

# Report by AHWP Secretariat 2018-2019

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24<sup>th</sup> AHWP Annual Meeting  
11-14 Nov 2019, Muscat, Oman

Mr. Benjamin Chan  
AHWP Secretariat



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# Secretariat Services Support Provided by HKMHDIA commencing from July 2019

Hong Kong Medical and Healthcare Device Industries Association  
(<http://www.medicaldevice.org.hk/>)



- Established since 2003 to represent stakeholder interest in the medical & healthcare device industries in Hong Kong with approx. 200 Corporate and Associate members
- With 6 functioning panels to oversee the developments of
  - Members affairs
  - Business networking
  - Corporate Communications
  - Product and Technology
  - Training and Education
  - Quality and Regulatory Affairs
- Actively participate in regulatory development locally and regionally

# Secretariat Supports to AHWP 2019

## Support to AHWP

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

## Support to AHWPTC

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

## Support to ASL

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

## Secretariat

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

# AHWP Strategic Framework Towards 2020

## *“The Foreseeable Harmonization Horizon”*



4 Framework Elements:

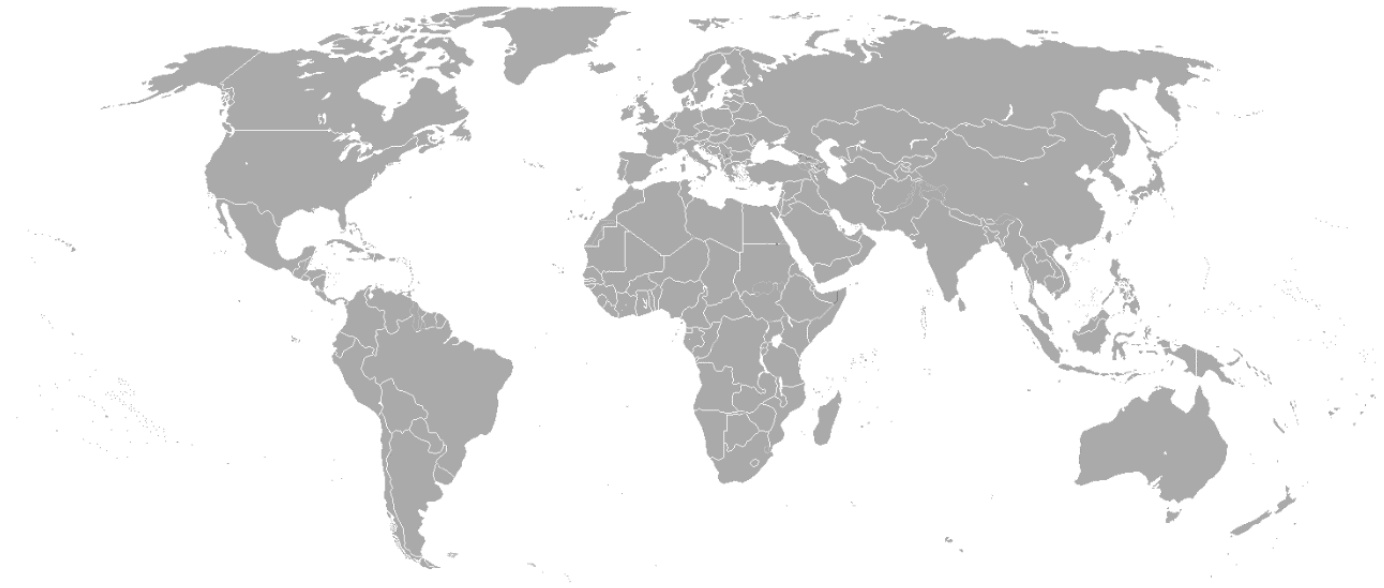


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# Secretariat Support to the New Application for Joining AHWP Member Economies

*Support  
to AHWP*

- Received **new application and endorsed in 2019 to become our 31<sup>st</sup> Member:**  
**Kyrgyz Republic**



# Secretariat Support to the New Application for Joining AHWP Member Economies



- **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 24<sup>th</sup> AHWP Annual Meeting, Muscat, Oman, 2019
- Application endorsed at the Annual Meeting
- Number of AHWP Member Economies: 30 (as of Mar 2019)

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		



# Summary of AHWP Annual Meeting in Kuala Lumpur, 22<sup>nd</sup> – 25<sup>th</sup> Oct 2018

*Support  
to AHWP*

- AHWP TC Workshop
- 22<sup>nd</sup> AHWP TC Meeting
- 23<sup>rd</sup> AHWP Annual Meeting

- Over 250 delegates
- ~30 member economies from Asia Pacific, Middle East, Africa, South America, North America, Europe regions
- 54 speakers
- 8 main themes and 3 panel discussions



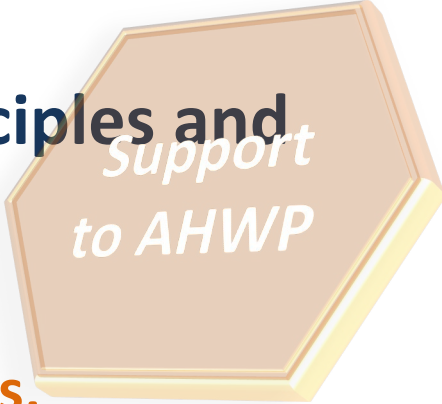
# Support to the AHWP Annual Meeting & Capacity Building



- 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 24th AHWP Oman Meeting, with topics:
  - AHWP Capacity Building Workshop
  - Networked Medical Device Cybersecurity and Patient Safety
  - UDI Implementation Experience
  - ISO13485:2016 Quality Management System for Medical Devices

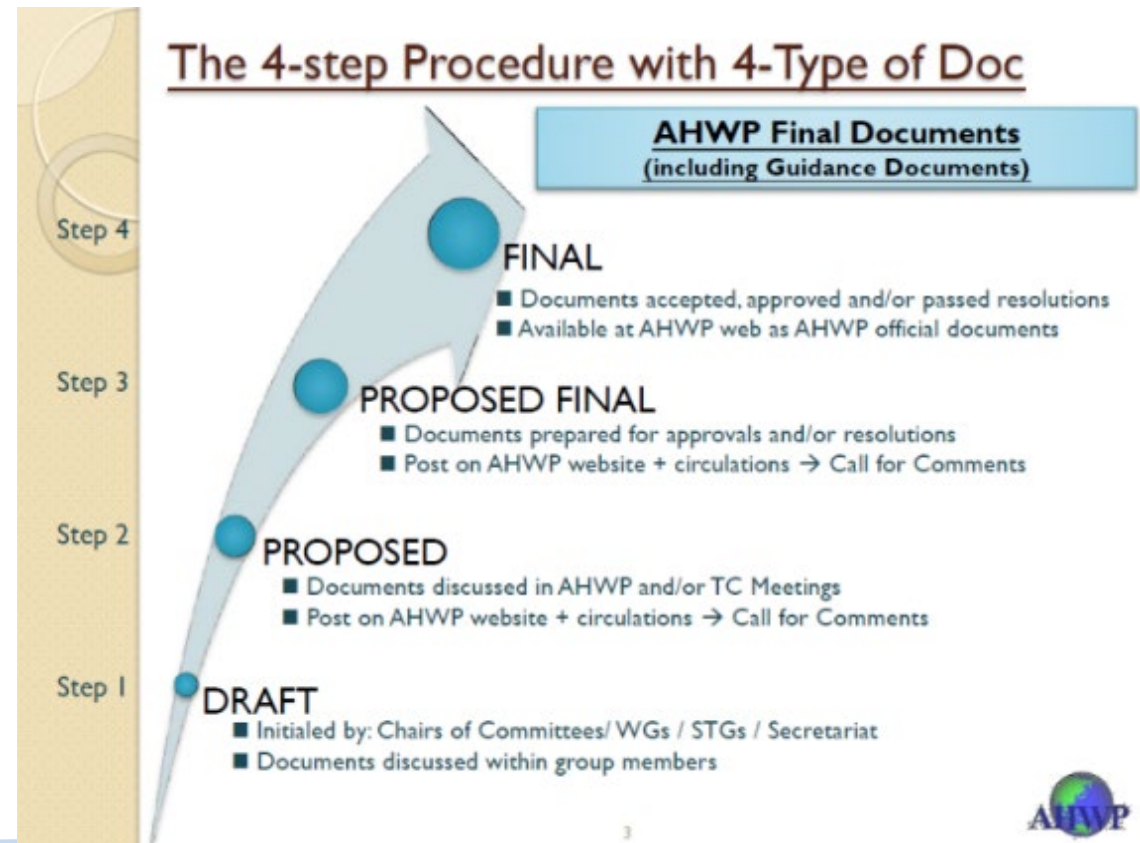


# Support to the Harmonization in Key Areas based on GHTF Principles and AHWP Guidance



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

- WG Reference Document to be endorsed in 2018:
  - Post-Market Surveillance (PMS) Survey Report 2017



# Support the Enhancement of AHWP's Global Partnership



- 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 24th AHWP Annual Meeting
  - APEC, ASEAN, APACMed, DITTA, GS1, IMDRF, WHO

# 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, 9<sup>th</sup> – 10<sup>th</sup> April 2019, Riyadh, Saudi Arabia

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



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



2

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

# 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 **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 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
- Future planning will be better utilize the financial resources available to support capacity building, training, as well as enhancing communications and public awareness



# Support to OC and Host of AHWP & TC Meetings



- **Formation and participation of Organizing Committee (OC)** of the 24<sup>th</sup> AHWP annual meeting and 23<sup>rd</sup> AHWP TC meeting
- AHWP Secretariat has **coordinated and supported** the **OC, local host** (Ministry of Health, Oman) and **speakers from different organizations** to facilitate the successful organization of **AHWP Event 2019**, including the Capacity Training Workshop, AHWPTC Workshops, 23<sup>rd</sup> AHWPTC Meeting and the 24<sup>th</sup> AHWP Main Meeting in Muscat 2019, 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

# Secretariat Services Support Provided by HKMHDIA

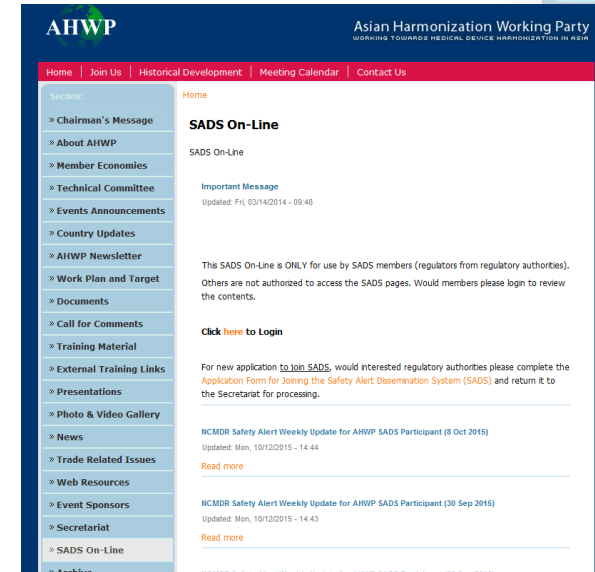


- Dedicated full time staff
- Maintenance of AHWP Membership Database
- Facilitation of Communication
- Maintenance of AHWP Website
- Support on AHWP Sponsorship Solicitation
- AHWP Meetings (AHWP Main Meeting, AHWP TC Meeting, AHWP TC Leaders Meeting, AHWP Secretariat Meeting, ASL Meeting)
- AHWP Nomination and Election Preparation
- Administrative Service to ASL
- Other Administrative Service

# AHWP SADS On-line weekly Update

Secretariat

- 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



# 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



Will to fully launched in December 2019 with all the updates with 2019 AHWP meeting information



# Thank You

AHWP Secretariat Contact:  
Mr. Benjamin Chan/ Ms. Anne Mando  
[secretariat@ahwp.info](mailto:secretariat@ahwp.info)