出國報告（出國類別：參加國際會議）

2016 亞洲醫療器材法規調和會技術委員會之領袖會議暨主管機關論壇

(2016 AHWP TC Leaders Meeting & AHWP Regulators Forum)

參會報告

服務機關：衛生福利部食品藥物管理署

姓名職稱：蔡文偉薦任技正

派赴國家：韓國

出國期間：105 年 4 月 26 日至 30 日

報告日期：105 年 7 月 25 日

摘要

本次「2016 亞洲醫療器材法規調和會技術委員會領袖會議暨主管機關論壇(2016 AHWP TC Leaders Meeting & AHWP Regulators Forum)」，由我國衛生福利部食品藥物管理署(Food and Drug Administration，簡稱 TFDA)蔡技正文偉以該組織技術委員會轄下體外診斷醫療器材工作小組(WG2 - Premarket: IVDD)主席身分，赴韓國首爾出席與會，會議日期為 105 年 4 月 26 日至 4 月 30 日，我國參會代表於本次會議中報告體外診斷醫療器材工作小組之工作規劃與進度，包括正研擬之 3 件體外診斷醫療器材相關基準文件等，另亦於主管機關論壇簡報我國醫療器材管理法規制度，與各國主管機關及業界代表進行交流。另外，我國參會代表於本次參會期間，安排與世界衛生組織體外診斷醫療器材預先認證小組代表進行未來合作討論會議，雙方初步建立合作共識。另藉由本次會議機會，蒐集技術委員會轄下各工作小組工作規劃資訊，早期取得法規趨勢資訊，可作為我國醫療器材管理相關法規研擬之參考資訊。

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壹、目的

亞洲醫療器材法規調和會(Asian Harmonization Working Party，簡稱 AHWP)為亞太地區推動醫療器材法規調和之重要組織，AHWP 大會轄下技術委員會(Technical Committee, TC)共包含 9 個工作小組(Working Group, WG)及 1 個特殊任務小組(Special Task Group, STG)，本署蔡技正文偉擔任其中體外診斷醫療器材工作小組(WG2 - Pre-market: IVDD)主席。AHWP 於每年舉辦一場技術委員會之領袖會議(Leaders Meeting)，邀請各工作小組及特殊任務小組之主席及副主席與會，報告其工作進度及未來工作規劃，本次 2016 年 AHWP TC Leaders Meeting，WG2 工作小組由蔡技正文偉代表，赴韓國首爾出席與會，日期為 105 年 4 月 26 日至 4 月 30 日，於會中報告 WG2 工作小組之工作規劃與進度，並受邀於併辦之主管機關論壇(AHWP Regulators Forum)簡報我國醫療器材法規管理制度。藉由參加此次會議，除瞭解 AHWP 目前各小組工作進度及未來規劃外，我國積極參與醫療器材法規國際調和相關事務，亦有助於提升我國國際能見度及國際形象。

貳、議程

本次會議中之 TC Leaders Meeting 為 AHWP 組織例行活動，另外，主辦單位(韓國 MFDS)藉本次已邀集各國官員與業界代表之機會，特別安排第三天下午的主管機關論壇會議，故本次會議議程共有三天，會議議程詳如下：

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP & TC Leaders Meeting, 27th-29th April, 2016

Day 1: AHWP Secretariat Meeting, Leadership pre-Meeting & WG Small Group Meetings

Date: Wednesday 27th April
Venue: Sejong Hotel, Seoul, South Korea
Participants: AHWP Chair and Vice-chairs, AHWPTC Chair and Co-chairs, Secretariat

Time	Agenda (Secretariat Meeting)	Responsible Person(s)
0900 - 0905	Welcome	AHWP Chair
0905 - 0910	Roll Call	Bryan So
0910 - 1145	Reporting and Discussion	Bryan So
	1. Status for expanding member economy	Bryan So
	2. Liasion or collaboration status with international organizations - WHO : collaboration method and progress so far - APACMed : collaboration status and plan - TC210 : collaboration method and progress so far(connection between AHWP WG8 etc.)	Bryan So
	3. Finalized budget status after Thailand meeting	Bryan So
	4. Collected comments for establishing Mission and Vision for AHWP	Bryan So
	5. Webpage renewal status	Bryan So
	6. Capacity Building Program status so far (CBP plan for Indonesia and Vietnam)	Tran Quan
	7. Preparation status for Annual meeting in Philippines	Bryan So / Cecilia
1145 – 1150	Group Photo	MFDS / Secretariat
1200 – 1300	**Lunch**	

16:00 - 18:00	**AHWP Leadership pre-Meeting Agenda**	**Responsible Person(s)**
	1. Meeting with Irene Prat & Tele-call with WHO (16:00 -17:00)	Tran Quan
	2. Agenda of TC Leaders Meeting in 28th & 29th April	TC chair
	3. Report of IMDRF Meeting in 7th – 10th March in Brasilia	Jeong-Rim Lee
	4. Co-work with OECD on developing a publication	Jeong-Rim Lee
	5. AOB	Jeong-Rim Lee
Time	**Agenda (WG Small Group Meetings)**	**Responsible Person(s)**
1330 - 1600	WG2 Meeting with WHO	WG2 Chair (WG2 members & invited participants)
16:00 - 18:00	WG5 Meeting	WG5 Chair (WG members & invited participants)

Day 2: AHWP TC Leaders Meeting

Date: Thursday 28th April
Venue: Sejong Hotel, Seoul, South Korea
Participants: AHWP Chair and Vice-chairs, AHWPTC Chair and Co-chairs, WG Chairs and Co-chairs, TC Advisors, Secretariat, observers

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
0900 - 0910	Welcome Remarks	AHWP Chair
0910 - 0920	Opening of Meeting	TC Chair
0920 – 0935	Adoption of the Agenda & Roll Call	TC Co-chair
0935 - 1145	AHWP TC's current status Individual WG work plan discussion 1. Work items (previous and new) 2. WGs update since the Bangkok meeting 3. WG2: Summary report on IVD document 4. Confirmation of IVD document of WG2	 WG Chairs & Co-chairs WG2 Chair TC Chairs
1145 - 1300	**Lunch**	
1300 - 1310	Congratulatory Remarks	Dr. Yeo-Won Sohn, Korea MFDS
1310 - 1325	**Group Photo**	
1325 – 1345	- AHWP TC's current status (continued, if needed) - Updates by Secretariat: • Upcoming AHWP Meetings • AHWP Vision & Mission • Amendment to AHWP TOR on endorsement mechanism for WG document(s)	All TC participants Bryan So
1345 - 1350	Closing Remarks	TC Co-chair
1400 - 1440	**Closed Door Meeting** for TC Advisors	TC Advisors **ONLY**
1400 - 2000	Tour Program provided by the Korea Medical Device Industry **(for Regulators only)** - Visiting Manufacturing Sites. - Dinner	Korea Medical Device Industry Association
2000 - 2100	Back to Hotel	Korea Medical Device Industry Association

Day 3: AHWP TC Leaders Meeting & AHWP Regulators Forum

Date: Friday 29th April
Venue: Sejong Hotel, Seoul, South Korea
Participants: AHWP Chair and Vice-chairs, AHWPTC Chair and Co-chairs, WG Chairs and Co-chairs, TC Advisors, Secretariat, observers

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
0900 – 0940	**Closed Door Meeting** for TC Leaders	AHWP & TC & WGs Chairs & Co-chairs & Secretariat **ONLY**
0940 - 1000	**Coffee Break**	
1000 – 1005	Opening of Meeting	TC Chair
1005 – 1015	Adoption of the Agenda & Roll Call	TC Co-chair
1015 – 1150	- TC Advisory Panel – Recommendations for TC works - TC Advisory Panel – Recommendations for AHWP Mission & Vision - AHWP WG future participation and relationship with IMDRF WG (round table discussion) - Relationship with Liaison & International organizations (ISO/TC210, etc) - TC Report Highlight - AOB - Summary and Conclusions	TC Advisors TC Advisors TC Leaders, WG Leaders TC & WG Leaders, Peter Linders TC Chair & Co-chairs TC Chair
1150 - 1200	Closing Remarks	TC Co-chair
1200 – 1300	**Lunch**	
Time	**Agenda (AHWP Regulators Forum)**	**Responsible Person(s)**
1330 -1400	Registration	
1400 -1410	Welcome Speech	Dr. Yeo-Won Sohn, Korea MFDS
1410 - 1420	**Group Photo**	
1420 - 1500	Chinese Taipei (Q & A -10 min included)	Wen-Wei Tsai Taiwan FDA, Chinese Taipei
1500 - 1540	India (Q & A -10 min included)	Dr. Ravi Kant Sharma, Ministry of Health & FW, India
1540 - 1600	**Coffee Break**	

1600 -1640	Malaysia (Q & A -10 min included)	Mr. Zamane Abdul Rahman, Ministry of Health, Malaysia
1640 - 1720	Saudi Arabia (Q & A -10 min included)	Mr. Ali M. Al Dalaan, Saudi Food & Drug Authority, Kingdom of Saudi Arabia
1720 -1750	Q & A	
1750 - 1800	Closing Remarks	Dr. Hee-Kyo Jeong, AHWP Chair, Korea MFDS

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、南美洲及非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,目前該組織會員經濟體包括阿布達比(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)、哈薩克斯坦(Kazakhstan)、寮國(Laos)、馬來西亞(Malaysia)、緬甸(Myanmar)、蒙古(Mongolia)、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)以及我國(Chinese Taipei)等 26 個國家，且會員國尚持續增加中。自全球醫療器材法規調和會(Global Harmonization Task Force，簡稱 GHTF)於 2012 年解散之後，AHWP 是目前全球擁有最多會員體的醫療器材法規調和組織，也是唯一由法規主管機關與業者代表共同組成的組織。

AHWP 大會轄下設有秘書處及技術委員會(Technical Committee, TC)，經 2014 年組織重整後，現技術委員會共包含 9 個工作小組(Working Group, WG)及 1 個特殊任務小組(Special Task Group, STG)，分別為 Work Group 1 (WG1) - Pre-market: General MD、Work Group 2 (WG2) - Pre-market: IVDD、Work Group 3 (WG3) - Pre-market: Software as a Medical Device、Work Group 4 (WG4) - Post-Market、Work Group 5 (WG5) - Clinical Performance & Safety、Work Group 6 (WG6) - Quality Management System: Audit & Assessment、Work Group 7 (WG7) - Quality Management System: Operation & Implementation、Work Group 8 (WG8) - Standards、Work Group 9 (WG9) - Training 以及 STG (U&N) - Special Task Group on UDI & Nomenclature 等小組。

我國食品藥物管理署醫療器材及化粧品組蔡技正文偉為現任 AHWP 技術委員會轄下體外診斷醫療器材工作小組(WG2 - Pre-market: IVDD)主席。AHWP 之主要任

務係要藉由與相關法規調和國際組織合作,制定醫療器材管理相關之法規指引文件，以期建立國際調和之醫療器材管理要求、審查程序及參考標準等，協助各國醫療器材主管機關建立共識並採用相同醫療器材管理模式，奠定國際間相互承認之基礎，進而促成國際醫療器材法規調和。

AHWP 於每年舉辦一場技術委員會領袖會議(Leaders Meeting)，通常由技術委員會主席主持，並邀請各工作小組及特殊任務小組之主席及副主席與會，報告其工作進度及未來工作規劃，通常亦會邀請來自各領域專家的 AHWP 技術委員會顧問團(TC Advisors)共同與會，提供各工作小組各項工作專家意見。本次 2016 年亞洲醫療器材法規調和會技術委員會領袖會議(2016 AHWP TC Leaders Meeting)，主辦單位為韓國食品藥物安全部(Ministry of Food And Drug Safety，簡稱 MFDS)，MFDS 為促進韓國醫療器材產業對各國相關法規之瞭解，於本次會議併同辦理主管機關論壇(AHWP Regulators Forum)。本次會議由蔡技正文偉以 WG2 工作小組主席身分，赴韓國首爾出席與會，時間為 105 年 4 月 26 日至 4 月 30 日，藉由參加此次會議，瞭解 AHWP 各工作小組目前工作進度及未來規劃，並於會中簡報 WG2 工作小組進度，及於主管機關論壇簡報我國醫療器材法規管理制度，增加我國於國際之能見度，並促進我國療器材法規國際調和化之願景。

本次會議第一天(4/27)，主要任務為進行 WG2 與世界衛生組織(World Health Organization, WHO)之未來合作會議，WHO 與會代表 Ms. Irena PRAT 為該組織下體外診斷醫療器材預先認證小組(IVD Prequalification Team，簡稱 IVD PQ Team)之組長，本次會議尚有 Ms. Petra KAARS-WIELE (AHWP TC Advisor)、5 位韓國 MFDS 代表及 5 位韓國業界代表等人，共同討論未來 WG2 與 WHO 之合作方案，並已有初步共識如下：

- IVD PQ Team 目前正執行體外診斷醫療器材預先認證計畫(IVD Prequalification Program，簡稱 IVD PQ Program)，未來將草擬體外診斷醫療器材預先認證相關文件,共計約二十份以上,清單將另提供 WG2 參考。

WHO 體外診斷醫療器材預先認證相關文件之研擬，可作為雙方初步合作之方向，共同討論文件內容。

- WHO IVD PQ Program 目前所遭遇之主要問題與挑戰，為受援助地區缺乏產品審查的能力與經驗，故需藉由其他國家地區之經驗，提供支援。
- WG2 正研擬之 AHWP IVD 相關基準，亦將邀請 WHO 提供意見，雙方相互提供專業知識之支援。

本次會議第二天(4/28)為 AHWP TC Leaders Meeting，會議由各工作小組代表簡報說明，並由技術委員會主席、副主席與顧問團提供意見。我國與會代表於會上說明 WG2 工作小組進度，包括正研擬之「Common Template for a Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices」、「Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices」及「Principles of In Vitro Diagnostic (IVD) Medical Devices Classification」等 3 件基準文件，及將起草本年度 AHWP TC 指派之新工作項目「Guidance for In vitro Companion Diagnostic Devices (IVD-CDx)」基準文件，簡報資料詳如附件 1，另有關其它各工作小組簡報重點摘要彙整如下表所示：

Work Group	現況及 2015- 2017 年工作規劃摘要
WG1 - Pre-market: General MD	● 現有 25 位成員 ● 目前正研擬且預定於本年度 AHWP 年會公告之文件： a. Guideline in the qualification of combination products and technical requirements during pre-market submission. b. Guideline of basic policy and responsibility fulfillment process for review and approval work c. Guideline on preparation of technical andsupporting documents for review and approval on medical devices manufactured by 3D printing d. Guideline on identifying minor changes to registered devices (i.e. not affecting safety and effectiveness)

	and regulatory procedure for their notification and implementation ● 將啟動醫療器材產品群組(Grouping)相關基準文件之工作，預定 2018 年完成
WG2 - Premarket: IVDD	● 現有 27 位成員 ● 目前正研擬且預定於本年度 AHWP 年會公告之文件： a. Common Template for a Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices b. Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices ● 其它已啟動研訂之文件清單如下： a. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification b. Guidance for In vitro Companion Diagnostic Devices (IVD-CDx)
WG3 - Premarket: Software as a MD	● 現有 11 位成員 ● 進行中之工作項目： a. Risk Classification of Medical Device Software /SaMD b. White paper / Position paper on Pre-market initial and change Submission format for SaMD c. Feasibility Study on QMS for SaMD, based on IMDRF guidance document
WG4 - Post-Market	● 現有 25 位成員 ● 重新審視國際上及 AHWP 內部各相關文件中，醫療器材不良事故之定義，確認該工作小組 Adverse Events (AE) Reporting 文件是否需修訂 ● 研擬特定醫療器材(如：冠狀動脈血管支架)不良事故通報基準文件 ● 將啟動之工作清單 a. Review and update the existing WG4 guidance

	documents on Safety Alert Dissemination System (SADS) b. Identify post market systems (AE or safety alert) or guidance from various regulatory authorities or sources
WG5 - Clinical Evidence for Performance and Safety	● 現有 27 位成員 ● 將針對 WG5 framework 進行 SWOT 分析 ● 持續代表 AHWP 參與 ISO 14155 修訂之相關活動，並監視 IMDRF 與臨床驗證相關之活動進度 ● 啟動研擬醫療器材/ 體外診斷醫療器材之臨床評估(Clinical evaluation)及臨床證據(Clinical evidence)相關指引
WG6 - Quality Management System: Audit & Assessment	● 現有 7 位成員 ● 審閱 IMDRF/MDSAP WG/N8R2 – "Regulatory Authority Assessment Method Guidance" 及 IMDRF/MDSAP WG/N24R2 – "MDSAP Audit Report Guidance"，並提供意見給 IMDRF ● 確認 WG6 及 WG7 兩工作小組研訂之文件內容無矛盾 ● 啟動審閱 IMDRF 文件，包括 IMDRF/MDSAP WG/N3、N4、N5、N6、N11 及 N22 等 ● 採認前述 IMDRF MDSAP 工作小組已公布之 6 件基準文件
WG7 - Quality Management System: Operation & Implementation	● 現有 15 位成員 ● 進行 AHWP 各會員經濟體對於 AHWP WG7 基準文件使用之訓練 ● 持續代表 AHWP 參與 ISO/TC 210 相關活動
WG8 - Standards	● 現有 8 位成員 ● 持續彙整共識標準(Common Consensus Standards)及採認基準文件清單 ● 招募積極參與 WG8 活動之核心成員
STG - UDI & Nomenclature	● 現有 27 位成員 ● 持續觀察美國第三等級醫療器材 UDI 的實施成果及其影響評估

	● 持續監視國際間對醫療器材命名規則之發展並參與法規調和工作 ● 持續監視國際間對醫療器材 UDI 之發展並參與法規調和工作

另外，由於去年(2015 年)於 AHWP 年會中，WG2 研擬之基準文件「Definition of the Terms 'Medical Device' and 'In vitro Diagnostic (IVD) Medial Device'」，因於採認程序前刻，臨時收到來自國際醫療器材官方論壇(International Medical Device Regulators Forum，簡稱 IMDRF)成員對該文件之意見，TC 臨時決議暫緩該文件之採認程序。於本次會上，我國與會代表針對此文件之現況進行說明，最終 AHWP TC 領袖作成決定，同意將於今年 AHWP 年會上採認該基準文件。會上 AHWP TC 領袖亦表達立場，在與其他組織的合作與尊重同時，亦不應因此而過度延誤 AHWP 之進度，本基準文件之狀況，或可作為未來類似情況之參考。另外，於會上亦宣布，有關本年度之 AHWP 年會，暫訂將於 11 月 21 日至 25 日在菲律賓宿霧舉辦，請各與會者預留時間，詳細議程如有新進展將再由 AHWP 秘書處提供更新。

此外，由於 AHWP 組織願景、任務與目標，部分內容已稍過時(例如：尚提及與 GHTF 之合作)，本次會議中，亦進行討論修訂內容，目前草案版本如下，並預訂將於本年度 AHWP 年會時公布。

- Vision：To achieve international harmonization and convergence of medical device regulations through collaborative efforts of regulators and the industry in Asia and beyond
- Mission：To strategically accelerate medical device regulatory convergence through promoting an efficient and effective regulatory model for medical devices
- Goals
  - To study, develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and beyond

- To work transnationally in collaboration with IMDRF, WHO and the related international organizations
- To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements
- To promote capacity building in member economies and to foster strategic membership expansion

本次會議第三天(4/29)主為主管機關論壇，我國與會代表亦受邀演講我國醫療器材之管理制度，簡報資料詳如附件 2，其他講者尚包括來自印度衛生部(Ministry of Health, India)的 Dr. Ravi Kant Sharma、馬來西亞衛生部醫療器材管理局(Medical Device Authority, Ministry of Health, Malaysia)的 Mr. Zamane Abdul Rahman(現任 AHWP Vice Chair)及沙烏地阿拉伯王國食品藥物管理署(Saudi Food & Drug Authority)的 Mr. Ali M. Al Dalaan(現任 AHWP TC Chair)等。

印度中央藥物標準管制中心(Central Drugs Standard Control Organization，簡稱 CDSCO)為該國藥品、醫療器材及化粧品之主管機關，負責新藥(含醫療器材)及臨床試驗之核准、輸入產品之註冊(Registration)與發證(Licensing)、違法藥物與化粧品取締、藥物檢驗等業務。該國法規訂定藥品的範圍，包括醫療器材及體外診斷試劑，有關印度醫療器材管理制度，較特別的是，政府不定期公布加強管制產品品項(Notified Devices/Kits/Reagents)，如為清單內產品辦理輸入時，其將同時要求製造廠登錄許可、產品上市前註冊(類似我國之查驗登記)及屢次輸入之許可；如為非清單內產品辦理輸入時，僅需製造廠登錄許可及屢次輸入之許可，即可免除上市前註冊。

在馬來西亞，醫療器材管理局(Medical Device Authority，簡稱 MDA)為醫療器材之主管機關，負責醫材製造廠管理、產品上市前及上市後管理等業務。該國醫療器材依產品風險程度，共分為四級(A、B、C、D)，產品上市前須經登記程序，較特別的是，該國為提升醫療器材審查之時效，設計多種簡化模式，包括指定國家上市簡化、符合性評估機構(Conformity Assessment Body，簡稱 CAB)認證簡化、符合豁免條件之簡化等一系列措施，其中，豁免條件包括低風險產品(未滅菌、非動力式且

不具量測功能)、研究用產品、緊急情況下之醫療人員使用產品、以及客製化產品等。接著，有關沙烏地阿拉伯王國的醫療器材管理制度中，較特別的是，該國針對境內藥商(包括醫療器材製造廠、輸出藥商、輸入藥商、經銷商、被授權代表)的登記管理，係採國家醫療器材註冊(Medical Device National Registry，簡稱 MDNR)線上系統登記方式，整體來說，該國對醫療器材之管理，較著重於上市後監視之機制。

肆、建議事項

1. 鼓勵國內醫材相關專家參與法規國際調和活動

   本次參會經驗，觀察得知 AHWP 組織內各工作小組之工作，韓國官方積極動員產、學、研界之資源，本次會議共有數十位來自學校、醫院及業界等專家，協助支援韓國 MFDS 官員執行醫療器材法規國際調和相關任務。建議未來鼓勵我國醫療器材產、學、研、醫界，多參與法規國際調和相關活動，以提升我國執行醫材法規國際調和之能量，並於適當機會導入我國產業需求於相關法規基準中。

2. 鼓勵醫療器材相關國產業者加入國際組織

   國產醫療器材廠商規模相對國際知名醫材廠較小，故投入資源於醫療器材國際法規相關事務之意願及比例也較低，建議國產醫療器材相關業者仍應關注國際法規趨勢，並鼓勵加入相關國際組織及參與國際會議活動，增加國內廠商參與國際法規事務之機會，藉此增進國產業者對其它國家法規現況瞭解，促進我國醫材產品向國外輸出的契機。

3. 加強與重要國際組織及各國之國際合作關係

   我國醫療器材法規及管理制度，於 AHWP 各會員經濟體中，屬相對較成熟完整，故我國具有豐富醫材管理經驗及眾多醫材領域專業人才，尚為與相關重要國際組織(如：IMDRF、WHO 或 ISO 等)及其它國家建立合作關係之優勢，加強實質之國際合作，除可間接促進與各國法規管理之國際調和外，亦可提升我國之國際形象。

附件 1

WG2 – Pre-market: IVDD

AHWP TC Leaders Meeting
28-29 Apr, 2016, Seoul

Asian Harmonization Working Party

Membership Status

- Chair: Dr. Wen-Wei TSAI
- Co-Chair: Ir Prof. Albert KF POON
- Advisor: Ms. Shelley TANG
- No. of WG members: 27
  - 11 regulators
  - 16 industries

Objectives 2015-2017

- To assist AHWP member economies in implementing regulatory framework of IVD medical devices by
  - Developing AHWP documents on premarket regulatory control of IVD medical devices.
  - Providing recommendations and useful guidelines on how to implement regulatory framework of IVD medical devices.
- To support regulatory convergence through
  - Participating in International/Global Organization collaboration and activities. (e.g. ISO/TC 212, WHO etc.)
  - Encouraging interest and participation of the AHWP member economies in establishing and reviewing the specific requirement of IVD premarket regulatory control.

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 Common Template for a Submission Dossier		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)	In Vitro Companion Diagnostic Devices (IVD-CDx)		Mar 2016 to Jul 2017
(6)	IVD Labelling		Oct 2017 ~
(7)	Advertising and promotion		Oct 2017 ~
2	Environmental scanning and survey for IVD premarket regulatory controls	Survey Report	Mar 2015 to Jun 2016
3	Participate in International/Global Organization collaboration and activities (e.g. ISO/TC 212, etc.)	Standard Guidance Comment	Attend the activities of ISO/TC 212/WG3 to work on standard regarding technical requirements for IVDs

WG Progress Update (I)

since last AHWP Bangkok TC Meeting in 2015

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	• IMDRF had no comments on the proposed final guidance. • Have modified the introduction of the guidance and call for comment again within WG1 and WG2. • Will send TC the final document by 29 Feb for the endorsement procedure.
		2) IVD Common Template for a Submission Dossier	Jun 2015 to Dec 2016	• Has discussed during telecon on 17 Mar. • Will circulate the working draft of Conformity Assessment for IVDs and Classification of IVDs in Q2. • Will complete the working draft of the IVD CTSD guidance by 2 FTF meetings.
		3) Conformity Assessment for IVDs	Aug 2015 to Aug 2017	
		4) Classification of IVDs	Aug 2015 to Aug 2017	
		5) In Vitro Companion Diagnostic Devices	Mar 2016 to Jul 2017	
3	Survey on IVD regulation status and premarket requirements for AHWP member economies	Survey Report	Mar 2015 to Jun 2016	• Partial results have been reported in Bangkok AHWP annual meeting. • Adding more countries' data in the report draft. • Seek TC/Secretariat's comment on the next step of the Survey Report. Follow up the comments.

WG Progress Update (II)

since last AHWP Bangkok TC Meeting in 2015

No.	Work Item	Deliverables	Timeline	Progress Update
4	Participation in International/ Global Organization collaboration and activities	1) Establish IVD WG representation to ISO/TC 212/WG3 regarding technical requirements for IVDs 2) Provide recommendations on the specific WHO IVD PQ program guidance	2015 to 2017	• ISO/TC 212 has accepted and added two WG2 contacts in TC 212 distribution list. WG2 will comment the draft IVD ISO standard. • Has provided the comments for WHO guidance: Establishing stability of an in vitro diagnostic for WHO Prequalification by 29 Feb. • Has provided the comments for WHO guidance: Reportable Changes to a WHO Prequalified In Vitro Diagnostic by 31 March 2016. • Will have a side meeting with Ms. Irena Frat of WHO IVD PQ program to discuss collaboration between the two group on 27 Apr.
5	Collaboration with other WGs		2015 to 2017	• WG1: Guidance Document of MD/ IVD Definition • WG5: Will organize a conference on IVD Medical Devices Regulation and Clinical Performance Evaluation in Taipei to provide training to the WG members.

WG Document towards Endorsement at the 21th AHWP Annual Meeting 2016

No.	Title/Content	Type of Document
1	Common Template for a Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	Guidance Document
2	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices	Guidance Document

Thank you

附件 2

Medical Device Regulations in Taiwan

藥求安全　食在安心

Presenter: Dr. Wen-Wei TSAI
Technical Specialist
Division of Medical Devices and Cosmetics

衛生福利部食品藥物管理署
Food and Drug Administration
Ministry of Health and Welfare
http://www.fda.gov.tw/

Outlines

- Organization and Responsibility
- Medical Device Regulatory Framework
- Comprehensive Consultation System
- Recent Changes in Medical Device Regulations
- Future Initiatives

Organization and Responsibility

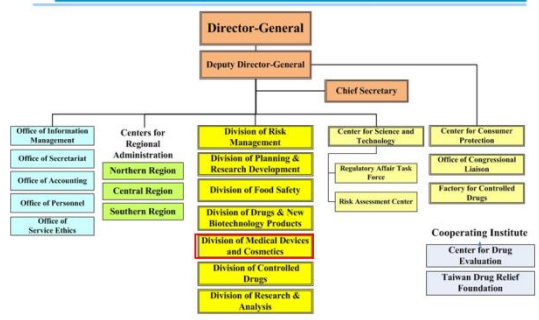
Establishment of TFDA

2009.6.3 TFDA Organization Act → 2010.1.1 TFDA Inauguration → 2011~2013 Government Restructure → 2013.7.23 TFDA Elevation

Bureau of...
- Food Safety
- Pharmaceutical Affairs
- Food and Drug Analysis
- Controlled Drugs

Consolidate → FDA

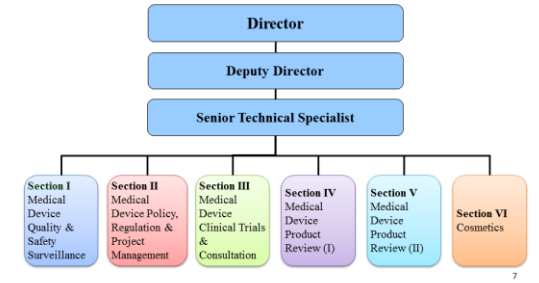
Organization Structure of TFDA



Roles and Responsibilities of TFDA

- Public Health Protection
  - Gate keeper
  - Prudent evaluation based on Good Review Practice
  - Safety, effectiveness and quality
- Health Promotion Through Facilitating Innovation
  - Efficient and transparent review process
  - International harmonization of regulation
  - Consultation mechanism

Organization Diagram of Division of Medical Device and Cosmetics



Vision and Mission

Safeguard public health
Create a new era for regulation of medical devices and cosmetics
Smart regulation and create win - win

Duties of Division of Medical Devices and Cosmetics

- Regulation, policy, and statute drafting of medical devices and cosmetics
- Review of medical devices and cosmetics registration, license amendment, transfer, and extension, and issuing, renewing, and reissuing of such licensing
- Safety surveillance, evaluation, and consultation assistance of medical devices and cosmetics
- Review and regulation of medical device human trials
- Regulation of medical devices for emergent uses
- Others matters relating to regulation of medical devices and cosmetics

9

Medical Device Regulatory Framework

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Medical Device Regulatory Framework

- National ADR Reporting System
- Active surveillance of international medical device safety alerts
- NCAR Exchange Program

Quality System Management GMP/QSD
Pre-market registration
Medical Device Distribution management
Post-market surveillance
Medical Devices

- GMP/QSD implementation: 1999
- Effective compliance letters total 4,325 (Data as of end 2015)

- Beginning of registration: 1973
- All medical devices, effective licenses total 41,293 (Data as of 15th Apr 2016)

(76.24% imported)

- Dealers, total 42,516 companies
- Open mail order sales for certain low risk devices

(Data as of end 2015)

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Medical Device Life Cycle Management

Medical Care Needs/ Fundamental Study → Product Design/ Prototype Development → Preclinical Validation → Clinical Trial → Premarket Application → Production → Postmarket Surveillance

General/Case Consultation
Product Designation
Laboratory Practices (GLP/GTP)
Clinical Trial Inspection (GCP)
Clinical Trial Protocol Review (TFDA/IRB)
Premarket Control
Registration (Approval/ Listing)
MD Advisory Committee
Postmarket Control
Production Quality System Control
Manufacturer's Quality System Audit (GMP)
ADR & Product Defect Reporting
Safety Surveillance & Alert Collection (GVP)
Consumer Health Education Promotion
Good Distribution Practice (GDP)

MDs : Medical Devices
GLP : Good Laboratory Practice
GTP : Good Tissue Practice
GCP : Good Clinical Practice
IRB : Institutional Review Board
GMP : Good Manufacturing Practice
ADR : Adverse Drug/Device Reaction
GVP : Good Vigilance Practice

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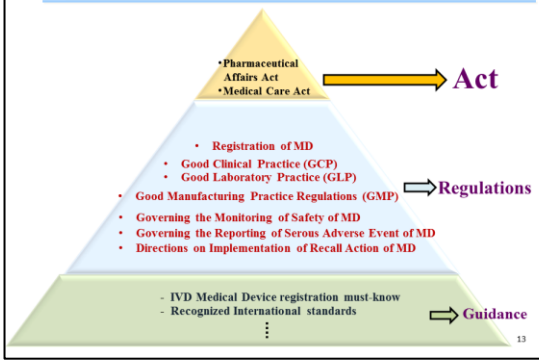
Basis of Medical Device Regulation



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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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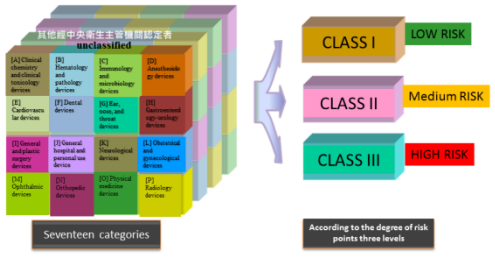
Medical device category

- Pursuant to Article 3 of Regulations for Governing the Management of Medical Device, medical devices classified by intended use and mode of action with seventeen categories.



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Medical device category

A. Clinical chemistry and clinical toxicology devices
B. Hematology and pathology devices
C. Immunology and microbiology devices
D. Anesthesiology devices
E. Cardiovascular devices
F. Dental devices
G. Ear, nose, and throat devices
H. Gastroenterology-urology devices
I. General and plastic surgery devices
J. General hospital and personal use devices
K. Neurological devices
L. Obstetrical and gynecological devices
M. Ophthalmic devices
N. Orthopedic devices
O. Physical medicine devices
P. Radiology devices

unclassified

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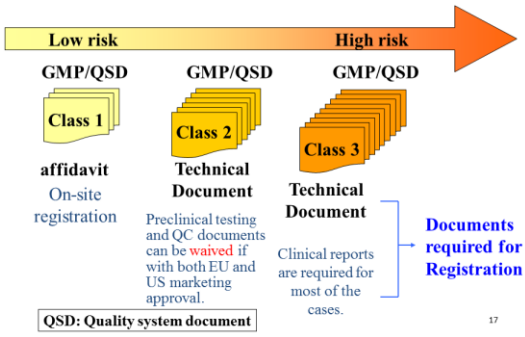
Risk Based Regulation



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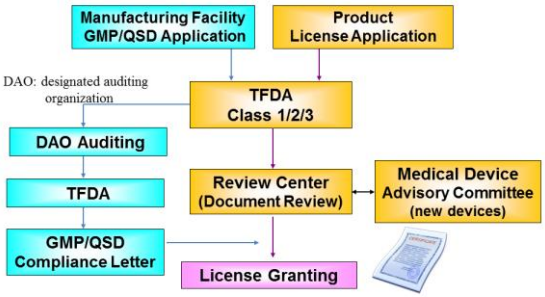
Before Marketing a Medical Device Product in Taiwan



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Class II/III MD/IVD Registration Requirements

Registration Requirements

- Application form
- Instructions, manual, packaging, and labels
- * Free sale certificate from original manufacturing country
- * Authorization letter issued by original manufacturer
- GMP/QSD compliance letter
- Information on product construction, materials, specifications, performance, uses, and drawings etc.
- The pre-clinical testing and quality control test specifications and methods, test records, and test report.
- Clinical evaluation reports (if required)

* Be required for **import** products only

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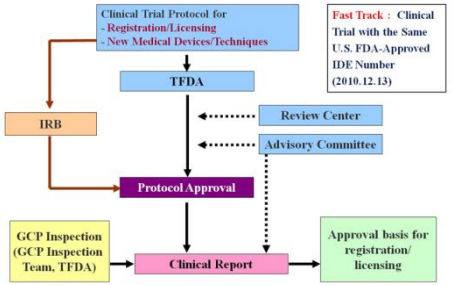
Clinical Protocol Review Process



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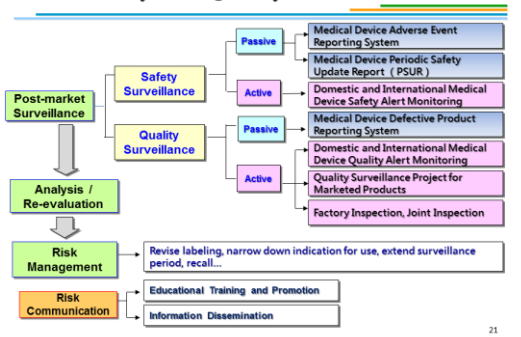
Medical Device Post-market Safety and Quality Surveillance



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On-line Reporting System

- Provide on-line reporting of adverse events

http://qms.fda.gov.tw

Hyperlink to get updated safety information

22

Safety information to the public

- Provide updated safety information

http://qms.fda.gov.tw

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Comprehensive Consultation System

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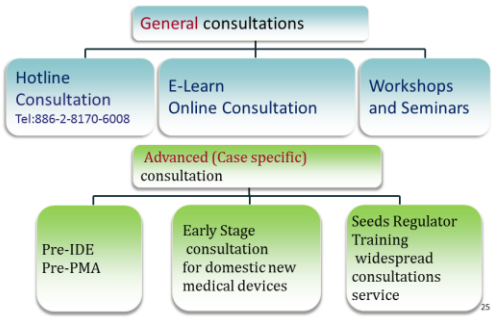
Comprehensive Consultation for Medical Device Industry



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Recent Changes in Medical Device Regulations

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Premarket Review (2014)

- Amended "**Regulations for Registration of Medical Device**"
  - Applications for pre-market approval of Class 3 devices must conform with the requirements specified in EP/STED Guidelines announced by TFDA.
- Announced "**Good Submission Practice**" (GSP)
  - Provide reference for device firms in the preparation of registration documents.
  - Help enhance the quality of submitted documents and accelerate the review efficiency.

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Premarket Review (2014~2015)

- Amended "**Regulations for Governing the Management of Medical Device**"
  - Timely amend the regulatory requirements of medical device classification, so to align with international regulatory trends and cope with domestic regulatory needs

Amendment Dates	Amendments	Revisions
2014.1.7	29	7
2014.9.22	0	9
2015.6.3	26	26

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Premarket Review (2015)-1

- Announced 59 technical guidance for medical device products (including 13 IVDs)
  - In order to improve review in consistency and transparency.
  - For products, such as coronary Stents and Associated Delivery System, Transcutaneous Electrical Nerve Stimulators (TENS), Human Papillomavirus Serological Reagents, Antinuclear Antibody Immunological test system, etc.

29

Premarket Review (2015)-2

- Announced "Medical Software Category and Classification" & "Nano-Medical Devices Identification", guidance for industry
  - Provide reference for device firms in the initial determination of product category and classification
  - Facilitate product research & development
  - Serve as a basis to be followed in the application for registration

30

Premarket Review (2015)-3

- Announced "Principles for Compiling Chinese Instructions of General Medical Devices" & "Principles for Compiling Chinese Instructions of IVD Medical Devices
  - Define and explain the basic contents that should be included in Chinese instructions
  - Provide reference for device firms to compile Chinese instructions
  - Ensure completeness of the contents of Chinese instructions

31

Clinical Trial

- Announced on October 16, 2015 the "Medical Device Good Clinical Practice" (GCP)
  - Establish a regulatory practice for clinical trials that is harmonized with the widely accepted and globally adopted ISO 14155:2011
  - Help enhance the quality of domestic clinical trials
  - To be implemented starting on January 1, 2016

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Distribution Management

- Announced on October 30, 2015 the "Unique Device Identification (UDI) System Practice", with Annex I "Introduction of Medical Device UDI" & Annex II "General Description of UDI Coding Standards", guidance for industry.
  - Contents primarily adopt the 3 UDI issuing agencies recommended by IMDRF & U.S. FDA and their coding standards (GS1 128, HIBBC HIBC, ICCBBA ISBT128)
  - Intend to achieve the following objectives:
    - Establish internationally acceptable UDI coding and barcode specification for imported and domestic medical devices
    - Communicate the development of UDI labeling and application
    - Facilitate building a foundation for automatic distribution management

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Postmarket Surveillance (2015)

- Promulgated on August 5, 2015 the "Regulations for Medicament Recall" to ensure consumer protection
- Announced on June 18, 2015 the "Medical Device Good Distribution Practice" (GDP) to ensure product quality during distribution and strengthen regulatory oversight of device firms.
- Implemented a "Pilot Program for Medical Institutions on the Medical Device Adverse Event Reporting and Evaluation by volunteered hospitals" to increase risk awareness of medical device use.

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Future Initiatives

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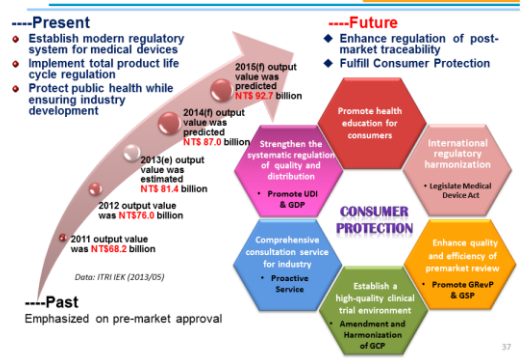
Future Regulatory Goals and Strategies for Medical Devices

Goal / Timeframe	Short term	Mid-term	Long term
Improve regulatory system	1-1. Establishment of dedicated law for medical devices		
	1-2. Build quality medical device clinical trial regulatory environment		
	1-3. Sustain training system for professionals		
Implement premarket regulatory oversight	2-1. Enhance medical device review quality and efficiency		
	2-2. Build a third party accreditation system for conducting regulatory review		
Build risk management mechanism to safeguard consumers' safety	3-1. Build a UDI system information platform for high risk medical devices		
	3-2. Promote medical device good distribution practice (GDP)		
	3-3. Strengthen the effectiveness of medical device post-market surveillance		
	3-4. Strengthen education of consumers on the risk of using medical devices		

Prospects



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