

Reports by AHWP/GHWP Secretariat 2020-2021

25th AHWP/GHWP Annual Meeting
30th Nov & 1st Dec 2021, Online

Ir Bryan SO
Executive Secretary General
AHWP/GHWP



Global Harmonization Working Party
Towards Medical Device Harmonization

Secretariat Supports

Support to AHWP/GHWP Leadership

- Secretariat Meeting
- OC and organization of AHWP Annual Meeting
- AHWP website upgrade and maintenance
- SADS on-line

Support to Capacity Building

- CB workshop speakers coordination
- CB workshop logistic support
- Circulation of CB white paper curriculum

Support to Technical Committee

- Support the organization of AHWP TC and WGs
- Facilitate WG Meetings
- Act as communication bridges for documents endorsements

Support to Admin Service Ltd (ASL)

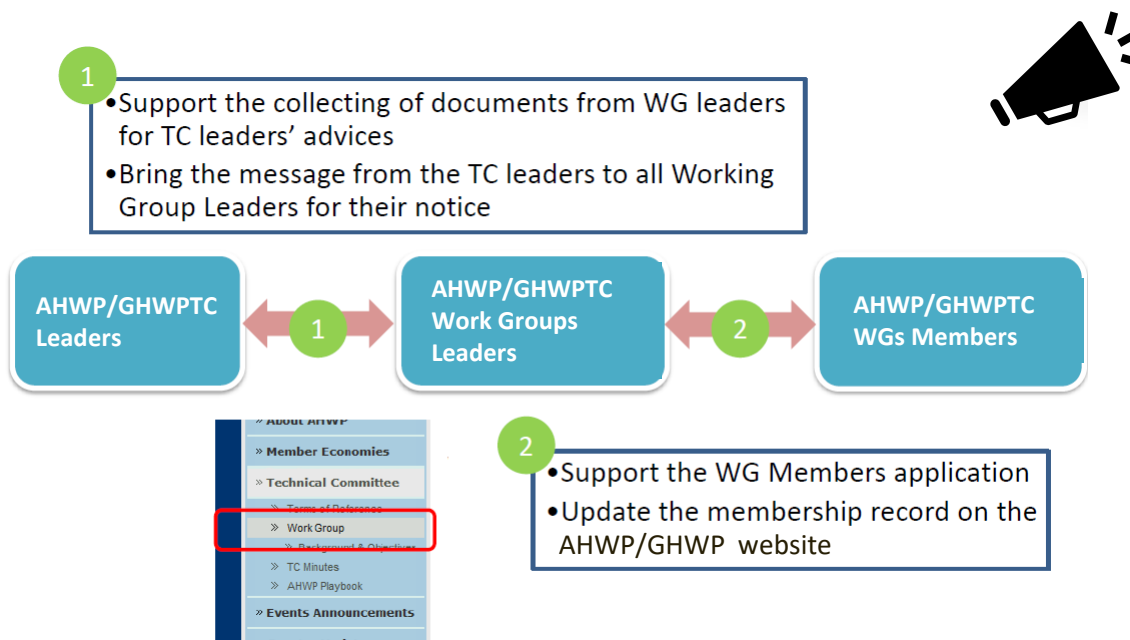
- Annual general meeting(s)
- ASL membership
- Management of AHWP Reserve/Fund

Secretariat Support for Application to Join as New Member & New Liaison Member

- **Procedures** for new application:
 - ✓ Official Letter by government authority
 - ✓ Nominated country representative(s) by the local Regulatory Authority
- Invite representatives from the new applicants to join the 25th AHWP/GHWP Annual Meeting Online 2021
- **Application endorsement** at the Annual Meeting
- Number of AHWP Member Economies: 31 (as of 30th Nov 2021)

Brunei Darussalam	Kazakhstan	Pakistan	Sultanate of Oman
Cambodia	Kingdom of Bahrain	People's Republic of China	Tanzania
Chile	Kingdom of Saudi Arabia	Philippines	Thailand
Chinese Taipei	Kyrgyz Republic	Republic of Kenya	United Arab Emirates
Hong Kong SAR, China	Laos PDR	Republic of Korea	Vietnam
India	Malaysia	Singapore	Yemen
Indonesia	Mongolia	South Africa	Zimbabwe
Jordan	Myanmar	State of Kuwait	

Act as Communication Bridges Between AHWP/GHWPTC Leaders and Working Groups



Support to AHWP ASL Operations and Meetings

AHWP Administration Services Limited (ASL)

- **Solicitation & handling of sponsorships for AHWP/GHWP**
- Collection & handling of company sponsorships for AHWP/GHWP meetings, CB and website
- Organization of Board of Directors Tele-con for reviewing of AHWP ASL financial position, special resolutions, etc.
- **Organization of Annual General Meeting (AGM) of AHWP ASL**
- Work with professionals(accountant, auditor, company secretary, legal advisor) to support AHWP ASL daily operations
- Supporting the **review and signatory of legal documents** between AHWP/GHWP and external organizations
- Processing new AHWP ASL membership applications

Management of AHWP/GHWP Reserve/Fund in AHWP ASL

- The **surplus from AHWP/GHWP website, Capacity Building Sponsorships and AHWP/GHWP Meetings** were pooled into the AHWP/GHWP Reserve/Fund under the AHWP ASL Account
- AHWP/GHWP Reserve/Fund has supported round-trip air tickets and hotel accommodations for the invited speakers and the sponsored regulatory representatives of AHWP member economies for their attendance to the AHWP/GHWP PHYSICAL Meetings
- Supported by the professional services providers, including accountants, auditors, company secretary and legal advisor, **ASL financial and statutory documents were prepared** according to companies ordinance in Hong Kong SAR, China
- Future planning will be better utilize the financial resources available to support capacity building, training, as well as enhancing communications and public awareness

Support in Organizing Committee (OC) and Support to Host of AHWP/GHWP Meetings & TC Meetings

Formation and holding Organizing Committee (OC) meetings for the 25th AHWP/GHWP annual meeting and 25th AHWP/GHWP TC meeting

- AHWP Secretariat has coordinated and supported the OC, localhost (for physical meeting) and speakers from different organizations to facilitate the successful organization of AHWP/GHWP Event 2020/21, including the Capacity Training Workshop, AHWP/GHWPTC Workshops, 24th AHWP/GHWP TC Online Meeting & 25th AHWP/GHWPTC Meeting and the 25th AHWP/GHWP Main Meeting online, including:
 - Website announcements
 - Review of event budget
 - Speaker invitation & delegates supports
 - Liaison with new Members and global organizations
 - Development of event programme & collecting presentations materials
 - Development of event sponsorship package
 - Recruitment of participants
 - other logistics

Secretariat Services Support Provided by HKMHDIA via Contract

- Secretariat Office in Hong Kong
- **Dedicated full-time staff - Ms Elizabeth Chan (Liz), Secretariat Officer**
- Maintenance of AHWP/GHWP Membership Database
- Facilitation of Communication
- Routine maintenance of AHWP/GHWP Website
- Support on AHWP/GHWP Sponsorship Solicitation
- AHWP/GHWP Meetings (AHWP/GHWP Main Meeting, AHWP/GHWP TC Meeting, AHWP/GHWP TC Leaders Meeting, AHWP/GHWP Secretariat Meeting, ASL Meeting)
- AHWP/GHWP Nomination and Election Preparation
- Administrative Service to ASL
- Other Administrative Service

AHWP/GHWP SADS On-line weekly Update

- Password-based on-line system launched since May 2014
- Collaborated by WG4 and Secretariat
- Supported by **Post Market Resource Center**
 - Facilitate the post-market surveillance information exchange among AHWP/GHWP members and IMDRF
- **New members applications** to SADS
- **Weekly update** of SADS on the AHWP/GHWP Website

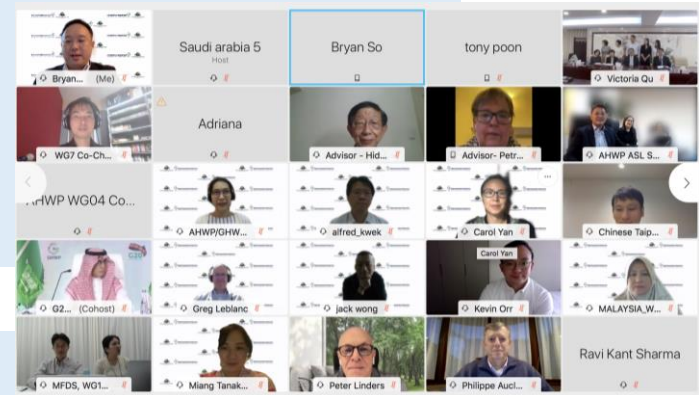


The screenshot shows the AHWP website interface. At the top right, the AHWP logo and name are displayed: "Asian Harmonization Working Party WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA". Below this is a navigation bar with links: HOME, CHAIRMAN'S MESSAGE, HISTORICAL DEVELOPMENT, MEETING CALENDAR, CONTACT, and a search bar. The main content area is titled "SADS Online" and features an "Important Message" box. The message states: "The current AHWP Safety Alert Dissemination System (SADS) only accepts regulatory authorities of AHWP member economies as members, please refer to the Guidance Document on AHWP SADS (AHWP/WG4/ F003.2016) for details. Interested parties could complete the Application Form for Joining the SADS and return it to the AHWP Secretariat via email (secretariat@ahwp.info) for processing. A Guidance Document on AHWP SADS (AHWP/WG4/F003.2016) was endorsed at AHWP Annual Meeting 2016. For details please refer to: AHWP SADS (AHWP/WG4/F003.2016) Final Document." To the left of the message is a sidebar menu with links: About AHWP, Members, Technical committee, News, Events Announcements, Events, Country/Region Updates, Documents, SADS Online, Trade Related Issue, Web Resources, Secretariat, and Archive. Below the menu is a "LOG ON HERE" section with fields for Username and Password.

Meetings and Capacity Building go Online during COVID-19

2020

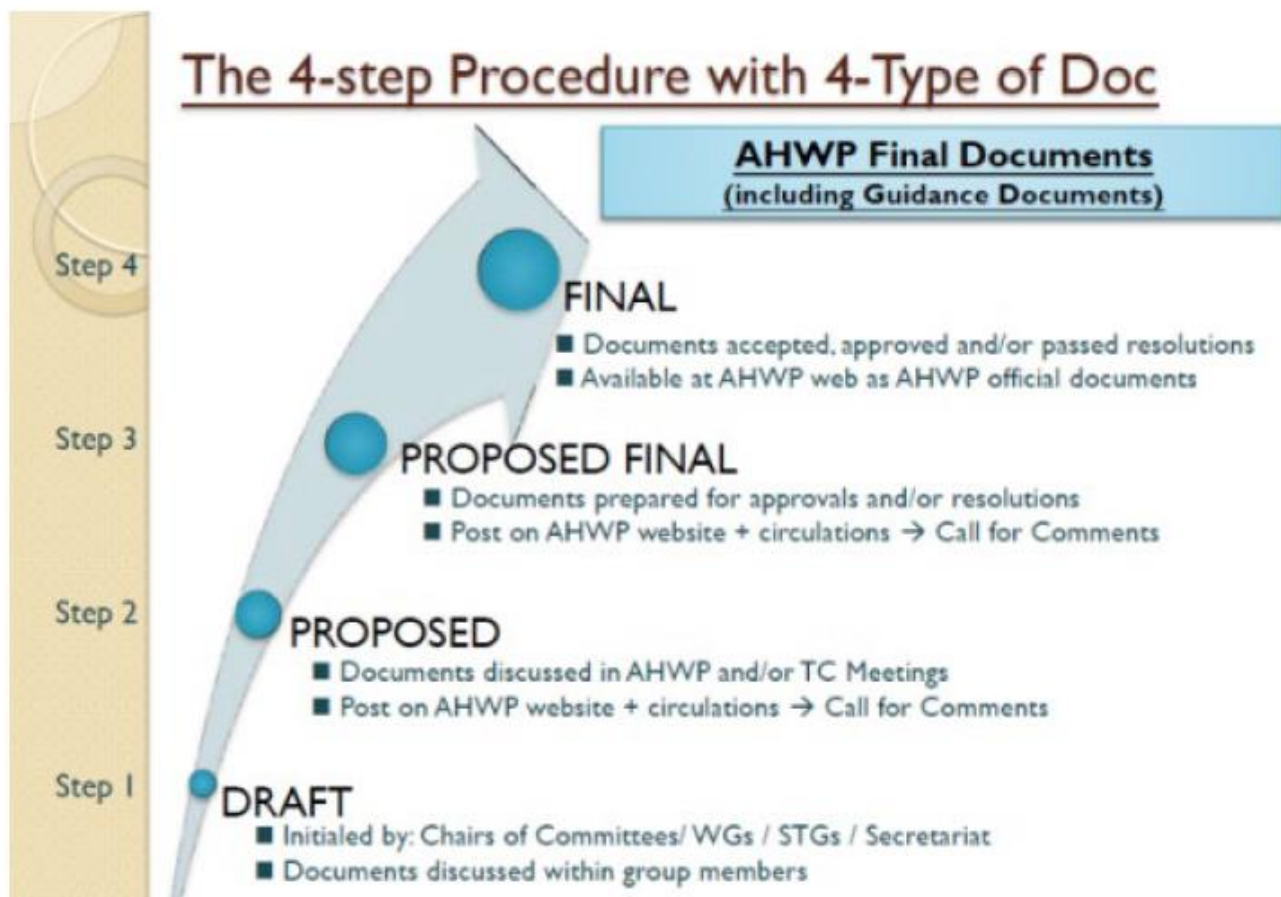
- TC Leaders Meeting 18th Mar
- TC Leaders Meeting 21st May
- Secretariat Meeting 26th Jun
- TC WGs Progress Meeting 9th Jul
- Secretariat Meeting 18th Aug
- TC Leaders Meeting 13th Oct
- Capacity Building 30th Nov - 3rd Dec
- Webinar on White Paper 30th Nov
- Secretariat Meeting 1st Dec
- TC WGs Progress Meeting 17th Dec



2021

- Secretariat Meeting 13th Jan, 15th Mar, 27th Apr and 29th Jun, Sep, Oct, Nov..
- TC WGs Progress Meeting 3rd Feb and 21st Jun
- Capacity Building Training 4th Feb, 22nd Mar, 22nd Apr and 29th Jun...

Secretariat Support on Endorsement of New Guidance Documents, White Papers and Change of TOR and House Rules



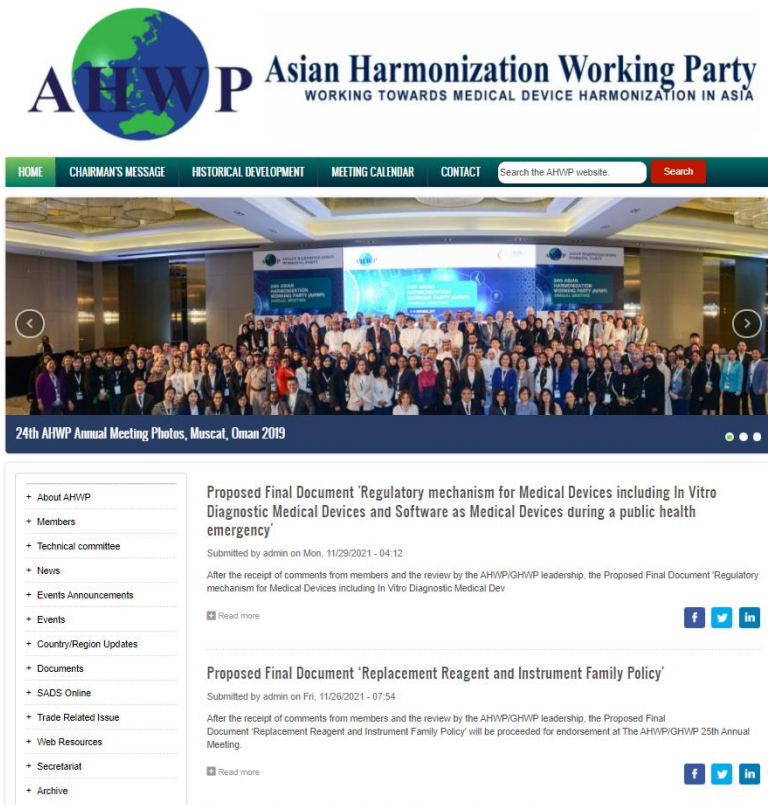
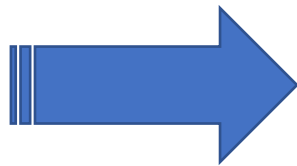


Global Harmonization Working Party

Towards Medical Device Harmonization

AHWP/GHWP Official Website

- Tablet and cell phone friendly
- Android and iOS
- Cybersecurity Updated



Financial Position

Financial Position Towards End of Year 2021

Financial Position Towards End of Year 2021		
Total Current Bank Balance (as of 5 November 2021) *including CB sponsorship		
(A) Balance in HKD		533,700.16
(B) Balance in USD		17,258.02
(C) Balance in Foreign Currency (THB)		1,603.73
	Amount (HKD Equivalent)	Amount (USD Equivalent)
Total Balance	668,368.19	85,688.23
Income	Amount (HK\$)	Amount (US\$)
(I-1) Sponsorship for the 25th AHWP/GHWP Annual Meeting	0.00	0.00
(I-2) Sponsorship for the AHWP/GHWP Capacity Building Program from APACMed and Roche	232,943.59	29,864.56
Expenditure Estimate	Amount (HK\$)	Amount (US\$)
(E-1) HKMHDIA Secretariat Services Support and Administration Fees (1 Oct 2021-31 Dec 2021)	105,300.00	13,500.00
(E-2) Professional accounting service, auditing, company secretary, legal service fees	24,400.00	3,128.21
(E-3) AHWP/GHWP Capacity Building Program (Phase 2 - curriculum for regulators)	232,943.59	29,864.56
(E-4) Website and Email Re-branding	6,630.00	850.00
(E-5) Company Secretary fee for Re-branding	4,000.00	512.82
(E-6) Renewal of web domain	210.40	27.04
(E-7) Domain for Cloud storage and database for 1 year renewal	2,376.00	691.00
Estimated Total Expenditure:	375,859.99	48,573.63
Estimated Net Balance (Balance - Expenditure Estimate)	292,508.20	37,114.60