

Report by AHWP Secretariat 2015-2016

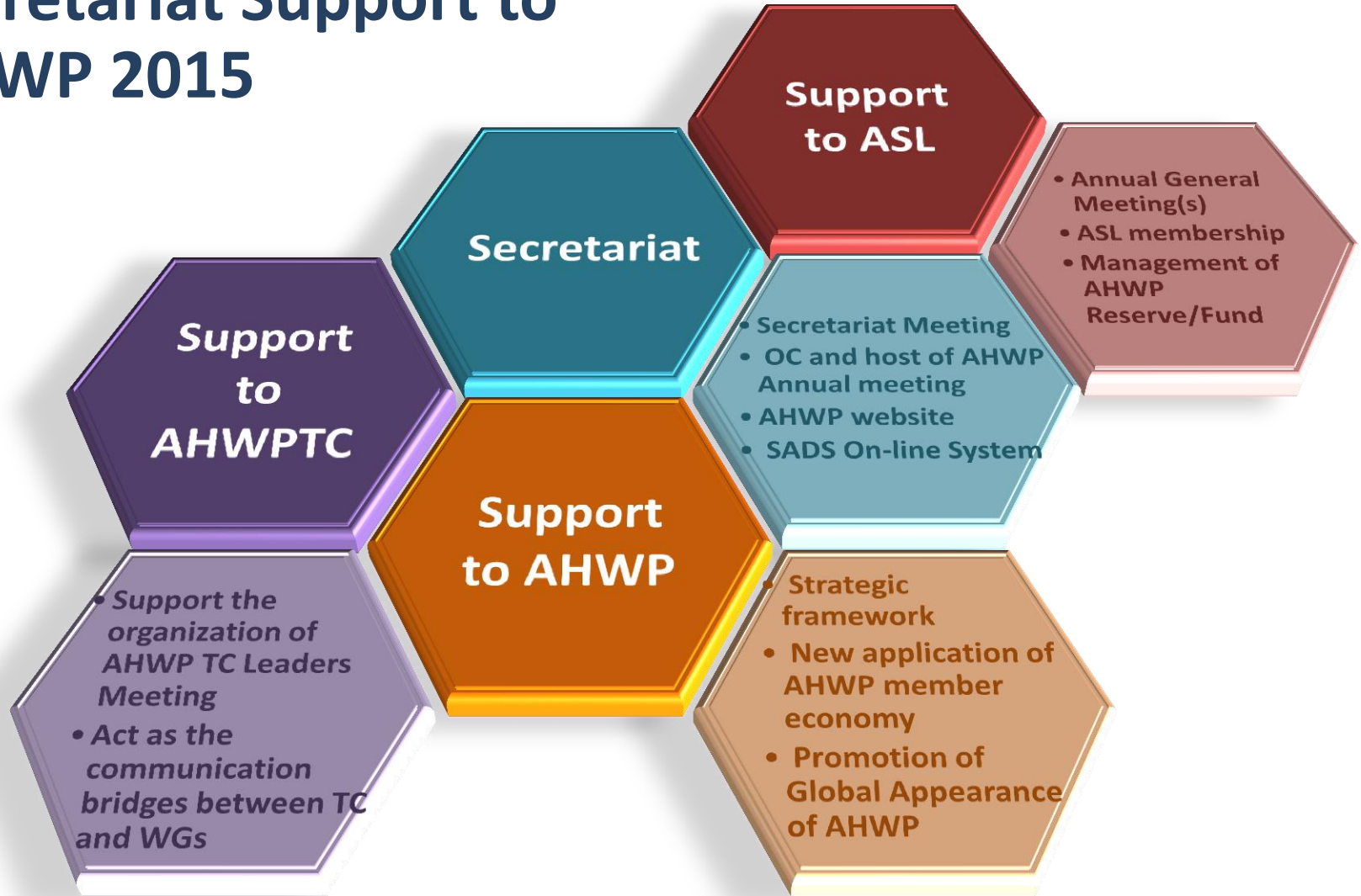
20th AHWP Annual Meeting
2-6 Nov 2015, Bangkok, Thailand

Mr Bryan SO
AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Secretariat Support to AHWP 2015



Support to AHWP

- Strategic framework
- New application of AHWP member economy
- Promotion of global appearance of AHWP

AHWP Strategic Framework Towards 2020

“The Foreseeable Harmonization Horizon”

*Support
to AHWP*

4 Framework Elements

*AHWP Member
Expansion*

*Harmonization in
Key Areas Based on
GHTF Principles
and AHWP
Guidance*

*Training and
Capacity Building*

*Enhance AHWP's
Global Partnership*

Secretariat Support to the New Application for Joining AHWP Member Economies



- Received **new applications**: Mongolia, Kazakhstan
- Facilitated communication & collection of **required documents**:
 - Official Letter by government authority
 - Nominated member economy representative(s) by Regulatory Authority
- Invited representatives from new member economy candidates to join the 20th AHWP Annual Meeting, Bangkok, 2015
- Towards **endorsement** at the Annual Meeting

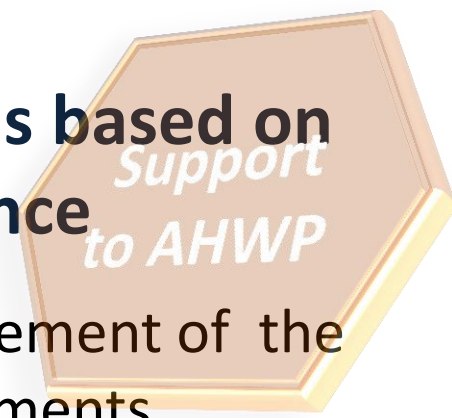


Support to the AHWP Training and Capacity Building

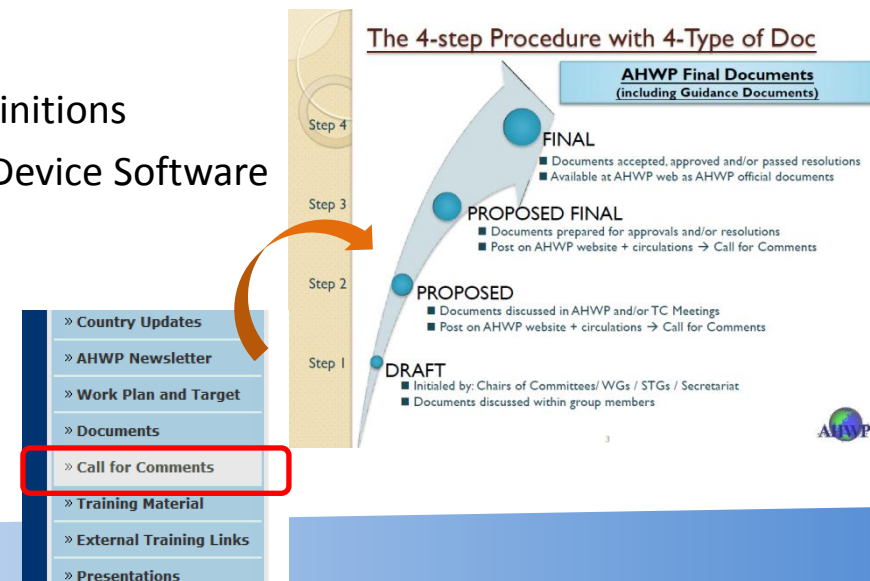


- Supported the organization of **trainings/workshops** for building capacity during the past Annual Meetings:
 - AHC-AHWP Joint Workshop on combination products, Chinese Taipei, 2012
 - AHWP-DITTA Joint Session on medical software, Chinese Taipei, 2012
 - 1st AHWP-RAPS Joint Conference, Malaysia, 2013
 - Working Group training, Malaysia, 2013
 - AHC-AHWP Joint Workshop, Seoul, 2014
 - Working Group training, Seoul, 2014
 - GS1 lunch Training Workshop, Seoul, 2014
- Supported the logistics, communication and coordination for arranging **trainings/workshops/panel discussions** during the 20th AHWP Bangkok Meeting, with topics:
 - AHWP Playbook Topics
 - Pre-market Cases
 - Post-market Cases
 - Clinical Evaluation
 - Software as Medical Device
 - Quality System Audit

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



- Facilitated the **4-step procedures** for the endorsement of the AHWP guidance documents and reference documents
- 13 AHWP guidance documents to be endorsed in 2015, in the following areas:
 - Pre-market CSDT Guidance
 - Combination products white paper
 - Pre-market submission – MD and IVDD Definitions
 - Qualification and Classification of Medical Device Software
 - Post-market surveillance on AE Reporting
 - Clinical Evidence on IVD Medical Devices
 - Regulatory Audit Report
 - Medical Device Nomenclature



Support to the Enhancement of AHWP's Global Partnership



Support
to AHWP

- AHWP Liaison member: **DITTA, GS1**
- AHWP is an affiliate organization to **IMDRF**
- TC Working Group collaborations with **ISO**:
 - ISO/TC210 (*QMS for medical devices*)
 - ISO/TC194 (*Biological & clinical evaluation of medical devices*)
 - ISO/TC212 (*Clinical laboratory testing & IVDD*)
- Facilitate the communication and logistics to invite global organizations to update at the 20th AHWP Annual Meeting
 - IMDRF, APEC, WHO, ASEAN, IEC, PAHWP

Support to AHWP TC

- **Support the organization of AHWP TC Leaders Meeting**
- **Support the channeling between WG leaders and TC leaders**

Support the Organization of AHWP TC Leaders Meeting



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

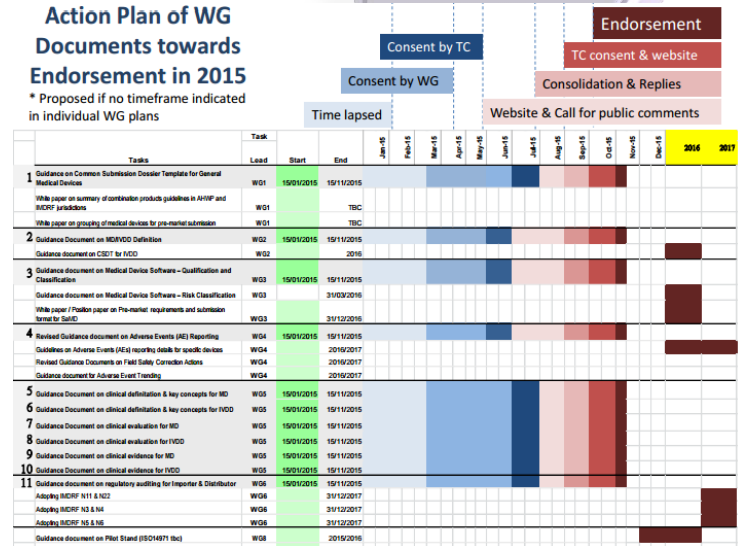


TC Leaders Meeting, 19-20 Mar 2015, Singapore

Support the WG Updates



- Support the TC WG 3-year plan for 2015-2017
- Channel between WG leaders and TC leaders on:
 - WG progress updates
 - Produce guidance and reference documents
 - Trainings



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 EGM **Tele-con**
- Organization of Annual General Meeting (**AGM**) of AHWP ASL
- Collection & handling of company **sponsorships for AHWP Annual Meeting**
- Solicitation & handling of **sponsorships for AHWP official website**
- Working 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 Annual Meeting** 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** according to the companies ordinance in HKSAR
- **In-progress of application for tax-exemption** under Section 88 of Inland Revenue Ordinance in Hong Kong

Next step: Endorse the new AOA of ASL at the coming AGM this year

Secretariat

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

Organization of Secretariat Meetings

Secretariat

- Supported the organization of **AHWP Secretariat Meeting**, participated by AHWP leaders, TC leaders, Secretariat and representatives from 19th AHWP annual meeting local host



Discussed Items During Secretariat Meeting



- AHWP 3-year plan for 2015-2017
- Preparation of the 20th AHWP Bangkok Annual Meeting
- Financial updates on AHWP ASL
- Website Enhancement

Support to OC and Host of AHWP & TC Meetings

Secretariat

- **Formation and participation of Organizing Committee (OC)** of the 20th AHWP annual meeting and 19th AHWP TC meeting
- AHWP Secretariat has **coordinated and supported** the **OC, local host** and **speakers from different organizations** to facilitate the organization of **AHWP Event 2015**, including the Playbook Seminar, AHWP Workshops, 19th AHWPTC Meeting and the 20th AHWP Annual Meeting in Bangkok, 2015, including
 - Website announcements
 - Review of event budget
 - Speaker invitation & delegates supports
 - Development of event programme & collecting presentations materials
 - Development of event sponsorship package
 - Recruitment of participants
 - Venue arrangements and other logistics

Act as Communication Bridges



- 1
- Support the collecting of documents from WG leaders for TC leaders' advices
 - Channel the advice/comments for TC leaders on WG plan, WG updates, WG guidance and WG trainings



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

AHWP SADS On-line weekly Update

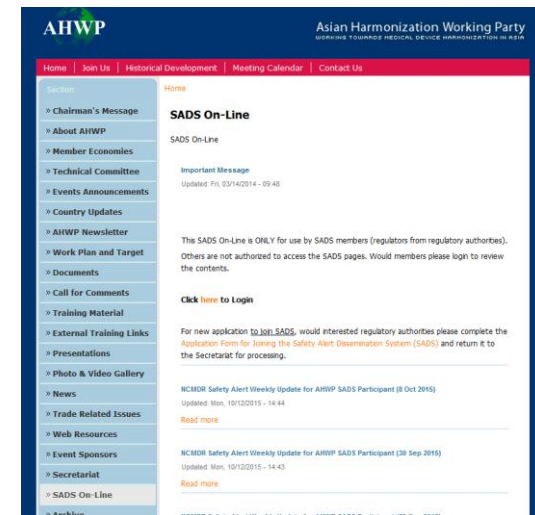
Secretariat

- Password-protected on-line system launched since May 2014
- Collaborated by WG4 and Secretariat
- Support the new members applications to SADS

A total of 18 Member Economies joined as the member of SADS as of 30 Oct 2015. New members joined in 2015 include:

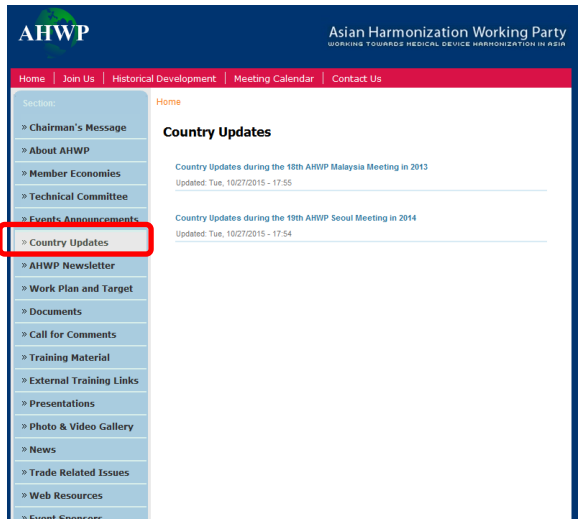
- Republic of Korea
- State of Kuwait
- Tanzania

- Support the weekly update of SADS on the AHWP Website





Highlighted Updates on the AHWP Official Website

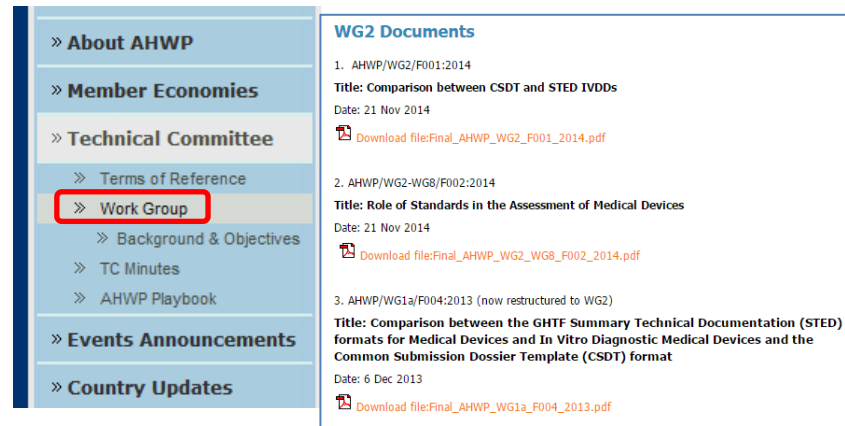


1. Country Updates

- A new tab – “Country Update” has been added at the left column of the AHWP website
- Allows a faster and more convenient track for visitors to identify the country updates at the past Annual Meetings

2. WG Documents

- WG Documents are now attached at the end of the page of each WG
- Allows visitors to take easier reference of the WG documents



Thank You

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