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(AHWP)
第 22 屆年會系列會議

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、吳正寧科長、
蔡文偉技正、李思鈺視察
派赴國家：印度
出國期間：106 年 12 月 3-10 日
報告日期：107 年 3 月 2 日

摘要

亞洲醫療器材法規調和會(Asia Harmonization Working Party, AHWP)第22 屆年會系列會議於印度新德里舉辦，系列會議包括為期 3 天的 Training Workshop、第 4 天之第 21 屆 AHWP Technical Committee (TC) Meeting 及第 5 天之第 22 屆 AHWP Annual Meeting。

本次第 22 屆年會為新一任 2018-2020 年的大會主席、副主席以及 AHWP TC、各工作小組 (Work Group, WG)等之主席、 副主席等職位選舉。本次年會共有來自 30 個不同國家，超過 240 名各界醫療器材領域專業人士共襄盛舉。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 (WG2-IVDD)主席之蔡文偉技正等一行 4 人代表與會。

於前 3 天 Workshop 中， 除由包括沙烏地阿拉伯、印度、新加坡、韓國及澳洲等的代表，簡介各國醫療器材法規概況外，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) MDSAP) 、ISO 13485 標準更新、臨床試驗環境、3D 列印等專題進行演講與討論。

第 4 天的第 21 屆 AHWP TC Meeting，由 AHWP TC 及各 WG 先進行閉門會議，並由 TC 及各 WG 的主席報告工作進度與展望。本署蔡文偉技正代表 WG2 進行報告，包括產出 IVD 產品管理相關指引文件以及辦理 WG2 面對面工作會議等。

第 5 天的第 22 屆 AHWP Annual Meeting 進行新一任的領袖選舉，由馬來西亞的 Mr. Zamane Abd Rahman (Chief Executive, Medical Device Authority, Ministry of Health)擔任 AHWP 大會主席，由沙烏地阿拉伯 Mr. Ali M. Al-Dalaan 擔任 AHWP TC 的主席，本署蔡文偉技正亦順利連任 WG2 主席一職，本次年會中表決通過肯亞成為 AHWP 第 31 個會員國。

關鍵詞（Keyword）：亞洲醫療器材法規調和會（AHWP）、國際醫療器材法規官方論壇（ IMDRF）、醫療器材單次稽核方案（MDSAP）、東南亞國家協會（ASEAN）、亞太醫療技術協會（APACMed）。

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壹、目的

亞洲醫療器材法規協和會（Asian Harmonization Working Party, AHWP）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，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，會員體橫跨亞洲、南美洲、非洲，於今年年會前已有 30 個經濟體加入其會員（member economies），成員包括主管機關及產業界代表，且有數個國際組織與其聯繫交流（liason members），以期建立全球醫療器材法規要求、程序與標準之調和。本次第 22 屆年會系列會議於 106 年 12 月 4 至 8 日在印度新德里舉行，包括了 3 天的 Workshop、第 21 屆 AHWP TC Meeting 及第 22 屆 AHWP Annual Meeting。

為與 AHWP 會員國之產官代表進行交流洽談，並爭取本署代表連任 AHWP TC 之 WG2 體外診斷醫療器材 IVDD 工作小組主席，本署由杜培文組長率同現任 WG2 主席之蔡文偉技正等一行 4 人共同出席會議，以參與年會間研商之重要決策，並說明我國主導 IVDD 工作小組之業務進度及未來規劃。另本署於本次年會首次推派官方代表觀摩 WG6，以期能將我國於醫療器材管理之成果及能力全面展現於國際舞台。

貳、過程

一、本屆 AHWP 年會系列會議，大會規劃分為 1.5 天的 AHWP Capacity Training、1.5 天的 AHWP TC Workshop、1 天的第 21 屆 AHWP TC Meeting 及 1 天的第 22 屆 AHWP Annual Meeting，為期共 5 天，日程總表如下，大會提供之詳細議程如附件一，會議實況部分未依該議程進行。

日期	會議/活動
12/4	AHWP 系列會議開幕及醫材法規資訊更新
12/5	AHWP Playbook Training Workshop
12/6	AHWP Playbook Training Workshop and TC WORKSHOP
12/7	第 21 屆 AHWP TC Meeting
12/8	第 22 屆 AHWP Annual Meeting

另外，除 AHWP 年會系列會議議程外，我國食藥署因擔任體外診斷醫療器材工作小組（WG2）主席，亦藉此會議已聚集 WG2 相關成員與專家之機會，特於 12/4 下午假印度國家生物研究院會議室召開 WG2 面對面工作會議，討論相關工作內容。本次工作會議，主要討論已撰擬的「Label and Instructions for Use for In vitro Diagnostic Medical Devices」指引草稿文件，針對 WG2 成員內部所收集之意見，逐項討論，由於本次工作會議時間有限，本次尚無法完成所有意見之檢視與討論，後續將於下次 WG2 工作會議，接續本次工作進度。此外，於本次會議，亦針對 WG2 下一任期(107 年至 109 年)工作項目，由 WG2 成員提案，並進行討論，作為 WG2 未來工作之參考。本次會議參加者來自 11 個國家，共有 14 位(詳如下表)。

項次	姓名	備註
1	蔡文偉技正	我國食品藥物管理署；WG2 主席
2	Mr. Albert Ka-Fat POON	香港；WG2 副主席
3	Dr. Petra KAARS-WIELE	德國 Abbott 公司；AHWP TC 顧問
4	Ms. Shelley TANG	澳洲前 TGA 退休官員；WG2 顧問
5	Ms. Marriamah KRISHNASAMY	馬來西亞 MDA 官員；WG2 成員
6	Dr. Paulyne WAIRIMU	肯亞官員(Pharmacy & Poisons Board)；WG2 成員
7	Mrs Nutchnat KITIWOURANON	泰國 ThaiFDA 官員；WG2 成員
8	Dr. Reba CHHABRA	印度 NIB 官員；WG2 成員
9	Mr. Young Wook, AHN	韓國 MFDS 官員；WG2 成員

10	Ms. YoungSook Park	韓國 Abbott 公司；WG2 成員
11	Mr. Sanoj PRABHAKARAN	沙烏地阿拉伯聯合大公國 BD 公司；WG2 成員
12	Mr. Daniel CHANG	我國 Giraffes Pharmaceutical 公司；WG2 成員
13	Dr. Adelheid SCHEIDER	新加坡 Roche 公司；WG2 成員
14	Mr. Christopher CHAN	我國工業技術研究院；WG2 成員

二、關於每日會議之重點內容，逐日摘要記錄如下：

第 1 天（12 月 4 日）

首日主要議程為印度、新加坡、日本、南韓等國之醫材法規現況更新，並另有 ISO 13485 要求介紹、國際技術標準應用及澳洲臨床試驗環境等議題。上午先分別由主辦國印度衛生家庭福利部(Ministry of Health and Family Welfare)轄下中央藥物標準控制局(Central Drugs. Standard Control Organization, CDSCO)官員 Dr. G. N. Singh、Dr. Jagdish Prasad 等人開幕致詞歡迎與會者，接著，因現任 AHWP 大會主席(Chair)韓國 MFDS 官員 Dr. Hee-Kyo Jeong 已屆齡退休，故未到本次會議現場，由現任 AHWP 大會副主席(Vice Chair)馬來西亞官員 Mr. Zamane Abdul Rahman 以代理主席身分開場致詞，揭開序幕。

接著，是由印度 CDSCO 官員 Dr. V.G. Somani 介紹印度醫材管理法規更新，其說明印度醫材管理主要法源為 Drugs and Cosmetics Act(D&C Act, 1940)及 Rules(D&C Rules, 1945)，為簡化相關管理法規，於 2017 年 1 月 31 日公告 Medical Devices Rules(MDR)，並自 2018 年 1 月 1 日起適用，過去依據 D&C Act 所核發之舊許可證，緩衝期僅可使用至 2018 年 7 月，如舊許可證到期日在緩衝期截止日之前，即依舊證到期日為限。MDR 新規則將覆蓋原 D&C Act 規定所發布的相關公告，包括醫材進口、生產、臨床調查及銷售等，予以規範。

新規定將醫療器材依風險由低至高分為 A、B、C、D 共四個等級，其中，申請輸入、新體外診斷醫材的臨床效能評估、製造 C 與 D 等級 IVD 產品，需向中央發證機關(Central Licensing Authority, CLA)提出申請，該部分之查廠，由藥品稽查員(Drug Inspector, DI)進行。另外，A 與 B 等級醫材產品的製造及銷售，需向各州發證機關(State Licensing Authority, SLA)提出申請，該部分之查廠，將由指定之第三方認證機構(Notified Body, NB)進行。此外，新規定規範，醫材產品製造、輸入與販售，如為無類似品者，則須有臨床調查(Clinical investigation, CI)佐證。

接著，由新加坡衛生科學部(Health Science Authority, HSA)官員 Dr.

Rama Sethuraman 介紹該國醫材管理法規更新，其說明新加坡自 2007 年頒布健康產品母法(Health Products Act)後，先以醫材上市後管理為重點，並經 2010 年公告健康產品相關子法規(Health Products Regulations)，逐步將上市前納為強制性要求管理的一環。此外，Dr. Rama Sethuraman 特別提及新加坡對醫材管理的新措施，包括針對創新產品的上市前法規諮詢制度及優先審查機制，以符合醫材多元發展的趨勢。

另外，由日本厚生勞動省官員 Mr. Hiroshi Yaginuma 介紹日本醫材管理法規更新，提及日本為滿足病患及時取得所需醫材，已有些管理新思維正在進行中，包括指定罕病產品的優先審查(Priority review)機制、有條件核准(Conditional approval)機制及針對全球第一等條件醫材之先驅審查(Forerunner Review or SAKIGAKE Review)機制，並說明厚生勞動省正在建構相關管理系統，以推動真實世界資料(Real World Data)的使用，提供高效率和低成本進行實用試驗(Pragmatic trials)之機會。

第 2 天（12 月 5 日）

本日接續第一天的 Playbook Training Workshop，第一場由 AHWP 現任副主席 Mr. Zamane Abdul Rahman 講解東南亞國家協會（ASEAN）在管理主動植入式醫療器材的經驗。後續邀請 Dr. Vincent Lam 講解醫療器材認可機構腳色，如何於法規主管機關及醫療器材產業間取得平衡。下午邀請韓國 MFDS 的 Dr. Mijung Son 從法規主管機關腳色講解醫療器材臨床試驗評估內容，接續由產業代表 Mr. Arthur Brandwood 講解從產業面角度來講解臨床試驗評估部分，最後邀請 Dr. Benny Ons 來講解 IVD 性能評估相關法規。

本日另於會場外舉辦 WG6 之訓練課程，主講者為 Dr. Vincent Lam，為馬來西亞 TUV SUD 之資深經理，亦為 WG6 資深顧問。AHWP 一向對於 IMDRF 的指引與法規調和工作計畫相當重視，目前許多 IMDRF 文件皆有轉換成 AHWP 指引文件供會員國使用，本次訓練主要說明 WG6 目前採用 IMDRF 共 4 份文件，包含 IMDRF/MDSAP/WG/N3、IMDRF/MDSAP WG/N4、IMDRF/MDSAP/WG/N11 及 IMDRF/MDSAP/WG/N22，其內容轉為 AHWP TC WG6 文件，並經 AHWP 年會認可後正式發行文件供各會員自由使用。訓練課程中包含主管機關認可醫療器材查核機構之要件、查核機構之能力及訓練要求、認可查核機構執行「醫療器材單次稽核方案」(MDSAP)之評鑑及決定程序、查核機構之評鑑及認可決定等相關程序等，訓練課程約計 10 人參加，主要為法規主管機關之代表，除本署代表李思鈺視察外，另外韓國代表 Dr. Choi Jang-yong 亦以觀察員身分首次參加，藉由此次訓練課程了解各國對於 IMDRF 文件之熟悉度，透過與各方代表間交流，並以本署代表身分提供本署對這些文件內容之了解程度及執行狀況，包含如何運用於管理制度上，可協助並加速各會員代表們應用於未來規劃。另 AHWP 各會員國目前一致採認 ISO 13485:2003 作為醫療器材

業者品質管理系統要求，然自 2016 年新版公布後至 2019 年 3 月起全面實施期間，各會員國間有鑑於資源分布，目前仍在各自發展中，其中如我國及韓國皆已著手修正醫療器材業者品質管理系統要求法規，與國際同步接軌。本次會議中，IMDRF 推動之醫療器材單一稽核方案(Medical Device Single Audit Program, MDSAP)亦成為本次 AHWP TC WG 6 面對面會議討論的焦點，自 2017 年起已進入實施階段後，各會員國間仍在靜待該方案減免重複查廠之實際運作發展。

第 3 天（12 月 6 日）

上午接續第二天的 Playbook Training Workshop，主要講解上市後安全之問題，首先邀請來自阿曼的 Mr. John Ramesh 講解上市後數位化醫療器材之網絡資安問題，尤其目前無線網路發達下，如何確保儲存於醫療器材內之資訊不被惡意竊取。接續由沙烏地阿拉伯 FDA 的 Dr. Nazeeh S. Alothmany 講解上市後如何防止仿冒品於市面上流竄及目前在沙烏地阿拉伯實際發生情形。之後由目前 AHWP TC 副主席 Mr. Er Alfred Kwek 來說明廣告及標示主題，如何透過標示來達到廣告效益，卻不應該超越其醫療器材本身之效能，又能達到產業行銷目的。

上午結束 Playbook Training Workshop 後，下午安排 TC Workshop 內容，首先安排亞太醫療技術協會（Asia Pacific Medical Technology Association，簡稱 APACMed）主辦部分，邀請 Abbott 的 Ms. Ann Graves 主講經由 Tele-medicine 及 e-Health 執行器材操作之風險，從法規上適當性來說明，後續安排韓國 MFDS 的 Dr. Jang Yong Choi 來主講 3D 列印醫療器材相關法規規範，從製造端、QMS 稽查、上市前申請、臨床試驗、不良事件通報及回收等內容。後續會場安排 2 場平行會議，1 場為接續為 TC Workshop，另 1 場針對印度產業召開 Indian Industry Workshop。

第 4 天（12 月 7 日）

第 21 屆 AHWP 技術委員會(TC)會議於今日召開，今日會議的主要內容，為 AHWP TC 所有工作小組就過去 3 年成果詳盡介紹。茲以表格方式將其報告重點整理如下：

工作小組	近 3 年已完成事項
WG1	• Guidance on regulatory practices for Combination products • Guidance for minor change reporting • Handbook for Approval of Patient-matched Medical Devices Using 3D Printers (Target endorsement Dec 2017) • Regulation and treatment of e-IFU and e-Label of Medical Devices - Review of International Practice (Target

	endorsement Dec 2017)
WG2（我國擔任主席）	• Guidance Document for Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' • Guidance Document for Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Devices • Guidance Document for Classification of IVDs • Guidance Document for In Vitro Companion Diagnostic Devices • Label and Instructions for Use for IVD Medical Devices • Guidance Document for Conformity Assessment for IVDs (to be endorsed 2017)
WG3	• Guidance document on Qualification of Medical Device Software • Guidance document on Risk Categorisation of SaMD(Software as Medical Device) • White paper on Pre-market Submission requirements for SaMD • White paper on Cyber Security for SaMD
WG4	• Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting • Develop guidelines on Adverse Events (AE) reporting for PCI devices • Review and update the existing WG4 guidance documents on SADS • Survey report on post-market control of medical devices (2017) • Analyze global and local adverse event report practices of medical devices (2017) • Update the post-market resource center, the hyperlinks submitted to the Secretariat for sharing at the AHWP website (2017)
WG5	• Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting • Develop guidelines on Adverse Events (AE) reporting for PCI devices

	• Review and update the existing WG4 guidance documents on SADS • Survey report on post-market control of medical devices (2017) • Analyze global and local adverse event report practices of medical devices (2017) • Update the post-market resource center, the hyperlinks submitted to the Secretariat for sharing at the AHWP website (2017)
WG6	• Reviewing IMDRF proposed documents N8R2 and N24R2 • Finalizing Importer & Distributor Guidance doc. • Conducting training session during annual meeting on I/D adopted guidance documents • Aligning WG6 documents with WG7 documents • Reviewing IMDRF final document N11 &N22 • Reviewing IMDRF final document N3 &N4 • Reviewing IMDRF final document N5 &N6 • Submit the IMDRF documents for comments as draft proposed documents for AHWP ME • Conduct training session on MDSAP document • Conducting training session during annual meeting on IMDRF MDSAP guidance documents • AHWP/WG6/NXPDRX <DRAFT> Guidance on Understanding the Roles of IMDRF documents concerning auditing
WG7	• Participated ISO13485 handbook, (25 Sept), reference AHWP guidance document in bibliography. Definitive guide for ISO13485 worldwide • Revised IAF MD9 (21 June), reference AHWP guidance document in bibliography, and included provision of up to 50% reduction in auditor man-days if the entity is an importer/distributor during ISO13485 certification. • Involved in ISO14971 drafting committee, ISO24971 drafting committee, DGuide 63 drafting committee, and PMS processes ISO TR20416 drafting committee – to release all standards and TR by 2019. • Attended every ISO TC210 plenary as AHWP representative for 3 consecutive years.
WG8	• Create List of Recognised Standards used in AHWP member

	economies
STG (U&N)	• Continue interaction and exchange progress with international platforms for UDI and nomenclature status • Exchange progress and knowledge during CIMDR in Aug. in China • US implementation and experience • EU MDR requirements • Industry practice and lesson learned • Update China progress • Share the status of AHWP countries • Visited US FDA in 2017 to get more understanding of US UDI practice • EU roundtable to understand EU requirements on UDI • Shared the IMDRF guidance documentation with WG members and extended the possibility of adopting IMDRF document in 2018 • Alignment to adopt and transform IMDRF document into AHWP guideline

第 5 天（12 月 8 日）

AHWP 第 22 屆年會於今日舉行，主辦國及 AHWP 主席致完開幕詞後，AHWP 副主席 Tran Quan 先就 AHWP 的沿革歷程做一簡介，除完成訂定法規調和化指引文件外，並將以致力完成的文件（Playbook 及法規指引）為基礎，對會員國辦理訓練及能力建立，同時擴大會員數及全球夥伴關係，並就重要管理領域進行調和工作。之後，由 AHWP 技術委員會主席 Ali Al-Dalaan 接續報告 2017 年的工作成果，其內容為摘述各工作小組於 12 月 7 日的報告重點。

今日議程並安排大陸、印度、亞太經合會（APEC）及東南亞國家協會（東協，ASEAN）等會員國及相關國際組織簡報其業務現況。後續由 AHWP 副執行秘書長 Bryan So 提請大會通過今年收到的 1 件新會員申請案（肯亞），此次會議亦表決接受肯亞成為 AHWP 第 31 個會員國。接著由 TC 報告文件採認情形、新增 WG9，以及預算經費等事務性事宜，並於下午進行 AHWP 新一任(2018-2020)之領袖選舉，選舉結果如下：

AHWP	
Chair	Mr. Zamane Abd Rahman, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia

Co-Chair	Mr. Gao Guobiao, Deputy Director General, Medical Device Registration Dept., China FDA, People's Republic of China
Co-Chair	Ms. Quan TRAN, Vice President, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed), Singapore
AHWP TC	
Chair	Mr. Ali M. AL-DALAAN, Executive Director, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
Co-Chair	Dr. Jeong-Rim LEE, Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety (MFDS), Republic of Korea
Co-Chair	Mr. Alfred Kwek, Director, Public Affairs, Edwards Lifesciences, Lao PDR
AHWP TC Work Group 1	
Chair	Mr. Park Seil, Assistant Director, Division of High-Tech Medical Devices, Ministry of Food and Drug Safety, Republic of Korea
Co-Chair	Ms. Kate HyeongJoo KIM, Director, Regulatory Strategy & Innovation, ASPAC; Director, Regulatory Affairs, North Asia, Johnson & Johnson Medical, Republic of Korea
AHWP TC Work Group 2	
Chair	Mr. Wen-wei TSAI, Technical Specialist, Division of Medical Devices and Cosmetics, Food and Drug Administration, Ministry of Health and Welfare, Chinese Taipei
Co-Chair	Ir Prof. Albert KF POON, Professor of Practice (Biomedical Engineering), Interdisciplinary Division of BME, Hong Kong Polytechnic University, Hung Hom, Hong Kong
AHWP TC Work Group 3	
Chair	Dr. Youngwoo Bae, Assistant Director, Orthopedic & Restorative Devices Division, Dept. of Medical Device Evaluation, Ministry of Food and Drug Safety (MFDS), Republic of Korea
Co-Chair	Mr. Tony YIP, Associate Director, Regulatory Affairs

	APAC Grifols (HK) Limited, Hong Kong SAR
AHWP TC Work Group 4	
Chair	Ms. Jennifer MAK, Senior Electronics Engineer, Medical Device Control Office, Department of Health, Hong Kong SAR, China
Co-Chair	Ms. Kitty MAO, RA Director, GE Healthcare, Singapore
AHWP TC Work Group 5	
Chair	Ms. Yuwadee PATANAWONG, Director, Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health, Thailand
Co-Chair	Ms. Sumati Randeo, Director Global Strategy, Regulatory Affairs & Advocacy, Abbott Quality and Regulatory, Abbott Laboratories, India
AHWP TC Work Group 6	
Chair	Mr. Abdullah AL RASHEED, Compliance and Enforcement Excutive Director, Saudi Food & Drug Authority, Kingdom of Saudi Arabia
Co-Chair	Mr. Vincent LAM Chee-Choong, Senior Product Specialist, TUV SUD Product Service, TUV SUD, Malaysia
AHWP TC Work Group 7	
Chair	Mr. WANG Ai Jun, Director, Center for Food and Drug Inspection, CFDA, People's Republic of China
Co-Chair	Mr. Ee Bin Liew, Owner and consultant, Access-2-Healthcare, Singapore
AHWP TC Work Group 8	
Chair	Mrs. Salbiah Yaakop, Senior Principal Assistant Director, Medical Device Authority, Ministry of Health, Malaysia
Co-Chair	Mr. Tony LOW, Director of QA/RA and Human Performance, Commissioning Agents International, Malaysia
AHWP TC Work Group 9	
Chair	Ms. Jun LI, Division Director of Medical Device Registration,

	Medical Device Registration Department, China Food and Drug Administration, People's Republic of China
Co-Chair	Ms. Victoria QU, Director Regulatory Affairs, Global Strategic Regulatory Abbott, People's Republic of China

參、心得與建議

我國為 AHWP 組織創始國之一，亦曾多次於 AHWP 組織中擔任重要職務，於該組織中提供醫療器材法規之台灣經驗，對於法規國際調和之努力與貢獻，一直深獲 AHWP 大會及各會員國的肯定，並與各會員國間已建立穩定之國際關係。透過本次派員參與年會，展現我國醫療器材法規國際調和現況，並可瞭解 AHWP 重要政策發展方向及標準指引採認現況，亦可與各國代表洽談雙邊或多邊未來可能合作機會，不僅能提升我國之國際能見度，亦能建立我國之國際形象，對於我國醫療器材相關產業走入國際市場亦有所助益，建議持續積極參與 AHWP 國際組織年會及相關事務對我國確有實質效益。

AHWP 屬法規國際調和技術層面之組織，相較於另一重要國際醫療器材法規論壇 IMDRF 組織，限制會員國申請，且工作項目與政策方向僅限會員國之法規主管機關人員參加，較為開放的 AHWP 組織會員國已達 31 國，法規國際調和亦不再侷限於亞洲區域，已漸受各國重視且具國際影響力。我國為 AHWP 組織正式會員，大陸於本次年會中積極爭取各項領袖選舉，修改組織章程，並間接影響我國有意爭取 2018 年 AHWP 年會之主辦權結果，我國過去持續參與 AHWP 相關活動並屢屢擔任要角，建議未來更需積極參與 AHWP 相關事務，建立並維護與各會員國間夥伴關係，以鞏固我國於 AHWP 之國際影響力，以能爭取各項議題之領導權力。

我國過去於體外診斷醫療器材工作小組中，協助產出多項法規文件獲得 AHWP 技術委員會認可，供所有 AHWP 會員國參考運用，本次年會順利完成 AHWP TC WG2 主席之連任，並首次推派官方代表參與 AHWP TC WG6 活動，AHWP 各會員國醫療器材主管機關雖一致採認 ISO 13485:2003 作為醫療器材業者品質管理系統要求，然自 2016 年新版公布後至 2019 年 3 月起全面實施期間，各會員國間仍在各自發展中，而我國已著手修改醫療器材業者品質管理系統法規，將於過渡期後如期與 ISO 13485:2016 相調和，我國於醫療器材業者品質管理系統之法規調和領先大多數會員國，且對於 IMDRF 之 MDSAP 已有相當之研究探討，未來能於 ISO 13485:2016 及 MDSAP 等議題上擁有相當領導能力，建議未來積極參與 AHWP TC WG6 運作，並以法規調和基礎下，推動交換稽查報告以減少各會員國間重複稽核工作，領導發展出適合 AHWP 的單一稽核方案，以開展我國於 AHWP 法規國際調和之另項價值。

爰此，建議我國應密切關注 AHWP 及 AHWP TC 之最新醫療器材法規及其實施情形外，亦應持續注意大陸於 AHWP 及 AHWP TC 之各項發展運作情形，持續提升我國現行醫療器材法規國際化之量能，帶領國內產業協助拓展國際市場，鞏固我國於 AHWP 國際組織之影響力及價值。

附件 1

Day 1 (4thDecember, 2017)

時間	內容/活動	講者/負責人
08:00-09:00	Registration	AHWP India Secretariat
09:00-09:10	Welcome address	**Dr. G.N. Singh** DCG(I), Ministry of Health and Family Welfare, GOI
09:10-09:20	Welcome address	**Dr. Jagdish Prasad** DG, DGHS, Ministry of Health and Family Welfare
09:20-09:30	Welcome address	AHWP Chair – **Dr. Hee-Kyo Jeong** Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea
09:20-09:35	Lamp lighting	Chief Guest and other officials
09:35 -09:50	Inaugural address	Hon'ble Guest from Ministry of Health and Family Welfare Hon'ble Guest from Ministry of Commerce and Industry
09:50-10:00	Opening Remarks	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia

10.00-10.40	India Regulatory Update • Brief overview India– opportunities for medical devices sector, Presence of Medical Devices and IVD industry, Availability and affordability of medical devices. • An overview of regulations of medical devices and IVDs in India. • Recent updates/major policy changes in medical devices regulations. • Policy for Import / Export. Major Policies for providing ease of doing business towards growth of the country.	Session Chairs AHWP Chair – • **Dr. Hee-Kyo Jeong** Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea • **Sh. Sudhir Kumar**, Joint Secretary(Regulation), MoHFW Session Co-Chairs • **Dr. G.N. Singh** Drugs Controller General (I), CDSCO • **Dr. S.E Reddy** Joint Drugs Controller (I), CDSCO Presenter • **Dr. V.G Somani** Joint Drugs Controller (I), CDSCO
10:40-11:00	**Tea Break**	
11.00-11:30	Singapore Regulatory Update An overview of regulations of medical devices and IVDs in Singapore	**Dr. Rama Sethuraman** Deputy Director, Health Science Authority, Singapore
	Japan Regulatory Update An overview of regulations of medical devices and IVDs in Japan	**Mr. Hiroshi YAGINUMA** Director, Office of Regenerative Medicine

11:30-12:00		Product Evaluation Medical Device Evaluation and Licensing Division Pharmaceutical Safety and Environmental Health Bureau, MHLW
12:00-12:30	South Korea Regulatory Update An overview of regulations of medical devices and IVDs in South Korea	**Mr. Seil Park** Assistant Director Division of High-tech devices Department of MD evaluation Korea MFDS **Mr. Young Wook Ahn** Assistant Director Division of In-vitro Diagnostic Devices Department of MD evaluation Korea MFDS
12:30-13:00	Australia Regulatory Update An overview of regulations of medical devices and IVDs in Australia	**Mr. Michael Flood** Ex-TGA, Locus Consulting Pty Ltd Australia
13:00-14:00	**Lunch**	
14:00-14:30	South Africa Regulatory Update An overview of regulations of medical devices and IVDs in South Africa ·	**Ms. Andrea Julsing Keyter** Deputy Director : Medical Devices, National Department of Health Inspectorate & Law Enforcement Unit, South Africa
14:30-15:00	Medical Device Single Audit Program (MDSAP)	Speaker needs to be confirmed
15:00-15:20	**Tea Break**	
15:20-15:50	Design controls, Risk Management, Verification and Validation and product	**Mr. Fred Viaud** VP Quality & Regulatory -

	release	Philips Philips Healthcare
15:50-16:20	Adapting your ISO 13485 to the new Requirements	**Mr. Grant Ramaley** Convener, Medical Device Working Group for ISO 13485 International Accreditation Forum, Aseptico, Director of Regulatory Affairs
16:20-16:50	Role of Technical Standards and updates on international technical standards	**Dr. Peter Linders** Director, Standards & Regulations, Regulatory Standards, Philips Healthcare
16:50-17:20	Clinical Trial Environment - Australia	**Dr. Catherine Bourgeois** Vice President, Field Clinical Affairs, Emerging Markets & ANZ, Abbott
17:20-17:30	Closing Remarks	**Dr. Jeong-Rim Lee** TC Co-Chair Director, Cardiovascular Devices Division Department of MD evaluation Ministry of Food and Drug Safety (MFDS)

Day 2 (5thDecember, 2017): AHWP Playbook Training Workshop

09:00-09:10	Welcome speech – TC Capacity Building Program	**Ms. Tran Quan** Capacity Building Team Leader, Vice President, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed), Singapore

9.10-9.20	Opening Speech Play Book Training Session	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director Medical Devices Sector Saudi Food & Drug Authority Kingdom of Saudi Arabia
	Introduction of the 2 Day Training Program	**Ms. Joanna Koh** AHWP PB Program Co-ordinator & Lead Trainer, Principal Consultant MDnet Regulatory Consultants Singapore
09:20-10.00	Preparatory steps to MD Controls – ASEAN experience / Centering on the AMDD elements	**Mr. Zamane Abdul Rahman** Chief Executive, Medical Device Authority, Ministry of Health Malaysia
10.00-10:40	"Takes 2 to Tango" – CSDT/EP and standards	**Mr. Seet Wing Gang** Head Regulatory Intelligence, Greater Asia, Becton Dickinson
10:40-11:00	**Tea Break**	
11:00-11:40	Classification Rules GMD/IVD D –Why The Rules? Is there an alternative?	**Mr. Greg LeBlanc** M.Sc., RAC, Director, Regulatory Affairs and Quality Systems, Cook (Canada) Inc.
11:40-12:20	CAB Role and Grouping – A balance between Regulatory Controls and Processes with the Economics of MD Industry	**Dr. Vincent Lam** MHS Manager and Senior Product Specialist, TUV SUD Product Service
12:20-13:00	Objectives and limitations: In-country Lab Testing	**Ms. Junya Onae** Manager, Asia-pacific manager, Global Technology Assessment Center, TUV Rheinland

		Mr. Petra Kaars-Wiele Senior Director Regulatory, Quality & Labeling, Abbott Diagnostics
13:00-14:00	**Lunch**	
14:00-14:30	Clinical Investigation and evaluation for Medical Devices: Regulator perspective	**Dr. Mijung Son** Regulator (MFDS) Korea
14:30-15:00	Clinical Investigation and evaluation for Medical Devices: Industry perspective	**Mr. Arthur Brandwood** Brandwood Biomedical, Founder and Principal Consultant
15:00-15:20	**Tea Break**	
15.20 – 16.00	Panel Discussion: Clinical Investigations and Real World Evidence	**MODERATOR:** **Ms. Sumati Randeo** Director Global Strategy Regulatory Affairs & Advocacy Abbott Laboratories
		Ms. Katy Peterson Director, Global RA Boston Scientific
		Ms. Kate Hyeong Joo Kim Director, Regulatory Strategy & Innovation, ASPAC Director Regulatory Affairs, North Asia, Johnson & Johnson Medical, Republic of Korea
		Mr. Kwan Han Ong Regional Associate Director, Clinical Affairs Asia Pacific Regional Associate Director, Regulatory Affairs, APAC

		Dr. V.G Somani Joint Drugs Controller (I), CDSCO
16:00-16:30	Performance evaluation of IVD regulation	**Dr. Benny Ons** Director of Regulatory Affairs at BD Diagnostics and BD Biosciences Europe, Becton Dickinson International Becton Dickinson B.V.
16:40-17:20	Closing Remarks	**Ms. Joanna Koh** AHWP PB Program Co-ordinator & Lead Trainer, Principal Consultant MDnet Regulatory Consultants Singapore
17:20-17:30	Affiliate Member (i) GS1 Updates (ii) UDI Databases: Useful Tools for Regulatory Controls. How to utilize them in the MD Life Cycle especially in referencing for Pre Market Assessments	**Ms. Ulrike Kreysa** Vice-President Healthcare, GS1 Global Office

Day 3 (6th December, 2017): AHWP Playbook Training Workshop and TC Workshop

09:00-09:10	Recap of PB session 1 and intro of session 2	**Ms. Joanna Koh** Principal Consultant MDnet Regulatory Consultants Singapore
09:10-09:55	Post Market - Medical Device Post market for Digital Healthcare: Cybersecurity prevention for MDs	**Mr. John Ramesh** Managing Director TUV Rheinland LLC, Oman & Regional Feild Manager, Bussiness Solutions, IMEA &

		APAC
09:55-10:40	Post Market - A Growing Global Concern: Counterfeit Medical Devices	**Dr. Nazeeh S. Alothmany** Vice Executive President, Medical Device Sector, Saudi FDA, KSA
10:40-11:00	**Tea Break**	
11:00-11:40	Advertisement and Labeling	**Mr. Er Alfred Kwek** Director, Public Affairs, Edwards Life Sciences S PL
11:40-12:10	Panel Discussion on the PB Initiatives and Road ahead	**Moderator:** **Mr. Scott Sanderson** 3M Health Care, International Regulatory Affairs and Quality Compliance Leader, Medical Division, Minnesota
		Dr. Adrianti Anaya Director of Medical Devices and Household Health Pdts Evaluation
		Ms. Agnes Sitta Kijo Manager, Medical Devices; Diagnostics Registration, Tanzania Food & Drugs Authority
		Mr. Grant Ramaley Aseptico, Director of Regulatory Affairs
12.10-12.20	Closing of AHWP PlayBook Training Program for the Current Cycle.	**Ms. Joanna Koh** AHWP PB Program Co-ordinator & Lead Trainer

		Principal Consultant MDnet Regulatory Consultants Singapore
AHWP Technical Committee (TC) Workshop		
12:20-12:25	Opening words by TC Chair	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director Medical Devices Sector Saudi Food & Drug Authority Kingdom of Saudi Arabia
APACMed SESSION		
12:25-13:00	Device & Operation Risks of Tele-medicine and e-Health: Regulatory Consideration across Jurisdictions	**Ms. Ann Graves** Vice President, International Regulatory Affairs, Abbott
13:00-14:00	**Lunch**	
1400:-14:30	Regulatory on Medical Devices using 3D Printing – From Manufacturing to AE Reporting (e.g. QMS, QMS audit, pre-market submissions, clinical trial, AE reporting and recall)	**Dr. Jang Yong Choi** Deputy Director, Division of Medical Device Safety Evaluation Medical Device Safety Bureau Ministry of Food and Drug Safety (MFDS)
14:30-15:00	Diagnostic Devices based on AI and Big Data Analytics –Thoughts on Validation and Risk Management	**Ms. Nicole Taylor Smith** Senior Director, Global Regulatory Affairs Policy & Intelligence, Johnson & Johnson
15:00-15:20	**Tea Break**	
15:20- 15:50	Panel discussion: Challenges and issues to regulate an innovative medical devices: Barriers and Enablers to development	**Moderator:** **Ms. Miang Tanakasemsub** Head, Regulatory Affairs

		(Asia & Russia), Alcon
		Mr. Biten Kathrani Director R&D for Boston Scientific India as the speaker) Senior International Trade Specialist, Industry & Analysis, U.S. **Mr. Matthew Hein** Senior International Trade Specialist Industry & Analysis U.S. Department of Commerce| International Trade Administration Office of Health and Information Technologies
		Sh. Somnath Basu Asst. Drugs Controller (I), CDSCO **Sh. Sunil Kulshrestha** Asst. Drugs Controller (I), CDSCO
Parallel Session		
AHWP TC Workshop (Parallel 1)		
15:50 -16:10	Changing global regulatory environment – opportunity and threat in industry - focused on premarket	**Mr. Jeongpyo Hong** Manager, Regulatory Affairs Health & Medical Equipment Business, Samsung Electronics
16:10-16:40	Pre- market approval – Essential Principles	**Mr. Michael Flood** Principal, Locus Consulting

	for safety, quality and performance	Pty Ltd
16:40-17:00	Use of Real World Evidence in clinical and regulatory decision from Industry experience	**Dr. Justin Yoo** Government Affairs Health Economics & Reimbursement, Manager Corporate Relations Ambassador St. Jude Medical Korea YH, Abbott
17:00-17:20	Post-market control of medical devices-How far we have gone towards harmonization	**Ms. Jennifer MAK Kit-shu** Senior Electronics Engineer (Medical Device Control Office), Department of Health Medical Device Control Office, Department of Health, Hong Kong China
17:20 -17:40	TGA Reforms for Medical Devices & IVDs and Clinical trial landscape in major countries in APAC	**Ms. Mie Ohama** Principal clinical quality specialist at Medtronic Clinical Research Institute, Interntional quality, Sydney Australia
17:40 – 18:00	Q&A	**Sh. Aseem Sahu** Dy. Drugs Controller (I), CDSCO
18:00 – 18:10	Closing Remarks	**Dr. Jeong-Rim Lee** TC Co-Chair Director, Cardiovascular Devices Division Department of MD evaluation Ministry of Food and Drug Safety (MFDS)
India Industry Workshop (Parallel 2)		

15:50 -16:10	Medical Devices Rules, 2017- Technical Requirements of manufacture and import of medical devices	**Sh. Aseem Sahu** Dy. Drugs Controller (I), CDSCO **Sh. Ravikant Sharma** Asst. Drugs Controller(I), CDSCO
16:10-16:30	Medical Devices Rules, 2017- Investigational Medical Devices/new IVD approval	**Sh. Ravikant Sharma** Asst. Drugs Controller(I), CDSCO **Sh. Somnath Basu** Asst. Drugs Controller(I), CDSCO
16:30-17:00	Panel Discussion: Opportunities and Way Forward in Manufacturing of Medical Devices (MD) and IVD sector –"Make in India Program" by Invest India (DIPP)	**Mr. Sanjay Arudi** Senior Director Regulatory Affairs Sustainable Healthcare Solutions, GE Healthcare
		Mr. R. Asok Kumar Vice President (QA&RA), Johnson & Johnson Medical, India
		Mr. Himanshu Baid Managing Director of Poly Medicure Limited, India
		Mr. Sudhakar Mairpadi Director - Quality & Regulatory Philips Electronics India Limited (Health Care sector)
		Mr. Rajiv Nath Forum Coordinator Association of Indian Medical Device Industry (AiMeD)
		Dr. V. G. Somani Joint Drugs Controller (I),

		CDSCO
17:00-17:30	Q & A	Q & A
17:30-17:40	Closing Remarks	**Dr. V. G. Somani** Joint Drugs Controller (I), CDSCO

Day 4 (7th December, 2017): AHWP TC Meeting

Day4: AHWP TC Meeting		
09:00-10:40	AHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting)	AHWP & TC & WG Leaders & TC Advisors
10:40-11:00	**Tea Break**	
11:00-11:05	Welcome Speech	
11:05-11:25	Opening of TC Meeting -Roll call -Adoption of Agenda -Announcement of the Election Arrangement for Office Bearers of AHWPTC and AHWPTC WGs	**Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia **Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
11:25-13:05 (20min each)	WG updates: WG1 WG2 WG3 WG4	WG Chair & Co-chairs

	WG5	
13:05-14:05	**Lunch**	
14:05- 15:25 (20min each)	WG updates (Continued) -WG6 -WG7 -WG8 -STG	WG Chair & Co-chairs
15:25-15:45	**Tea Break**	
15:45-16:15	Highlight of AHWP PB Training	**Ms. Joanna Koh** Principal Consultant MDnet Regulatory Consultants Singapore
16:15-16:45	Speech by TC Advisors Representative	TC Advisor Representative
16:45-16:55	Closing Remarks	**Mr. Alfred Kwek** Regional Director, Government Affairs/HME Samsung Electronics, Singapore **Mr. Ali M. Al-Dalaan** (TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
19:30:00 onwards	**Gala Dinner**	

Day 5 (8th December, 2017): AHWP annual meeting

09:00-09:30	Opening Ceremony -Congratulation Address -Opening Speech by AHWP Chair -Group Photo	**Official,** Ministry of Health and Family Welfare, India **Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea All Participants
09:30-09:45	Roll Call Adoption of Agenda Adoption of 21st AHWP Annual Meeting Minutes	**Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea Supported by **Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
09:45-10:15	Updates by AHWP and AHWP TC AHWP AHWP TC	**Ms. Tran Quan** AHWP Vice Chair Vice President, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed), Singapore **Mr. Ali M. Al-Dalaan**

		(TC Chair, AHWP), Executive Director, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
10:15-10:30	Announcement of Election Arrangement for Office Bearers of AHWP	**Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
10:30-11:00	**Tea Break**	
11:00-12:00 (15min each)	AHWP Member Economy updates -China -India -Tanzania -APEC - ASEAN	 **Mr. GAO Guo Bia** Deputy Director General of Medical Device Registration Department, China Food and Drug Administration People's Republic of China **Dr. V. G. Somani** Joint Drugs Controller, CDSCO, India **Mr. Mitangu Adam Fimbo** Director of Medicines and Complementary Products., Tanzania FDA **Dr. Arianti Anaya** Director of Medical Devices and Household Health Pdts Evaluation, MOH, Indonesia

		Mr. Zamane Abdul Rahman Chief Executive, Medical Device Authority, Ministry of Health Malaysia
12:00-12:30 (10 min each)	AHWP Liaison Member Updates -APACMed - DITTA	**Mr. Fredrik Nyberg** CEO APACMed
12:30-13:15 (10 min each)	Endorsement of New Member Economies - Mexico (TBC) To be finalized by AHWP - Kenya (TBC) To be confirmed by AHWP Speech by New Liaison - GMDN (TBC) To be confirmed by AHWP	**Ms. Carol Liu** AHWP Secretariat, Vice President, Regulatory Affairs, ASPAC Johnson & Johnson People's Republic of China
13:15-14:15	**Lunch**	
14:15-14:35	Secretariat Updates - Secretariat Report - Financial Report	**Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
14:35-14:45	Resolutions - Amendment to AHWP TOR/HR – Participation of WG activities - STG change to WG - To be confirmed by AHWP	**Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea Supported by **Mr. Bryan So** AHWP Secretariat

		Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
14:45-16:00	Election of AHWP Leadership of 2018-2020 - Briefing on Election Rules and List of Candidates - Election - Endorsement of Newly Elected Office Bearers of AHWP - Endorsement of Newly Elected Office Bearers of AHWPTC - Endorsement of Newly Elected Office Bearers of AHWPTC Working Group	**Mr. Bryan So** AHWP Secretariat Principal Consultant Biomedical, Optical & Precision Engineering Unit Hong Kong Productivity Council Hong Kong SAR, China
16:00-16:30	**Tea Break**	
16:30-16:40	Announcement of 23rd AHWP Annual Meeting Host	**Dr. Hee-Kyo Jeong** Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea
16:40-16:50	Speech by Newly Elected Chair of AHWP	
16:50-17:00	Closing Remarks by Outgoing Chair of AHWP	**Dr. Hee-Kyo Jeong** AHWP Chair Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea
17:00-17:30	The 6th AHWP ASL Annual General Meeting (AGM)	**ASL Members only** **(Transfer to another room)**

附件 2

WG2 – Pre-market: IVDD

AHWP Annual Meeting
7th Dec 2017

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: 28
  - 10 regulators
  - 18 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

	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 Submission Dossier		Jun 2015 to Nov 2016
(3)	Conformity Assessment for IVDs		Aug 2015 to Nov 2016
(4)	Classification of IVDs		Aug 2015 to Nov 2016
(5)	In Vitro Companion Diagnostic Devices (IVD-CDx)		Mar 2016 to Nov 2017
(6)	IVD Labelling		Jan 2017 ~

Proposed Work Plan 2015-2017

	Work Item	Deliverables	Action Plan and Timeline
2	Participate in International/Global Organization collaboration and activities (e.g. ISO/TC 212, WHO etc.)	Standard Guidance Comment	Attend the activities of ISO/TC 212/WG3 to work on standard regarding technical requirements for IVDs

WG2 Activities 2015 - 2017

2015

1. WG2 1st Teleconference: 11 Mar
2. WG2 1st FTF meeting: 11-13 Aug (Taipei)
3. WG2 2nd Teleconference: 13 Aug
4. WG2 2nd FTF meeting: 2 Nov (Bangkok)
5. Side meeting with WHO IVD PQ program team: 6 Nov (Bangkok)

2016

1. WG2 1st Teleconference: 17 Mar
2. Side meeting with WHO IVD PQ program team: 27 April (Seoul)
3. Conference on IVD Medical Devices Regulation and Clinical Performance Evaluation: 13 July (Taipei)
4. WG2 1st FTF meeting and 2nd teleconference: 14 ~ 15 July (Taipei)
5. AHWP Annual meeting + WG2 2nd FTF meeting: 21 ~ 25 Nov (Cebu)

2017

1. WG2 1st Teleconference, 16 Feb
2. WG2 1st FTF meeting: 1st March (Hong Kong)
3. WG2 2nd FTF meeting: 11th -13th July (Taipei)
4. WG2 3rd FTF meeting: 4th Dec (India)

WG Progress (I)

	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	to Nov 2017	28 members in total • 10 Regulator Members; • 18 Industry Members
2	Development of AHWP Guidance Document	1) Definition of MD/ IVD	Mar 2015 to Nov 2016	• Documents endorsed in Cebu Annual meeting, 2016
		2) Classification of IVDs	Jun 2015 to Nov 2016	
		3) Conformity Assessment for IVDs	Aug 2015 to Nov 2016	
		4) IVD Common Template for a Submission Dossier	Aug 2015 to Nov 2016	
		5) In Vitro Companion Diagnostic Devices	Mar 2016 to Nov 2017	• Documents to be endorsed in New Delhi Annual meeting, 2017
		6) Label and Instructions for Use for IVD Medical Devices	Mar 2017~	• Workgroup draft document under revision

WG Progress (II)

	Work Item	Deliverables	Timeline	Progress Update

3	Participation in International/ Global Organization collaboration and activities	1) Establish IVDWG 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	• AHWP WG2 has joined ISO/TC 212 as liaison member to participate in standard discussion and contribution from regulators and industry's point of view.
				• Side meetings with WHO IVD PQ team to discuss collaboration between the two groups
				• Participate in WHO expert consultation on G6PD IVDs, 26~28 Sept 2015
				• Collect and consolidate comments from WG2 members on the WHO documents, including:
				  ◦ Technical guidance series documents
				  ◦ Technical specifications series documents

WG Progress (III)

	Work Item	Deliverables	Timeline	Progress Update
4	Collaboration with other WGs		2015 to 2017	• WG1: Guidance Document of MD/ IVD Definition, 2015 • WG1: Survey on regulation and treatment of e-IFU and e-Label of MD and IVD MD, 2017 • WG5: Conference on IVD Medical Devices Regulation and Clinical Performance Evaluation, 2015

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WG Document towards Endorsement at the 22nd AHWP Annual Meeting 2017, India

No.	Title/ Content	Type of Document
1	Guidance for Approval and Assessment of In vitro Companion Diagnostic Devices (IVD-CDx)	Guidance Document

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AHWP/WG2/P001:2017 – Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices

- Scope of paper:
  - This document applies to all products that fall within the definition of Companion In vitro Diagnostic Medical Devices.
- Objective of paper:
  - This guidance document is intended to guide staff of RAs and CABs who are assessing Companion In Vitro Diagnostic Medical Devices (IVD-CDx) for possible premarket regulatory pathways and assist manufacturers of the IVD-CDx to develop and demonstrate relevant performance characteristics for their products.
- Rationale:
  - Recent development of scientific technology has led to the development of personalized medicine for treatment. The process for selecting appropriate therapeutic products, based on a patient's characteristics has grown in importance. IVD-CDx provide information that is essential for the safe and effective use of a therapeutic product, for example such information can be based on the expression levels of genes, or the occurrence of any mutations. Guidance is required on the process for collecting, documenting and assessing the performance of an IVD-CDx in relation to the therapeutic product with which it is intended to be used.

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WG2 Project highlights and notables 2015-2017

- 4 Guidance adopted and 1 guidance to be endorsed in the current AHWP meeting
- Extensive collaboration with WHO, ISO and IMDRF countries like Brazil.

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Proposed Work Plan 2018-2020

- 3 Guidance and future trend study:
  1. Label and Instructions for Use for In vitro Diagnostic Medical Devices
  2. Advertising and promotion for In vitro Diagnostic Medical Devices
  3. Guideline for Approval of Reagent for Instrument Family
     - Future trend study: Bridging LDT and IVD
- Support AHWP and TC in promoting and reaching out with AHWP IVD regulatory requirement harmonization

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Thank you

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