出國報告（出國類別：參加國際會議）

2018 亞洲醫療器材法規調和會技術委員會領袖會議

(2018 Asian Harmonization Working Party Technical Committee Leaders Meeting)

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：中國北京

出國期間：107 年 5 月 7 日至 5 月 11 日

報告日期：107 年 6 月 11 日

摘要

「2018 亞洲醫療器材法規調和會技術委員會領袖會議 (2018 AHWP TC Leaders Meeting」,由我國衛生福利部食品藥物管理署(Food and Drug Administration,簡稱TFDA)蔡技正文偉赴中國北京出席與會，會議日期為 107 年 5 月 8 日至 5 月 9 日，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，在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，並與各國主管機關及業界代表進行交流。並於 5 月 10 日召開 WG2 Face-to-Face 工作小組會議，針對 WG2 刻正研擬之體外診斷醫療器材仿單編寫指引草案。

藉由參加此次會議，瞭解 AHWP 目前各小組工作進度及未來規劃，並於會議中呈現由我國主導之 WG2 小組工作成果，不但提升我國國際能見度，亦提前取得法規趨勢資訊，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)於1999 年成立，目前已有 30 個正式會員國(Member Country, 簡稱 MC)，並持續增加中，會員涵蓋範圍，從創始之初的亞洲地區(含大部分新南向政策國家)，擴及東歐、南美以及非洲地區，為亞太及非洲地區推動醫療器材法規調和之重要組織，也是唯一由各國(地區)法規主管機關與業界代表共同組成的組織。AHWP 技術委員會(Technical Committee, 簡稱 TC)負責技術工作任務，目前 AHWP 轄下 TC 共包含 9 個工作小組(Working Group, 簡稱 WG)。

我國係 AHWP 組織之正式會員國，本署蔡技正文偉擔任 TC 轄下體外診斷醫療器材工作小組(WG2 - Pre-market: IVDD)主席，AHWP 致力於研究並推動醫療器材法規調和，於每年定期舉辦一場 TC 之領袖會議(Leaders Meeting)，參加本次領袖會議，除可於會上呈現我國積極推動醫療器材法規國際調和工作，並邀請與會代表來台參加相關研討會議，以促進雙、多邊合作關係，並於會上報告 WG2 工作進度及未來工作規劃，包括體外診斷醫療器材(In Vitro Diagnostic, IVD)相關國際指引研擬、與國際組織之合作、與 TC 轄下各工作小組之合作等，並與參會之 TC 領袖及顧問團進行工作內容討論。另外，本次出國計畫，並藉由相關官員與專家聚集之機會，安排於 5 月 10 日召開 WG2 面對面(Face-to-Face)工作會議，邀請相關專家與 WG2 成員，共同討論 IVD 相關國際指引文件之研擬，並討論 WG2 後續工作計畫。

藉由參加本次會議，除瞭解 AHWP 目前各小組工作進度及未來規劃外，亦展現我國積極參與醫療器材法規國際調和相關事務，有助於提升我國國際能見度及國際形象。

貳、議程

本次會議之 TC Leaders Meeting 為 AHWP 組織每年例行活動，於 5 月 8 日至 9 日舉辦。我國所領導之 WG2 工作小組，藉本次會議已邀集各國官員與業界代表之機會，於 5 月 10 日舉辦 WG2 面對面工作會議，討論相關工作事項，相關會議議程詳如下：

Agenda
2018 AHWP TC Leaders Meeting

May 8-9, 2018
The Merchantel, Beijing, 北京广电国际酒店
No.2 Xi Bian Men Wai Da Jie Xicheng District, Beijing

Day 1 May 8th, 2018
Meeting Room: Banquet hall B, The Merchantel, Beijing

Time		Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
08:45 - 09:00		Registration	Secretariat
09:00 - 09:30		Congratulatory & Welcome Remarks By China	IMDRF Chair
		Congratulatory & Welcome Remarks By AHWP Chair	Mr. Zamane Abdul Rahman, AHWP Chair
		Group Photo	All participants
09:30 - 09:35		1. Adoption of the Agenda & Roll Call	Mr. Bryan So, Secretariat
09:35 - 09:40		2. Opening address	Mr. Ali M. Al-Dalaan, TC Chair
09:40 - 10:00		3. China Medical Device Supervision Overview	Mr. Guobiao GAO, AHWP Vice-Chair
10:00 - 10:20		4. China Medical Device Industry Overview	CAMDI
10:20 - 10:40		Tea Break	All TC participants
10:40 - 12:00		5. AHWP TC's Current Status & Plan （WG1 to WG4) Individual WG work plan discussion 1)Work update since the Delhi meeting 2)WGs items (new) 3)WGs 3-yr plan	All TC participants
	10:40 - 11:00	WG 1	Mr. Seil Park Ms. Kate HyeongJoo Kim
	11:00 - 11:20	WG 2	Mr. Wen-Wei TSAI
	11:20 - 11:40	WG 3	Mr. Tony Yip
	11:40 - 12:00	WG 7	Ms. Wang Aijun Mr. Ee Bin Liew
12:00 – 14:00		Lunch	All TC participants

14:00–15:30		6. AHWP TC's Current Status & Plan （WG5 to WG9) Individual WG work plan discussion 1）Work update since the Delhi meeting 2) WGs items (new) 3) WGs 3-yr plan	All TC participants
	14:00 - 14:20	WG 4	Ms. Jennifer MAK
	14:20 - 14:40	WG 5	Ms. Yuwadee PATANAWONG Ms. Sumati Randeo
	14:40 - 15:00	WG 6	Mr. Abdullah AL RASHEED Mr. Vincent LAM Chee-Choong
	15:00 - 15:20	WG 8	Mrs. SalbiahYaakop Mr. Tony Low
	15:20 - 15:40	WG 9	Ms. Jun Li Ms. Victoria Qu
15:40 - 15:50		Tea Break	All TC participants
15:50 - 16:00		7. IMDRF Meeting Update MC meeting and Stakeholders Forum in Shanghai, China in March 2018	Mr. Ali M. Al-Dalaan, TC Chair
16:00-16:20		8. WHO update	Ms. Irena Prat
16:20 - 17:00		9. AHWP Capacity Building initiatives 9 a) AHWP-Deloitte-APACMed Regulatory Competency Study kick off	Ms. Tran Quan, Vice-Chair Ms. Miang Tanakasemsub, APACMed
17:00 - 17:20		10. OECD Report Case Study of International Regulatory Co-operation	Dr. Jeong-Rim Lee, TC Co-chair
17:20 - 17:35		11. Updates by Secretariat: •Upcoming AHWP Annual Meetings • AHWP website upgrade	Ms. Sasikala Devi Thangavelu, Mr. Bryan So, Secretariat Mr. Ee Bin Liew
17:35 - 17:40		12. Closing Remarks for Day One	Mr. Alfred Kwek, TC Co-chair

Agenda
2018 AHWP TC Leaders Meeting

May 8-9, 2018

The Merchantel, Beijing, 北京广电国际酒店

No.2 Xi Bian Men Wai Da Jie Xicheng District, Beijing

Day 2 May 9th, 2018

Meeting Room: **Meeting room 1, The Merchantel, Beijing**

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
09:00-09:45	12. Closed Door Meeting for TC Advisors	TC Advisors ONLY

Meeting Room: **Banquet hall B, The Merchantel, Beijing**

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
09:00-09:45	12. Closed Door Meeting for TC Leaders - WGs activities plan - Upcoming AHWP Annual Meetings - AOB	AHWP TC & WGs Chairs & Co-chairs & Secretariat ONLY
09:45-10:00	Tea Break	All TC participants
10:00-11:50	13. TC Advisory Panel's Recommendations for TC works	TC Advisors
	14. Three-year wok plan of AHWP TC	All TC participants
	15. Collaborating activities with International Organizations (including Liaisons)	All TC participants
	16. AOB	All TC participants
11:50-12:00	17. Closing Remarks	Mr. Alfred Kwek, TC Co-chair
12:00 -13:30	Lunch	All TC participants

Meeting Room: Banquet hall B

Time	Open Session to Local Industry	Responsible Person(s)
13:30-14:00	Registration	CAMDI
14:00-14:30	18.AHWP Introduction	Mr. Zamane Abdul Rahman, AHWP Chair
14:30-15:00	19. Saudi Arabia Medical Device Supervision Overview	Mr. Ali M. Al-Dalaan, AHWP TC Chair
15:00-15:30	20. AMDD Implementation in ASEAN	Ms. Miang Tanakasemsub, APACMed
15:30-16:00	21.Chinese Hong Kong Medical Device Supervision Overview	Ms. Jennifer MAK
16:00-16:30	22.Recent Development on MDR/IVDR in EU	Dr. Petra Kaars-Wiele, AHWP TC Advisor
16:30-17:00	23.Interactions	All Meeting Participants

AHWP TC Work Group 2 2018 1st Face-to-Face Meeting

Date: 2018.5.10 (Thursday)

Venue: Abbott Beijing (Room 1709-1716 Canway Building,No. 66 Nanlishi Lu, Xicheng District, Beijing, China)

Date	Time	Proposed Topics
05/10 (Wed.)	09:30~12:00	1. Roll Call and Adoption of the Agenda 2. International and AHWP internal Collaboration with WG2 3. New work item discussion 4. Development of IVD guidance document: - Label and Instructions for Use for IVD Medical Devices
	12:00~13:30	Lunch
	13:30~16:00	5. Development of IVD guidance document (cont.): - Label and Instructions for Use for IVD Medical Devices 6. AOB

參、會議內容及心得

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)、哈薩克斯坦(Kazakhstan)、巴林(Kingdom of Bahrain)、沙烏地阿拉伯王國(Kingdom of Saudi Arabia)、寮國(Laos)、馬來西亞(Malaysia)、蒙古(Mongolia)、緬甸(Myanmar)、巴基斯坦(Pakistan)、中國(People's Republic of China)、菲律賓(Philippines)、韓國(Korea)、新加坡(Singapore)、南非(South Africa)、科威特(State of Kuwait)、阿曼(Sultanate of Oman)、坦桑尼亞(Tanzania)、泰國(Thailand)、阿拉伯聯合大公國(United Arab Emirates)、越南(Vietnam)、葉門(Yemen)、辛巴威(Zimbabwe)以及我國等 30 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經濟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。

本次會中，AHWP TC 提及今年墨西哥將申請加入 AHWP，由於 AHWP 會員國涵蓋地理區域已遠超越亞洲，故 AHWP TC 提出討論 AHWP 是否需改名。TC 主席 Ali 支持改名以更符合 AHWP 的願景及更能推廣 AHWP 的工作，但不必急於今年完成討論或投票。中國及泰國對 AHWP 改名有保留，亦有人認為 AHWP 的品牌建立不易，建議不要輕易更改名稱。由於本次會議針對 AHWP 改名一事，仍有諸多正反面意見，TC 主席裁示，將於後續秘書處會議或年會，再續討論。

AHWP 大會轄下設有秘書處及技術委員會(TC)，經 2014 年組織重整後，技術委員會原包含 9 個工作小組(WG)及 1 個特殊任務小組，後於 2017 年年會時，組織再度改編，將原 WG9 負責訓練之工作小組刪除，相關工作納入 TC 秘書處權責。另原特殊任務小組(STG)，因該任務小組尚需持續研討分析相關國際調和工作，故將該工作小組改制為正式之工作小組。因此，目前之 TC 現況工作小組共有 9 個，分別為：

1. Work Group 1 (WG1) - Pre-market: General MD
2. Work Group 2 (WG2) - Pre-market: IVDD
3. Work Group 3 (WG3) - Pre-market: Software as a Medical Device
4. Work Group 4 (WG4) - Post-Market
5. Work Group 5 (WG5) - Clinical Performance & Safety
6. Work Group 6 (WG6) - Quality Management System: Audit & Assessment
7. Work Group 7 (WG7) - Quality Management System: Operation & Implementation
8. Work Group 8 (WG8) - Standards
9. Work Group 9 (WG9) - UDI & Nomenclature

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。

每年舉辦一場 AHWP 技術委員會領袖會議(Leaders Meeting)，通常由技術委員會主席主持，並邀請各工作小組之主席及副主席與會，報告其工作進度及未來工作規劃，亦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 2018 年亞洲醫療器材法規調和會技術委員會領袖會議(2018 AHWP TC Leaders Meeting)，會議第一、二天(5 月 8 日至 9 日)，為 AHWP TC Leaders Meeting，會議由各工作小組主席與副主席簡報說明各工作小組之工作進度與未來工作規劃，並由 TC 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，包括研擬中的 AHWP IVD 相關指引文件 Guidance on Label and Instruction for use for IVD Medical Devices 等，預訂於今年完成，簡報資料詳如附件。於 WG2 報告後，TC

指示 WG1、WG2、WG3 應加強合作，共同研擬上市前相關指引，例如：Guidance for Promotion and Advertisement 應考量由 WG1、WG2 與 WG3 共同研擬。另外，WG2 亦與 WG5 及 WG8 討論未來可能合作方案，包括更新 WG5「Clinical Performance Studies for IVD Medical Devices」指引，及配合 WG8 所提工作規劃，合作採認「ISO 16142-2:2017, Medical devices - Recognized essential principles of safety and performance of medical devices - Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards」或草擬相關指引等工作。

此外，由於 WG9 未來 3 年將分別草擬有關 UDI 之報告及規則，WG9 主席李軍邀請 WG2 共同參與 IVD 之 UDI 工作。另 TC advisors 認為 UDI 持續影響醫療器材產業，故建議 WG9 在 AHWP 年會期間，舉辦一天 UDI 訓練活動。

AHWP TC 秘書處報告，說明規劃委託外界辦理 AHWP 各會員國法規能力研究(Regulatory Competency Study)(如：調查法規系統完整度、審查人員能力等)，請各國官方協助，有利未來 AHWP Capacity Building 之規劃，未來秘書處可能透過 AHWP 正式管道詢問各國代表，協助相關事務，並取得較具代表性之資訊。

另有關本次 AHWP TC Leaders Meeting，由 AHWP TC 秘書處製作之會議紀錄，包括各工作小組現況、簡報重點摘要、TC 意見及後續追蹤事項等，詳如附件 2。

會議第三天(5 月 10 日)，主要任務為進行 WG2 面對面工作會議，本次工作會議，參會者包括來自德國、新加坡、中國及我國等共 6 名官方代表與專家與會，主要進行 WG2 年度工作討論，研擬 AHWP IVD 相關國際指引文件，包括針對 Guidance on Label and Instructions for Use for IVD Medical Devices 指引已蒐集 WG2 內部成員之意見討論及 Guidance for Promotion and Advertisement of Medical Devices and IVD Medical Device 文件架構與分工討論，其中，Guidance on Label and Instructions for Use for IVD Medical Devices 指引文件，規劃於今年 AHWP 年會上受大會採認為該組織之文件。

另外，亦針對 WG2 規劃之年度各項工作活動進行討論，預訂於 7 月 9 日至 13 日

當週舉行 WG1-WG2-WG3 跨工作組之聯席會議(Joint Meeting)。此外，本次會議尚有其它討論重點摘要如下：

- WG2 將維持與 WHO 的合作，協助收集及提供對 WHO 指引之意見，另針對 WHO 將於 2019 年舉辦之 Global Medical Device Forum，WG2 可提供會議 IVD 內容建議。
- 會上討論，未來 WG2 可將有關「Significant change for IVD products」指引之研擬，納入工作計畫。
- 將由 WG2 成員協助從東協 AMDD 及歐盟 IVDR 之角度，評估 Guidance on Label and Instructions for Use for IVD Medical Devices 指引草案內容，確保法規調和。

肆、結論與建議事項

本次參會除持續進行我國所領導之 WG2 相關工作任務，亦蒐集 AHWP TC 轄下各工作小組之工作進度與規劃，相關資訊有助於我國醫療器材管理國際調和會。有關參加本次會議，建議事項如下：

1. 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。

2. 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，建議加強實質之醫療器材法規國際合作，除可間接促進與各國醫療器材法規管理之國際調和外，亦可提升我國之國際形象。

3. 持續參與 AHWP 相關活動以推動南向政策

   AHWP 組織囊括了大部分新南向政策之國家， AHWP 組織活動除可作為新南向政策所需醫療器材管理相關資訊之收集平台，建議可透過 AHWP 相關會議活動，面對面邀請重要官員或專家來台交流，有利新南向政策之推動。

附件 1

WG2 – Pre-market: IVDD

AHWP TC Leaders Meeting
8th May 2018

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: 43 (as approved by AHWP TC)
  - 15 regulators
  - 25 industries
  - 3 Observers

2

Objectives 2018-2020

- 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.

3

Proposed Work Plan 2018-2020

	Work Item	Deliverables	Action Plan and Timeline
1	Develop AHWP documents	Guidance Document	
(1)	Label and Instructions for Use for In vitro Diagnostic Medical Devices		Start: Jan 2017 Submit for adoption: 2018
(2)	Advertising and promotion for In vitro Diagnostic Medical Devices		Start: Jan 2018 Submit for adoption: 2020
(3)	Guideline for Approval of Reagent for Instrument Family		Start: Jan 2018 Submit for adoption: 2019
2	Future trend study & survey: Bridging LDT and IVD	Survey report	Start: Jan 2019 Submit for adoption: 2020

4

Proposed Work Plan 2015-2017

	Work Item	Deliverables	Action Plan and Timeline
3	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

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WG2 Activities 2018

2018

1. WG2 1st Teleconference, 12 Feb
2. WG2 FTF meeting: W2 July (Taipei)
3. WG2 FTF meeting: 22nd Oct (Malaysia)

6

Thank you

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附件 2

AHWP TC Leaders Meeting Minutes

Date: 8~9 May 2018
Location: The Merchantel, Beijing, China

Congratulatory and Welcome Remarks by Mr. Lin YUAN (IMDRF chair)

Congratulatory and Welcome Remarks by Mr. Zamane (AHWP chair)

Meeting agenda adopted and roll call

Opening address by Mr. Ali M. Al-Dalaan, TC Chair

China Medical Device Supervision Overview by Mr. Guobiao GAO, AHWP Vice-Chair
China Medical Device Industry Overview by Xiaodong Fan, CAMDI

WG update (WG presentations will be shared in AHWP website)

WG1 presentation by Mr. Seil Park and Ms. Kate HyeongJoo Kim

- 3D printing guidance document will be used as a reference in IMDRF Work. We have two members working in the IMDRF PMD WG. It is a good plan to align with them.
- Ali requested WG1 will review Definition and Classification of Artificial intelligence and report during in Annual meeting

WG2 presentation by Mr. Wen-Wei TSAI and Chris

- Alfred suggested WG1, WG2, WG3 to work on one guidance document on advertisement and promotion as there are many common elements among 3 WGs
- WG2 clarify the guidance on how reagent to be approved, it also cover other part of system e.g. analyzer, calibrator

WG3 presentation by Tony Yip

- New Chair Dr Abdullatif Watban
- Ali recommend to consider guidance document on Cyber security
- Comments (Ee bin) – Inclusion of Health devices in IEC62304 in new revision draft
- Reply (Tony Yip) – it is also our concern when dealing with this issue among our members. We will definitely discuss further about it.

- Alfred mentioned “Nomenclature for revision control” is helpful for registration and even change control for medical devices in general. TC Advisor (Peter Linder) fully agree and it is still in progress

WG7 presentation by Ms. Wang Aijun and Mr. Ee Bin Liew

- Welcome our new chair Ms Wang
- For comparison study of new ISO 13485 vs QMS requirements in each country, looking for volunteers within the Workgroup to coordinate
- Scott and Grant mentioned the team should be aware of many challenges while comparing/mapping ISO13485 with US and EU, for example. WG7 chair/co-chair acknowledge and will take note. Scope is just comparing the QMS requirements and restricted to that.
- Peter mentioned, TC210 will do a systemic review of ISO13486 in2019. A survey on experience of using ISO 13485 will be rolled out. Recommend WG7 to connect closely Scott group on this. Ee Bin is in the same group (TC210 WG1)
- Tran asking whether 3D printing part is of WG7 scope? Ee Bin mentioned that it is not in WG7 scope yet due to workload

AHWP website update by Carol Liu, Mr Ee Bin Liew

- Source file is transferred to HKPC during Aug-Oct 2017
- Identify timeslot to work with Mr Ee Bin group to fix further technical issues by end May 2018

WG4 update by Jennifer Mak

- Peter suggest working closely with ISO TC210 to ensure AHWP comment being heard, and assist & give comment to TC210 document

WG5 update by Ms. Yuwadee PATANAWONG

- 7 action items

WG6 update by Mr. Abdullah AL RASHEED

- Comments (Alfred) – audit duration – this is something that has been always asked. It would be good to look at this in class types, product types, etc.
- Reply (Abdullah) – we will be having the discussion to specify them.
- Comments (Ali) – may need to recruit more members from RA, Bryan will help you to do it.

WG8 update by Mrs. Salbiah Yaakop

- Salbiah new appointed chair
- Alfred comment the “Code of Practice for good engineering maintenance management of medical device” is great document. Please consider to share with other economies.

WG9 update by Ms. Jun Li

- Comments (Alfred): regarding code of practice, are you referring to MS205 standards? FYI, this is a very good standard for active MDs. Another question is that you mentioned that it would bring this to ISO level to be considered. Have you started the process because it takes long time to do
- Suggestion (Alfred): Making this standard available for free to all AHWP members
- Yuwadee suggest the evaluate impact to regulator and industry especially on cost effectiveness. Victoria mentioned want to map out current status on UDI and will help address Yuwadee concern and China UDI is not finalized yet
- Petra suggest to ask what is UDI use for you. Collect less information will need less resource but the database may not meet your use.

Other presentation (presentations will be shared in AHWP website)

IMDRF Meeting Update MC meeting and Stakeholders by Mr. Ali M. Al-Dalaan, TC Chair

- 3D printing is considered personal medical device
- IMDRF welcome regulators to join as observer

WHO update by Ms. Irena Prat

- IVD Prequalification program introduction, financing model, timetable, guidance document etc was shared
- Next WHO Global Forum tentative date is Feb 2019 in India
- WHO global benchmarking tool collecting information from Regulatory authorities and affiliated institution
- Alfred has a question that do WHO also consider the accessories list link with the IVD. Irena indicated WHO provide clear brand name, accessories need to be used with it

AHWP Capacity Building initiatives by Ms. Tran Quan, Vice-Chair Ms. Miang Tanakasemsub, APACMed

- AHWP-Deloitte-APACMed Regulatory Competency Study and 2018-2020 plan
- Activities included In-country training, annual meeting workshop and competency handbook
- Petra mentioned that capacity building concern is people turnover in authority.
- Scott mentioned survey should be more comprehensive in regulator vs industry
- Salbiah Yaakop shared Malaysia experience

OECD Report Case Study of International Regulatory Co-operation by Dr. Jeong-Rim Lee, TC Co-chair

- AHWP presented in OECD meeting
- Dr Lee shared the AHWP guidelines development process, implementation progress, quality mechanism
- Benefits and Challenges of AHWP was shared

Updates by Secretariat by Ms. Sasikala Devi Thangavelu, Mr. Bryan So, Secretariat

- 30 members now. Potential member application is Mexico
- Upcoming AHWP Annual Meetings will be on 22-25 Oct 2018 in Malaysia (exact location TBC)

Action items summary

What	**When**	**Who**
review Definition and Classification of Artificial intelligence	report during in Annual meeting	WG1
work on one guidance document on advertisement and promotion	report during in Annual meeting	WG1, WG2, WG3
New work item (if any) should be submitted one month before Annual meeting. It needed to review by TC leadership	One month before Annual meeting	All WGs
consider to develop guidance document on Cyber security	report during in Annual meeting	WG3
Identify timeslot to work with Mr. Ee Bin group to fix further technical issues by end May 2018	By end May 2018	Carol Liu and Ee Bin
It seems unlikely we will have one global UDI system. As a AHWP	report during in Annual meeting	WG9

group, we should group and discuss next steps for AHWP members		
Presentation of meeting shared in AHWP website	May 2018	Carol Liu

TC Advisory Panel's Recommendations for TC works by Scott

- During AOB, Ali mentioned the following regarding the arrangement of fact-to-face meeting, that would be helpful guideline to all WG leaders:
    - The WG leaders are welcomed to make their own meeting arrangement, whether it is FTF meeting or telecon, however, it should not be at the same time as the TC leaders meeting, and should not be a burden to the host of the TC leaders meeting host.
    - WG are welcome to arrange side meeting or workshop during AHWP annual meeting, and preferably on the first day of the meeting, so as to minimize disturbance to the annual meeting. Interested WG should contact the secretariat as early as possible, so that the meeting organizing committee can make arrangement as soon as possible

AHWP chair and TC chair on AHWP name

- Recognize different generation of AHWP chairs contribution
- AHWP is expanding and getting more global with 30 members
- Suggest to change name of AHWP (Asian Harmonization Working Party) to GHWP (Global Harmonization Working Party)
- Mr. Gao commented
    1. The WG need a diverse membership to gather expertise
    2. Regulators and Industry collaboration is important in regulatory system
    3. Ensure guidance document can contribute members
- Mr. Gao found the AHWP name change to GHWP is critical issue and need AHWP members support. GHWP position and role need to be identified and aligned with IMDRF position and role.
- Petra mentioned there are countries (e.g. Mexico) who has no harmonization organization to join. GHWP name will welcome and attract these countries. Regulator in other region has a platform to learn from regulators in our organization
- Peter and Grant mentioned GHWP name is more welcoming.
- Scott found current AHWP members include Chile, Saudi etc and may be confusing to others AHWP seems not only Asia. Governance need to make it clear to avoid domination
- Asai-san and Irena mentioned name should represent our activities

- Jack mentioned that AHWP has a focus on Asia needs in the beginning. GHWP position is more reflecting our current work, global harmonization, inviting to more countries to join us. Rotation of chair avoid any country domination
- Alfred shared the concern of AHWP resource to support more members, one of AHWP success is collaboration of Government and Industry
- Miang and Carol Yan mentioned name change depends on our overall direction (focus in Asia or global). Need to ensure resource to support if more members
- Bryan mentioned that AHWP do indicate we want to achieve international harmonization in our vision
- Rasheed mentioned that AHWP still accepting new comer now even without name change. New comer will add resource to AHWP
- Yuwadee found the name change is not important. Each members should have active role. AHWP is an attractive name
- Mr Gao agreed that we should consider our overall AHWP direction, and prefer to keep the name Asia as our chair may not come from Asia if we change to GHWP
- Zamane suggested we need to review this topic more relating AHWP direction, unquietness, resource, governance, branding etc

Summary of follow up

What	When	Who
Letter to all AHWP primary and secondary representatives to stress the importance to provide feedback/contribute to WGs and Secretariat, give nomination of members to support WGs	By end May	AHWP Chair
Review the idea of name change of AHWP to GHWP	Discuss in coming AHWP Secretariat meeting (28-29 Jun in KL, Malaysia)	AHWP and TC Chair

--- Meeting Adjourned ---