality and safeguard consumer health
Waive advertisement preapproval for low-risk medical devices
Enhance manufacturer self-management


Capacity building for Clinical Trails
Harmonizing international regulations and guidelines
Establishing information platform of medical device clinical trials
Strategies
Enhancing quality control of clinical trials
Training clinical trial professionals
Improving efficiency of clinical trial reviews


Innovative Organization
Quality System Management
Legal Framework
Pre-market Registration
CONSUMER PROTECTION
International Cooperation
Distribution Management
Consultations & Training
Post-market Surveillance
Increase administrative efficiency


THANK YOU FOR YOUR ATTENTION
FDA