出國報告（出國類別：參加國際會議）

2019 亞洲醫療器材法規調和會技術委員會領袖會議

(2019 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：沙烏地阿拉伯利雅德

出國期間：108 年 4 月 7 日至 4 月 12 日

報告日期：108 年 7 月 8 日

摘要

「2019 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)蔡技正文偉赴沙烏地阿拉伯利雅德出席與會,會議日期為108年4月7日至4月12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4月9日當天TC領袖會議會後,召開跨工作小組領袖研商會議,邀集一般醫療器材上市前工作小組(WG1 - Premarket: General MD)及軟體醫療器材上市前工作小組(WG3 - Premarket: Software as a Medical Device)之主席及副主席,針對跨工作小組合作事項,進行分工及期程規劃討論。

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 10 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，並向 AHWP 主席爭取，以 AHWP 代表之身分，向國際醫療器材法規論壇(International Medical Device Regulators Forum, IMDRF)新成立之體外診斷醫療器材分類原則工作小組(Principles of IVD Medical Devices Classification)，提出成員申請。

另外，本次出國計畫，藉由聚集各工作小組領袖之機會，安排於 4 月 9 日召開跨工作小組領袖研商會議，邀集 WG1 及 WG3 之主席及副主席，針對跨工作小組合作事項，進行分工及期程規劃討論。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 4 月 9 日至 10 日舉辦，會議議程詳如下：

Agenda
2019 AHWP TC Leaders Meeting
April 9th-10th, 2019

FOUR SEASONS HOTEL, KINGDOM CENTRE
Riyadh, Saudi Arabia

Day 1 April 9th, 2019

Meeting Room: London A&B, Four Seasons Hotel Riyadh

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
08:45 - 09:00	Registration	Secretariat
09:00 - 09:30	Welcome and Opening	HE.Prof.Hisham Al Jadhey. CEO ,SFDA
	Opening speech	Mr. Ali M. Al-Dalaan. AHWP Chair
	Message from Vice Chair(Mr. Gao Guobiao)	By Dir. Huang Qin
	Group Photo	All participants
09:30 - 09:35	1. Adoption of the Agenda & Roll Call	Secretariat
09:35 - 09:40	2. Opening address	TC Chair Ms. Sasikala Devi Thangavelu
9:40 - 12:00	3. AHWP TC's Current Status & Plan （WG1 to WG6) Individual WG work plan discussion 1)Work progress update since the Kuala Lumpur meeting 2)WGs items (new)	All TC participants
9:40 - 10:00	WG 1	Mr. Seil Park Ms. Kate HyeongJoo Kim
10:00 - 10:20	WG 2	Mr. Wen-Wei TSAI Mr. Albert Poon
10:20 - 10:40	WG 3	Dr. Abdullatif Alwatban Mr. Tony Yip
10:40 – 11:00	Break	All TC participants
11:00 – 11:20	WG 4	Ms. Jennifer MAK Ms. Kitty Mao
11:20 – 11:40	WG 5	Mr. Fikriansyah Bin Irman Ms. Sumati Randeo
11:40 - 12:00	WG 6	Mr. Abdullah AL RASHEED Mr. Vincent LAM Chee-Choong
12:00 – 14:00	Lunch	All TC participants

12:00 – 14:00	Lunch	All TC participants
14:00 – 14:20	WG 7	Ms. Wang Aijun Mr. Ee Bin Liew
14:20 – 14:40	WG 8	Mrs. SalbiahYaakop Mr. Tony Low
14:40 – 15:00	WG 9	Ms. Jun Li Ms. Victoria Qu
15:00 - 15:20	Tea Break	All TC participants
15:20 - 15:40	7. IMDRF Meeting Update	Mr. Ali M. Al-Dalaan
15:40-16:00	8. Discussion	All TC participants
16:00 - 16:30	9. Closing Remarks for Day One	Mr. Alfred Kwek, TC Co-chair

Day 2 April 10th, 2019

Meeting Room: London A&B, Four Seasons Hotel Riyadh

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
09:00-09:45	10. Closed Door Meeting for TC Advisors	TC Advisors ONLY

Time	Agenda (AHWP TC Leaders Meeting)	Responsible Person(s)
09:00-09:45	11. 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
10:00-10:30	12. TC Advisory Panel's Recommendations for TC works	TC Advisors
10:30-11:00	13. AHWP/APACMed/Deloitte project white paper	Miang Tanakasemsub & Quan Tran
11:00-11:50	14. Collaborating activities with International Organizations (including Liaisons) 15. AOB	All TC participants
11:50-12:00	16. Closing Remarks	Mr. Alfred Kwek, TC Co-chair
12:00 -13:30	Lunch	All TC participants

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，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。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 WG9 工作小組。後於 2018 年時，AHWP 組織考量教育訓練係推動國際指引之重要方法，故又於該年度 AHWP 年會，宣布將成立第 10 個工作小組「WG10 - Training」，因此，目前之 TC 現況工作小組共有 10 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
10. Work Group 10 (WG10) - Training

AHWP 主席 Mr. Zamane Abd Rahman 於 2018 年底退休，主席之位由原 TC 主席

Mr. Ali M. Al-Dalaan 接任，而 AHWP TC 主席職位則由馬來西亞 Medical Device Authority (MDA) 之 Ms. Sasikala Devi Thangavelu 接任。另外，AHWP 之副主席為中國代表高國標，前年因業務調任至海南島，據本次出席之中國國家藥品監督管理局醫療器械監督管理司綜合處黃勤處長表示，高國標預估明年將調回中央，接續中國醫療器材主管機關職務及 AHWP 相關工作。本次會議，中國由黃勤處長代理高國標出席，帶隊共三人與會。本次 2019 年亞洲醫療器材法規調和會技術委員會領袖會議(2019 AHWP TC Leaders Meeting)，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 Change Management for Registered Medical Devices 等，預訂於今年完成，簡報資料詳如附件 1。此外，本次 TC 領袖會議會後，由秘書處 Jack Wang 提供會議紀錄如附件 2，尚有其它討論重點摘要如下：

- 針對 WG1 的報告及工作進度，TC 主席認同 WG1 在新醫療技術的工作及新貢獻，如：3D 列印醫材指引等，但希望 WG1 能研究有關人工智慧(Artificial Intelligent, AI)醫療器材管理指引。WG1 主席 Mr. Seil PARK 表示，雖韓國已有 AI 醫療器材之管理指引，但實際應用上仍有許多問題，另 WG1 顧問 Mr. Arthur Brandwood 表示 AI 醫療器材產品的開發及使用，尚為新興議題，未來的發展、改變及不確定因素太多，美國 FDA 也在研究中，也許會有管理方向變更，現階段不宜訂立指引，宜持續觀察，待相關產業、主管機關對 AI 醫療器材產品有一定的經驗及更瞭解 AI 醫療器材產品的型式及風險等，才為較合適訂定指引之時機。另 WG1 表示，該工作組人員多非為軟體或 AI 專家，TC 認同相關工作，如有需要應邀請相關專家共同討論。

- AHWP Chair Ali 認同 WG2 的工作進度及 WG2 與其他工作小組的合作。另有關 AHWP WG2 派員加入 Principles of IVD Medical Devices Classification 之工作小組，由於過往經驗 IMDRF 可能只接受 AHWP 提出部分專家名單，Ali 將參考 WG2 所提名單進行優先排序，再向 IMDRF 遞交申請。

- WG3將依據white paper草擬SaMD submission相關指引可作為pre-submission format。WG3同時亦報告了有關IEC 62304改版及醫療器材cybersecurity之要求發展。

- AHWP WG5 (Clinical Evidence for Performance and Safety)新任工作小組主席為 Mr. Fikriansyah Bin Irman, Health Administrator, Directorate of Medical Devices and Household Health Products Evaluation, Directorate General of Pharmaceuticals and Medical Devices, Ministry of Health, Republic of Indonesia。因應未來WG5將轉化多份GHTF文件為AHWP文件，包括IVD相關之臨床性能研究文件。AHWP主席希望WG2與WG5加強合作，以確認臨床及IVD相關專業用詞及定義，因此WG2與WG5將安排於5月舉行電話會議，討論未來合作事宜。

- TC 顧問 Mr. Scott Sanderson 亦為 ISO/TC 210 成員，在 WG6 報告時表示，ISO 13485 小組正尋求可能之新工作項目，另 ISO 13485 品質系統並非取代法規於品質系統上之要求，而是協助法規要求的執行有所依循。

- WG7主席在會上報告，現該工作小組成員，僅有2位來自主管機關，希望能有更多會員國參加。另 TC 顧問 Mr. Grant Ramley 亦為國際認可論壇(International Accreditation Forum, IAF)成員，其表示IAF將在其官方網站上提供ISO13485証書資料庫供免費搜索。

- WG9 小組報告工作進度包括歐盟 UDI 已從 GMDN 改為依據意大利開發的 CND (Classificazione Nazionale dei Dispositivi medici)。CND提供免費公開資料，歐盟將規劃進行CND與GMDN之對照。

- WG10 訓練工作小組由TC主席Ms. Sasikala Devi Thangavelu兼任，未來工作包括推廣AHWP指引相關之訓練。

- AHWP TC Leaders 會議上討論，為加強會員國間之合作，以及 AHWP 指引文件之施行，並使工作小組之工作更順暢，建議在年會中加入 AHWP TC 會員國代表之會議。另主席 Ali 及 Jack 提醒各工作小組主席應盡早聯繫 TC 及年會 Organization Committee，提出工作小組所需之會議場地要求。
- TC 於會上亦報告 AHWP-Deloitte-APACMed 聯合進行醫材法規能力需求研究(Regulatory Competency Study)進度，細節將於年會上報告。
- 2019 AHWP 年會預定於 2019 年 11 月 11-14 日在阿曼 Grand Millennium (暫定)舉行。會議資訊將在 AHWP 網站上公告。

本次出國計畫另一重點任務，即與 WG1 及 WG3 之主席與副主席，召開跨工作小組研商會議，討論合作分工與期程等事務。本次跨工作小組領袖研商會議，已有初步共識，預計將於本年度 8 月在我國辦理一場跨工作小組聯合工作會議，研訂與討論合作之兩份國際指引草案。

肆、結論與建議事項

本次參會除簡報說明我國所領導之 WG2 相關工作進度外，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，且積極爭取代表 AHWP 參與其他國際組織活動，成果具體豐碩。有關參加本次會議，建議事項如下：

1. 鼓勵國產醫療器材業者參與法規調和國際組織活動

   醫療器材國際大廠大多積極參與法規調和國際組織活動，相較之下，國產醫療器材業者所投入資源鮮少，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，增加提早瞭解國際法規趨勢動態之機會，提早準備因應，有利我國醫材產品全球布局。

2. 持續參與 AHWP 相關事務以提升我國國際形象

   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)建立合作關係之優勢，建議可藉由 AHWP 組織代表之方式，實質參與其他重要國際組織之活動，貢獻我國醫療器材管理之經驗，提升我國之國際形象。

附件 1

WG2 – Pre-market: IVDD

Chair: Dr. Wen-Wei TSAI
Co-Chair: Ir Prof. Albert KF POON
Advisor: Ms. Shelley TANG
Secretary: Dr. Christopher CHAN

AHWP TC Meeting
April 9th-10th, 2019 Riyadh

Asian Harmonization Working Party

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.

WG2 Project Activities 2019

- 2019 Activities
  - WG2 1st Teleconference, 20th Feb
  - WG2 1st FTF meeting: Aug(Taipei) (with WG1, WG3 joint session scheduled)
  - WG2 2nd FTF meeting: Nov (Oman)
- Guidance development:
  - Guidance on e-labeling, e-IFU for Medical Device (collaboration with WG1)
  - Guideline for Management of Change Notification for Approved Medical Device (drafting, to be completed in 2019) (collaboration with WG1 & WG3)

WG Progress (I)

	Work Item	Deliverables	Timeline	Progress Update
1	Confirmation of WG membership	WG2 member list	to Apr 2019	44 members in total • 16 regulators • 25 industries • 3 Observers 3 applications to be processed by TC
2	Development of AHWP Guidance Document	1) Labelling for In vitro Diagnostic Medical Devices	Jan 2017 to Oct 2018	• Document endorsed in KL Annual meeting, 2018
		2) Guideline for Management of Change Notification for Approved Medical Device (Joint with WG1 and WG3)	Jul 2018 to Nov 2019	On going: Initial draft prepared by WG2, revising for 2nd draft based on comments from WG1 and WG3
		3) Guideline for Approval of Reagent for Instrument Family	Jan 2019 to Nov 2020	
3	Future trend study & survey	Bridging LDT and IVD survey report	Jan 2019 to Nov 2020	To develop the format and drafting of the survey in 2019

WG Progress (II)

	Work Item	Deliverables	Timeline	Progress Update

3	Participation in International/ Global Organization collaboration and activities	1) Contribution to International IVD Standards
		2) Contribution to WHO Technical Specification Documents
		3) Contributions to IMDRF in IVD Guidance
			2018 to 2020	• WG2 has joined ISO/TC 212 as liaison member to participate in standard discussion and contribution from regulators and industry's point of view.
				• Continuous contact with WHO IVD PQ team to maintain technical communication
				• Collect and consolidate comments from WG2 members on the WHO documents, including:
				  • TSS-6: Syphilis Rapid diagnostic tests
				  • TSS-7: Rapid diagnostic tests to detect hepatitis C antibody or antigen.
				  • TSS-8: Immunoassays to detect hepatitis C antibody and/or antigen
				• Potential Collaboration - IMDRF's New Work Item "Principals of IVD medical devices Classification"
				  • Subject to TC approval, WG2 representatives participate the New Work Item

WG Progress (III)

	Work Item	Deliverables	Timeline	Progress Update

4	Collaboration with other WGs		2018 to 2020	• WG1 & WG2:
				  • e-labeling, e-IFU for Medical Devices (2019)
				• WG1, WG2 & WG3:
				  • Management of Change Notification for Approved Medical Device (2019)

Thank you

附件 2

AHWP TC Leaders Meeting Minutes

Day One
Meeting started at 9:11am
Venue: Saudi Arabia

Welcome and Opening by HE.Prof.Hisham Al Jadhey. CEO, SFDA
Opening speech by Mr. Ali M. Al-Dalaan. AHWP Chair
Message from Vice Chair (Mr. Gao Guobiao) By Dir. Huang Qin

Adoption of the Agenda & Roll Call
Opening address by TC Chair Ms. Sasikala Devi Thangavelu

WG Presentations as attached below
WG activities comment and discussion summarized as below

WG1 update (by Mr. Seil Park)

- For Artificial Intelligence, WG1 still monitoring IMDRF on guidance document. There are challenges in classification. US FDA is developing guidance document on AI as well.
- For Personalized medical device guidance, WG1 is monitoring IMDRF progress and will decide whether it is needed to develop AHWP guidance.
- For innovative device, it will be good to have guidance document to assist and fast track approval.

WG2 update (by Wen-Wei Tsai)
IMDRF has invited AHWP to nominate IVD experts to join their work item on IVD classification. AHWP will support WG2's nomination, and invite other interested expert to submit forward, by next week.

WG3 update (by Tony Yip)
For Cybersecurity, suggest to include Singapore and Kitty happy to support. We should also consider on how to implement. Japan also developing guidance document on cybersecurity.

WG4 update (by Jennifer Mak)

- ISO 20416 available for member to review.

- Ali recommend other authority to participate coming ISO TC 210 WG 06 meeting in US.

WG5 update (by Mr. Fikriansyah Bin Irman)

- Comment on how members can benefit from the guidance document.
- A lots of guidance document developed are based on GHTF, please consider to update/revise according to latest IMDRF.

WG6 update (by Mr. Abdullah AL RASHEED)

Saudi plan to use latest ISO 13485 to apply on distributor.

WG7 update (by Mr. Ee Bin Liew)

- For implementation purpose, consider to suggest how pharmaceutical companies (with GMP) transit to medical companies (with ISO 13485 standard).
- Members may consider to suggest IMDRF to raise a new project to handle GDP (without rewriting ISO 13485). ISO 13485 could be the unified standard, Current GDP is based on different international and local standards and accreditation of certification bodies are also challenge.

WG8 update (by Mrs. SalbiahYaakop)

Good engineering maintenance management of medical device to be developed and to be shared with ISO TC210.

WG9 update (by Ms. Victoria Qu)

No further question.

WG10 update (by Sasikala)

- It is a new working group on capacity building.
- Encourage regulator and industry participate the WG.
- WG10 objectives will align with AHWP mission statement.

WG identify strategic plan focus below

- Survey (done by APACMed).
- Develop curriculum.
- Identify trainers.
- Please also stress on “How to utilize AHWP guidance documents”.

All WGs

- Ali stressed that all WGs chair should also work together to harmonize and avoid duplication.
- Sasikala stressed the importance of measurement.

IMDRF Meeting Update (by Mr. Ali M. Al-Dalaan)
- AHWP will nominate WG2 experts on IVD, Personalized medical device to support IMDRF on their new work item.
- AHWP will participate more in ISO projects.

Discussion (by All TC participants)
- WG chairs need to refresh their member list base on their active participation.
- WG Chair has the right to identify more external experts if required.
- AHWP continue to support some regulator members to attend annual meeting if travel expense support required.

Closing Remarks for Day One by Sasikala

Day Two
Meeting started 9:15am

Communication channel with IMDRF

TC economies member support
- Need more regulators participation in WG.
- WG7 need members support to update the standard.
- Will arrange a team call to welcome Sasikala, discuss role of TC economies members to support WG activities, any document to be endorsed need to be circulated 3 months before Oman meeting, TC update before Oman meeting, TC meeting arrangement in coming Oman meeting (Jack will arrange TC economies member and WG chairs and co-chairs call during April/May time).

WG membership refreshment
WG chairs to refresh the membership, submit to Sasi if there is new members.

Canada regulatory 101 resource FYI
https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=42&lang=en&hootP

ostID=acc6e04d9471a524dfc0eb9e2c6bf793

TC advisors input

- Congratulation to the new leadership
- Again the WG have shown nice progress on their work plans to support the strategic objectives of AHWP
- It is good to see the collaboration and liaison connections being used with ISO and IMDRF
- A positive observation was the interaction between AHWP WGs and the recognition that some work affects several working groups

Suggestions from TC Advisors

- Membership focus – rules for engagement, need to increase regulators support of WG. Consider active invitation.
- WG should be encouraged to reach out to experts especially on complex subjects.
- Some items should be monitored only at this point (e.g. Artificial Intelligence), WG could provide periodic updates on these monitoring activities.
- Maximize liaison memberships by AWHP members actively joining ISO and IMDRF working groups, additionally encourage IMDRF participation at the AHWP meetings.

Meeting suggestions

- A common report for WG format.
- Using TC and Annual meetings as a platform for face-to-face WG meetings.
- Continue and expand dedicated capacity building event.
- Concern on less and less regulator involvement in general trend (Jack will arrange TC economies member and WG chairs and co-chairs call during April/May time).
- Need more expert e.g. software expert in the team (Scott and Advisors team please provide more recommendation of expert to be included).

Current revision process of IEC 62304 by Peter

- Medical device software to health software (as medical device definition is varied among countries).
- AHWP/APACMed/Deloitte project white paper by Miang Tanakasemsub & Quan Tran.
- White paper will be shared.

Collaborating activities with International Organizations (including Liaisons)

- Need strong engagement with IMDRF.
- China update was shared.

AHWP annual meeting

- Location, Grand Millenium Muscat, Sultanate of Oman.
- Dates 11-14-2019.
- WG chairs inform any need of meeting room requirement (number of participants, time) for their WG meeting during Oman Annual meeting (WG chairs inform TC Secretariat (Jack, Carol, Miang) and Faiza (our regulator in Oman, 'Faizaalzadjali30@hotmail.com') by end April).

Closing Remarks for Day One by Sasikala

--- Meeting Adjourned ---