Report by AHWP Secretariat 2017-2018
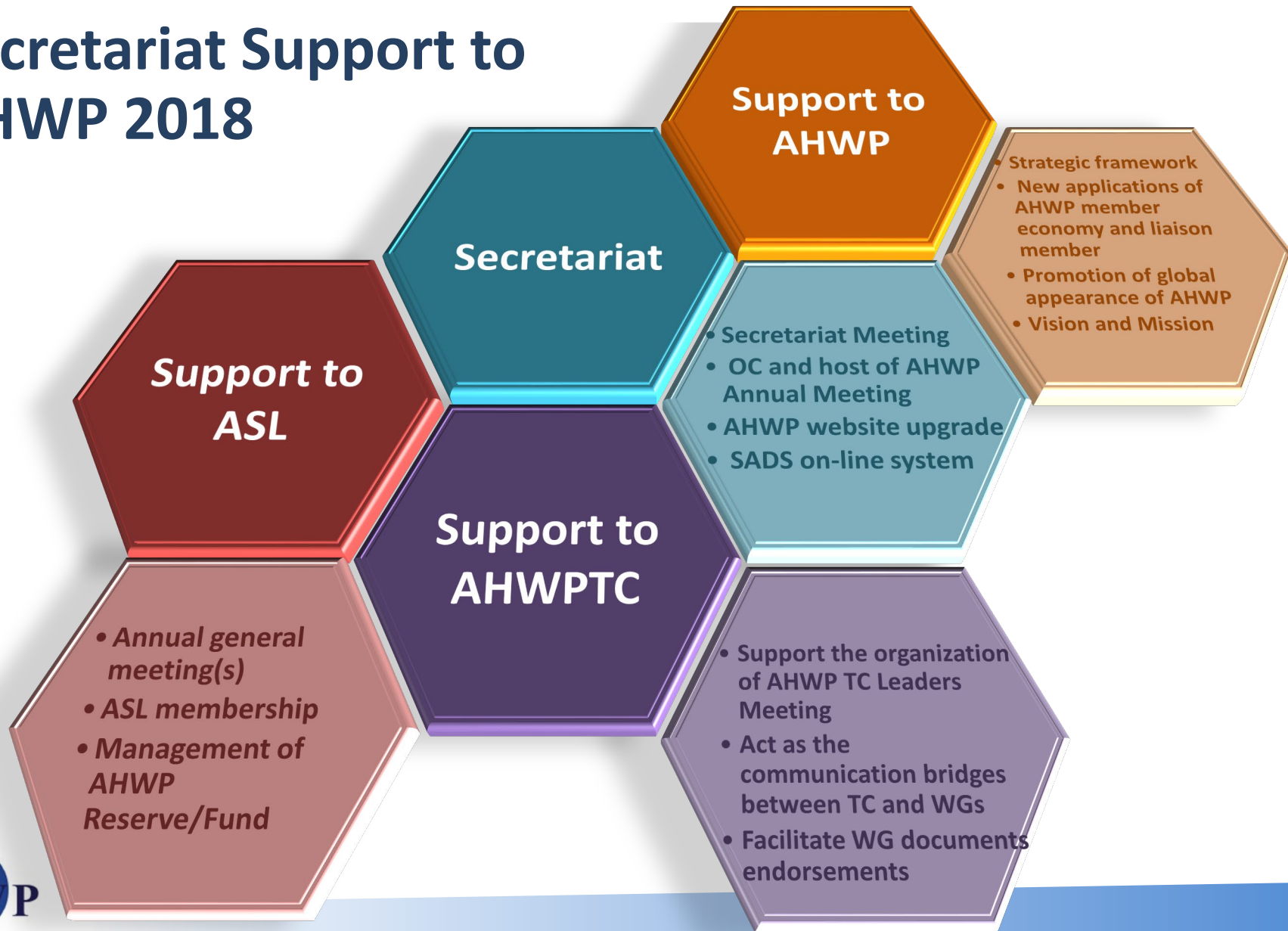
23rd AHWP Annual Meeting

22-28 Oct 2018, Kuala Lumpur, Malaysia

Dr. Lawrence POON

AHWP Secretariat

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Secretariat Support to AHWP 2018

Secretariat

Support to AHWP
- Strategic framework
- New applications of AHWP member economy and liaison member
- Promotion of global appearance of AHWP
- Vision and Mission

- Secretariat Meeting
- OC and host of AHWP Annual Meeting
- AHWP website upgrade
- SADS on-line system

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

Support to AHWPTC
- Support the organization of AHWP TC Leaders Meeting
- Act as the communication bridges between TC and WGs
- Facilitate WG documents endorsements

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2

Support to AHWP

- Strategic framework
- New applications of AHWP member economy and liaison member
- Promotion of global appearance of AHWP
- Vision and Mission

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AHWP Strategic Framework Towards 2020
"The Foreseeable Harmonization Horizon"

Support to AHWP

4 Framework Elements:

- **AHWP Member Expansion**
- **Training and Capacity Building**
- **Harmonization in Key Areas Based on GHTF Principles and AHWP Guidance**
- **Enhance AHWP's Global Partnership**

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Secretariat Support to the New Application for Joining AHWP Member Economies

Support to AHWP

- **Procedures** for new application:
  - Official Letter by government authority
  - Nominated country representative(s) by the local Regulatory Authority
- Invited representatives from the new applicants to join the 23rd AHWP Annual Meeting, Kuala Lumpur, Malaysia, 2018
- Towards **endorsement** at the Annual Meeting
- Number of AHWP Member Economies: 30 (as of Mar 2018)

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

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Quick Summary of AHWP Annual Meeting in Delhi, 4-8 Dec 2017

- AHWP Playbook Training
- AHWP TC Workshop
- 21st AHWP TC Meeting
- 22nd AHWP Annual Meeting
- New Leadership Election

- Over 360 delegates
- ~30 countries from Asia Pacific, Middle East, Africa, South America, North America, Europe regions
- 51 speakers
- 13 main themes and 4 panel discussions
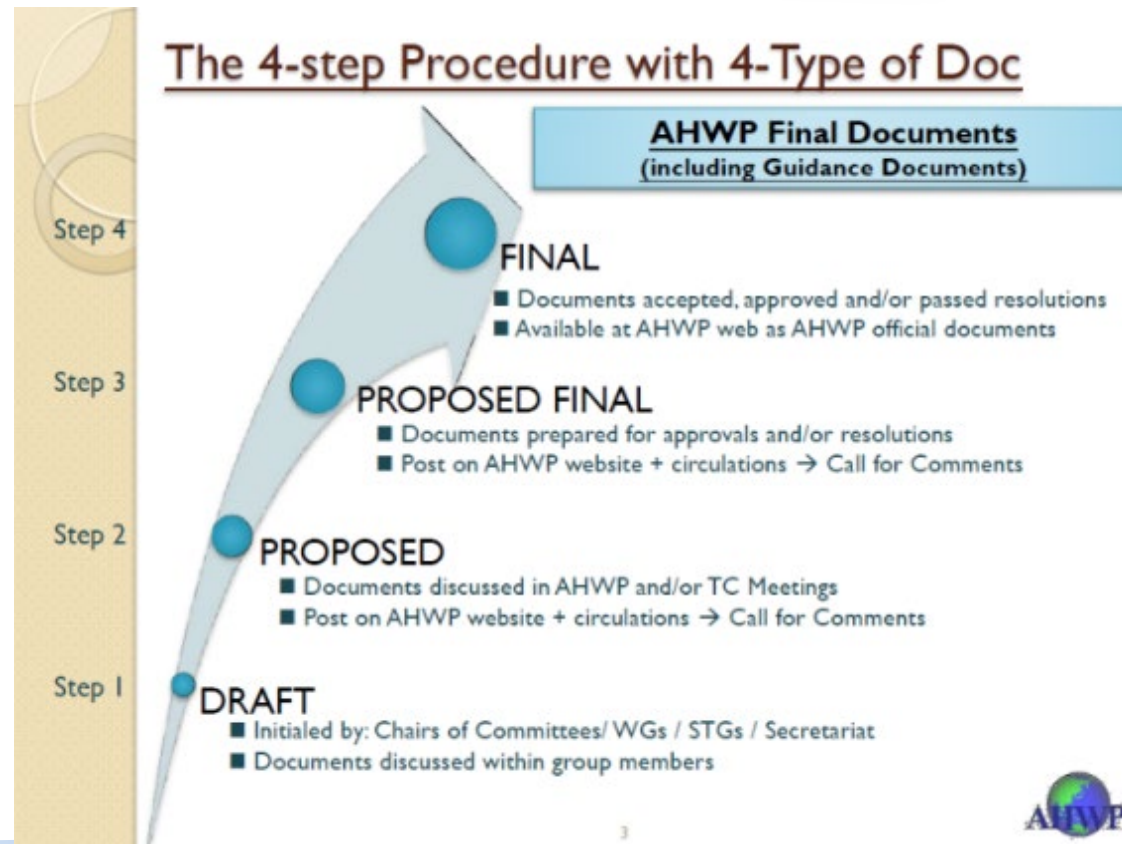
Support to the AHWP Annual Meeting & Capacity Building

Support to AHWP

- Supported the organization of **trainings/workshops** for building capacity during the past Annual Meeting/year:
  - AHWP , APACMed, Deloitte Competency Framework for AHWP Regulators

- Supported the logistics, communication and coordination for arranging **workshops/panel discussions** during the 23rd AHWP Malaysia Meeting, with topics:
  - Artificial Intelligence in Healthcare
  - Digital Innovation & Best Practices for Cybersecurity
  - IVD Regulatory requirements
  - Digital Health Regulations
  - UDI regulatory requirements
  - Quality System Certification & Standard

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Support to the Harmonization in Key Areas based on GHTF Principles and AHWP Guidance

- Supported the **4-step procedures** of AHWP **Guidance Documents, White papers**

- Working Group Reference Document endorsed in 2018:
  - Post-Market Surveillance (PMS) Survey Report 2017

The 4-step Procedure with 4-Type of Doc

AHWP Final Documents
(including Guidance Documents)

Step 4 — **FINAL**
- Documents accepted, approved and/or passed resolutions
- Available at AHWP web as AHWP official documents

Step 3 — **PROPOSED FINAL**
- Documents prepared for approvals and/or resolutions
- Post on AHWP website + circulations → Call for Comments

Step 2 — **PROPOSED**
- Documents discussed in AHWP and/or TC Meetings
- Post on AHWP website + circulations → Call for Comments

Step 1 — **DRAFT**
- Initialed by: Chairs of Committees/ WGs / STGs / Secretariat
- Documents discussed within group members

Support to the Enhancement of AHWP's Global Partnership

Support to AHWP

- AHWP Liaison members: **DITTA**, **GS1, APACMed**

- AHWP is an affiliate organization to **IMDRF**

- Support the communication and logistics to invite global organizations to update at the 23rd AHWP Annual Meeting
  - APEC, ASEAN, APACMed, DITTA, WHO

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Support to AHWP TC

- Support the organization of AHWP TC Leaders Meeting
- Act as the communication bridges between TC and WGs
- Facilitate WG Documents Endorsements

Support the Organization of AHWP TC Leaders Meeting

- Supported the organization of **AHWP TC Leaders Meeting**, participated by AHWP TC leaders, WG leaders, TC Advisors, AHWP leaders and Secretariat
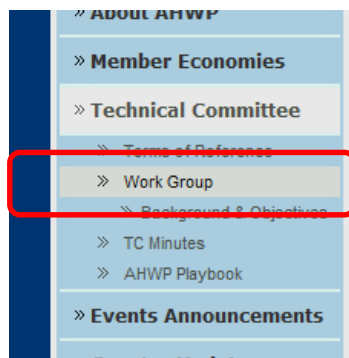

TC Leaders Meeting, 8-9 May 2018, Beijing

Act as Communication Bridges Between AHWP TC Leaders and Working Groups Level

Support to AHWPTC

1
- Support the collecting of documents from WG leaders for TC leaders' advices
- Bring the message from the TC leaders to all Working Group Leaders for their notice

AHWP TC Leaders	← **1** →	AHWP TC Working Group Leaders	← **2** →	AHWP TC Working Group Members

» About AHWP
» **Member Economies**
» **Technical Committee**
    » Terms of Reference
    » Work Group
        » Background & Objectives
    » TC Minutes
    » AHWP Playbook
» **Events Announcements**

2
- Support the WG Members application
- Update the membership record on the AHWP Website

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Support to AHWP ASL

- Annual General Meeting(s)
- ASL membership
- Management of AHWP Reserve/Fund

Support to AHWP ASL Operations and Meetings

Support to the operation of AHWP Legal Entity

– AHWP Administration Services Limited (ASL)

- 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

- Collection & handling of company **sponsorships for AHWP meetings**

- Solicitation & handling of **sponsorships for AHWP official website**

- 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 and external organizations

- Processing **new AHWP ASL membership** applications

Management of AHWP Reserve/Fund in AHWP ASL

- The **surplus from AHWP website and AHWP Meetings** were pooled into the AHWP Reserve/Fund under the AHWP ASL Account

- AHWP Reserve/Fund has **facilitated** the 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 Meetings**

- Supported by the professional services providers, including accountants, auditors, company secretary and legal advisor, **ASL financial and statutory documents were prepared** based on the companies ordinance in HKSAR

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Secretariat

- Secretariat Meeting
- OC and host of AHWP Annual meeting
- Upgrade of AHWP website
- SADS On-line System

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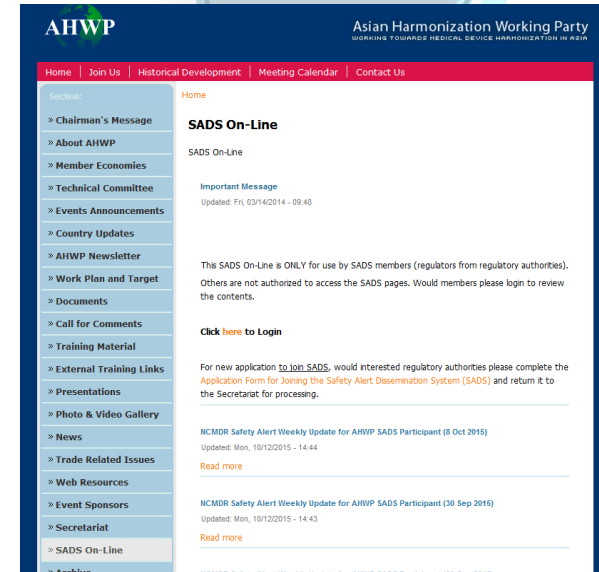# Support to OC and Host of AHWP & TC Meetings

Secretariat

- **Formation and participation of Organizing Committee (OC)** of the 23rd AHWP annual meeting and 22nd AHWP TC meeting

- AHWP Secretariat has **coordinated and supported** the **OC**, **local host** (Federation of Indian Chambers of Commerce and Industry) and **speakers from different organizations** to facilitate the successful organization of **AHWP Event 2018**, including the Capacity Training Workshop, AHWPTC Workshops, 22nd AHWPTC Meeting and the 23rd AHWP Main Meeting in Kuala Lumpur, 2018, including
  - Website announcements
  - Review of event budget
  - Speaker invitation & delegates supports
  - Liaison with new Member Economies and global organizations
  - Development of event programme & collecting presentations materials
  - Development of event sponsorship package
  - Recruitment of participants
  - Venue arrangements and other logistics

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AHWP 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 members and IMDRF

- **New members applications** to SADS
  - A total of 23 Member Economies joined as the member of SADS .
  - **Weekly update** of SADS on the AHWP Website

ASIAN HARMONIZATION WORKING PARTY

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AHWP Official Website Revamp

Goal:

- To **enhance the effectiveness and user-friendliness** of AHWP web as a communication/information exchange **platform** for **members and stakeholders**

AHWP Official Website Revamp
What's left

Completed Tasks

- User Acceptance Test (UAT) by secretariat at development server
- Website **vulnerability test** at server of Hong Kong Productivity Council (HKPC)
- **Transfer** of AHWP new website files to HKPC server for UAT

What's left

- **Security Test** by HKPC
- **User Acceptance Test** by AHWP leadership for final check of website

Thank You

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