

Report by AHWP Secretariat 2015-2016

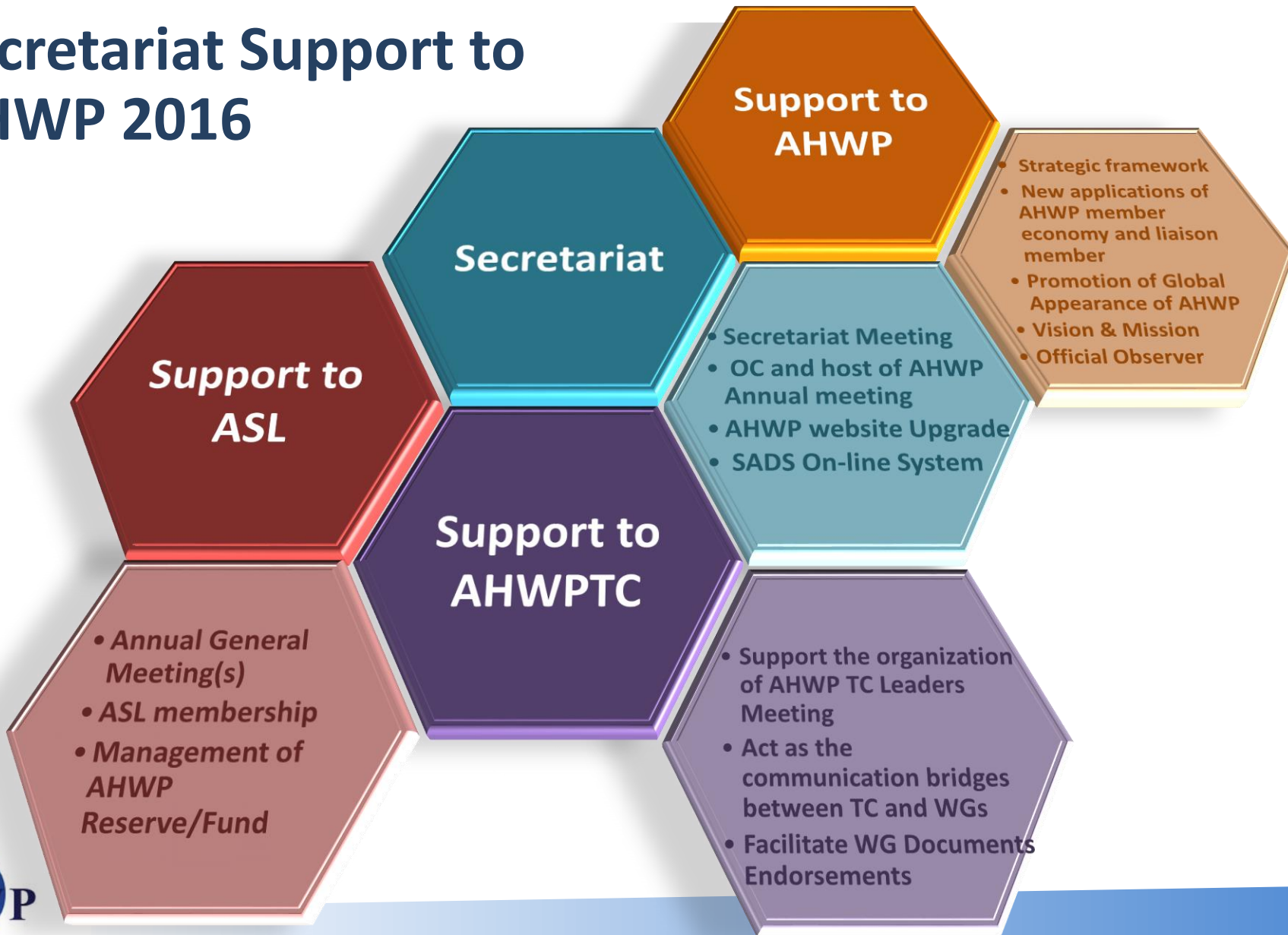
21st AHWP Annual Meeting
25 Nov 2016, Cebu, Philippines

Mr Bryan SO
AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Secretariat Support to AHWP 2016



Support to AHWP

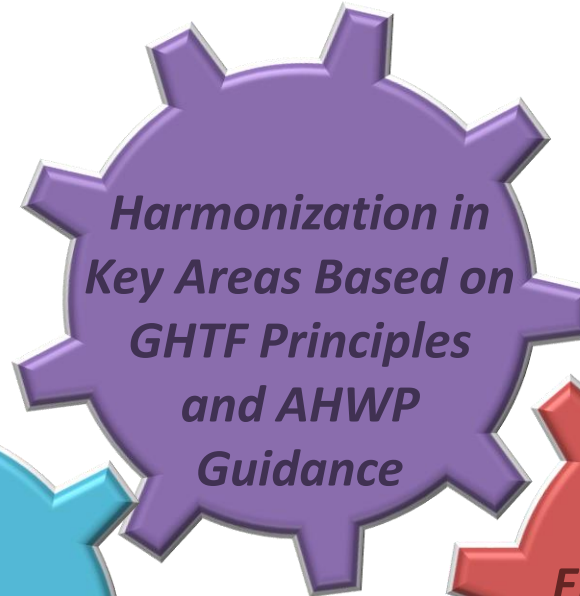
- Strategic framework
- New applications of AHWP member economy and liaison member
- Promotion of Global Appearance of AHWP
- Vision & Mission
- Official Observer

AHWP Strategic Framework Towards 2020

“The Foreseeable Harmonization Horizon”

*Support
to AHWP*

4 Framework Elements:



Secretariat Support to the New Application for Joining AHWP Member Economies



- Received **new applications in 2016**: Kingdom of Bahrain, Sultanate of Oman, United Arab Emirates and Zimbabwe.



Kingdom of Bahrain



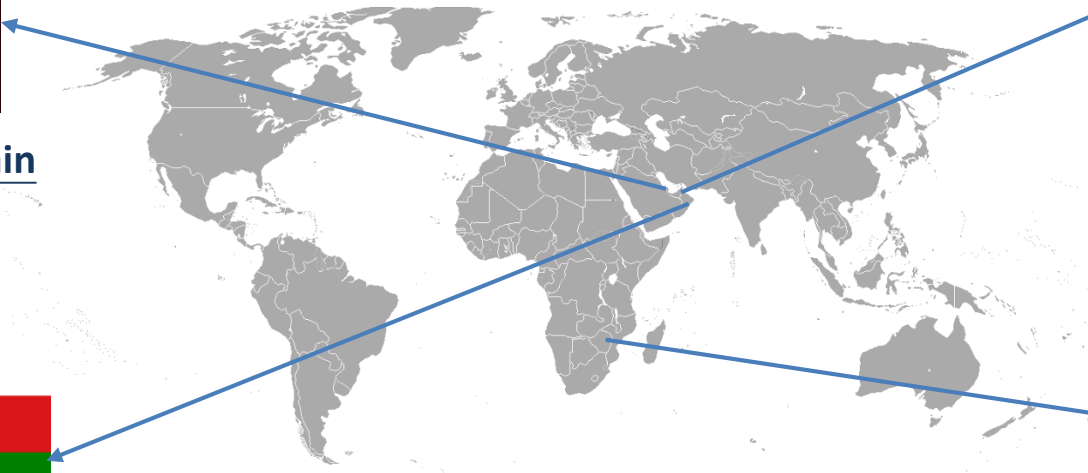
United Arab Emirates



Sultanate of Oman



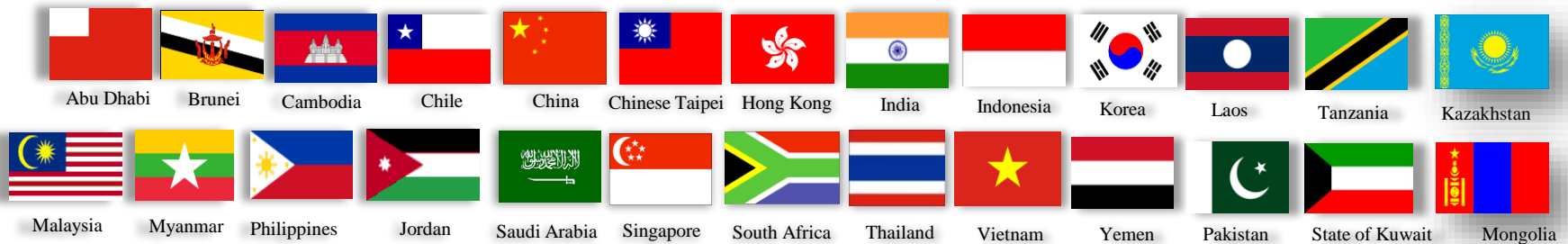
Zimbabwe



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
- Invited representatives from the new applicants to join the 21st AHWP Annual Meeting, Cebu, 2016
- Towards endorsement at the Annual Meeting



Support to the AHWP Annual Meetings and Capacity Building



- Supported the organization of **trainings/workshops** for building capacity during the past Annual Meeting/year:
 - AHWP-DITTA Joint Session, Bangkok, 2015
 - WG Training sessions, Bangkok, 2015
 - Capacity Building – Playbook Workshop, Bangkok, Nov 2015
 - Capacity Building - in-country training, Indonesia, Jul 2016
 - Capacity Building –in-country training, Vietnam, Aug 2016
- Supported the logistics, communication and coordination for arranging **trainings /workshops/panel discussions** during the 21st AHWP Cebu Meeting, Nov 2016, with topics:
 - Capacity Building - Playbook Training Workshop
 - Pre-market Cases
 - Post-market Cases
 - Standards
 - Clinical Investigation & Evaluation
 - Software as Medical Device
 - Harmonization

Quick Summary of AHWP Annual Meeting in Bangkok

2-6 Nov 2015

*Support
to AHWP*



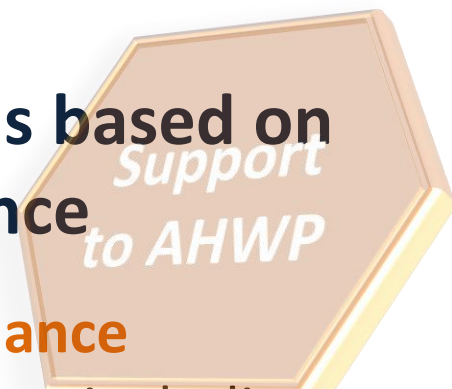
- ◆ AHWP Playbook Workshop
- ◆ AHWP TC Workshop
- ◆ 19th AHWP TC Meeting
- ◆ 20th AHWP Annual Meeting

- 241 delegates
 - 40 delegates from government authorities
 - 201 industrial delegates
- 28 countries from Asia Pacific, Middle East, Africa, South America, USA, Canada, Europe regions
- 11 other international organizations' representatives
- 36 speakers
- 11 main themes & 6 panel discussion sessions
- 2 new member economies



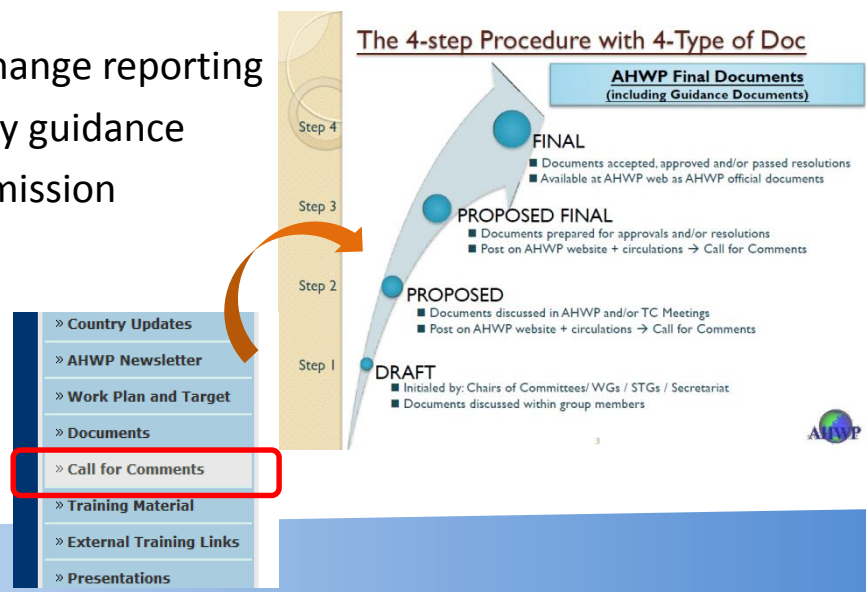
THAILAND

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



- Supported the **4-step procedures** of AHWP **Guidance Documents, Reference Documents, White papers**, including endorsed Working Group guidance papers
- 15 Working Group documents to be endorsed in 2016 in the following areas:

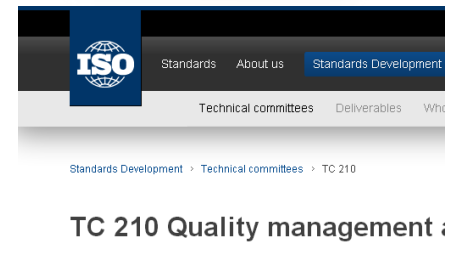
- Pre-market general medical device minor change reporting
- Pre-market combination products regulatory guidance
- IVD Definition, Classification & Dossier Submission
- Risk Categorization of SaMD guidance
- Post Market AE reporting
- Regulatory audit
- QMS requirements



Support to the Enhancement of AHWP's Global Partnership



- AHWP Liaison members: **DITTA**, **GS1**
- New Liaison member in 2016: **APACMed**
- AHWP is an affiliate organization to **IMDRF**
- TC Working Group collaborations with **ISO**:
 - ISO TC/212 (Clinical laboratory testing and IVD test systems)
 - ISO TC210 (QMS)
 - ISO TC194 (*Clinical investigation*)
- Support the communication and logistics to invite global organizations to update at the 21st AHWP Annual Meeting



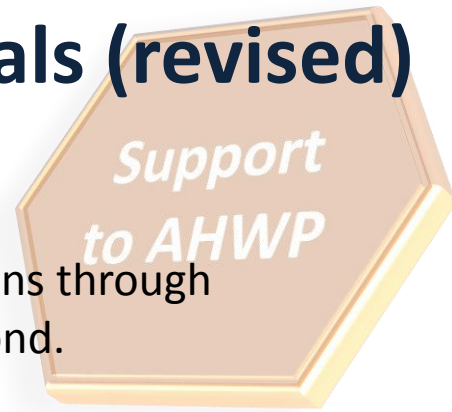
Organizations in liaison:

[AHWP](#), [DITTA](#), [EDMA](#), [EUCOMED](#), [EUROM](#), [WHO](#)

Organizations in liaison (Category A and B):

[AHWP](#), [ASLM](#), [BBMRI-ERIC](#), [BIPM](#), [EC](#), [EC4](#), [EDMA](#), [EFLM](#), [EUROM](#), [ICSH](#), [IFBLS](#), [IFCC](#), [ILAC](#), [IUPAC](#), [OECD](#), [WASPALM](#), [WHO](#)

AHWP Vision & Mission (new) and Goals (revised)



Vision

To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry in Asia and Beyond.

Mission

To Strategically Accelerate Medical Device Regulatory Convergence through Promotion of an Efficient and Effective Regulatory Model for Medical Devices.

Goals

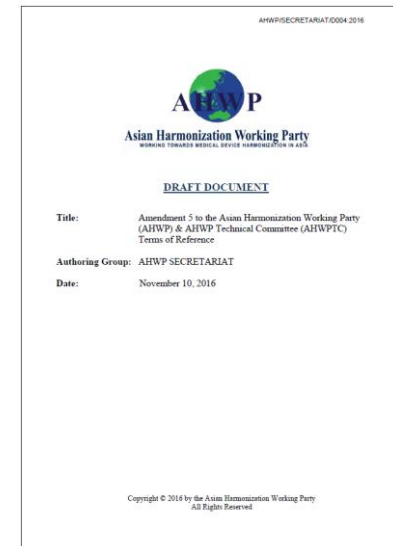
- To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and beyond.
- To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.
- To promote capacity building in member economies and to foster strategic membership expansion.
- To work in collaboration with related international organizations such as IMDRF, WHO, ISO, IEC.

Official Observer



Aim:

To set up a role of Official Observer of AHWP for close collaborating partnership with international organizations and other regulatory authorities, which have constraints to join AHWP liaison membership.



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 **AHWPTC Leaders Meeting**, participated by AHWP TC leaders, WG leaders, TC Advisors, AHWP leaders and Secretariat

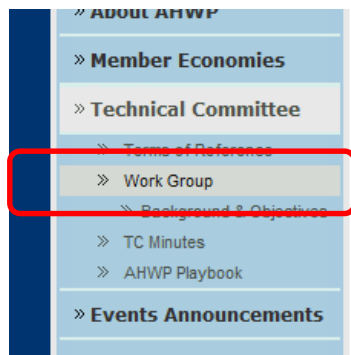


TC Leaders Meeting, 27-29 Apr 2016, Republic of Korea

Act as Communication Bridges between AHWP TC Leaders and Working Groups



- 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

Facilitate Work Group Technical Documents for Endorsement



- Amendments on AHWP Terms of Reference and House Rules
- To facilitate the endorsement of technical documents and white papers initiated by Work Groups under AHWPTC through electronic means and/or at AHWPTC Meetings by AHWPTC Representatives



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
- **In-progress of application for tax-exemption** under Section 88 of Inland Revenue Ordinance in Hong Kong. The new AOA of ASL was endorsed in AGM last year. Pending for Company Registry and legal confirmation on the charitable status

Secretariat

- Secretariat Meeting
- OC and host of AHWP Annual meeting
- Upgrade of 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 WHO (invited session)



Secretariat Meeting, 25 Feb 2016, Republic of Korea



Secretariat Meeting, 27 Apr 2016, Republic of Korea

Support to OC and Host of AHWP & TC Meetings

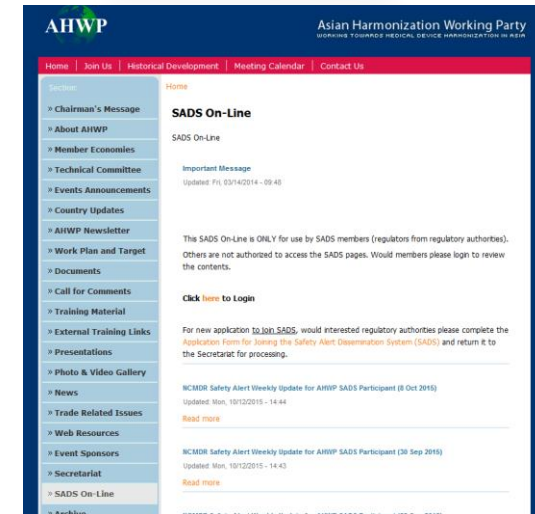


- **Formation and participation of Organizing Committee (OC)** of the 21st AHWP annual meeting and 20th AHWP TC meeting
- AHWP Secretariat has **coordinated and supported** the **OC, local host** (Philippines Association of Medical Device Regulatory Affairs Professionals) and **speakers from different organizations** to facilitate the successful organization of **AHWP Event 2016**, including the Capacity Training Workshop, AHWPTC Workshops, 20th AHWPTC Meeting and the 21st AHWP Main Meeting in Bangkok, 2015, 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

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 GHTF
- AHWP Secretariat Support:-
 - **New members applications** to SADS
 - A total of 18 Member Economies joined as the member of SADS .
 - **Weekly update** of SADS on the AHWP Website



AHWP Official Website Revamp

Secretariat

Goal:

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

The screenshot displays the AHWP website interface. At the top left is the AHWP logo, which consists of a globe with the letters 'AHWP' overlaid. To the right of the logo, the text reads 'Asian Harmonization Working Party' in a large, bold, serif font, with the tagline 'WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA' in a smaller, sans-serif font below it. In the top right corner, the text 'DEMO ONLY' is displayed in a large, blue, sans-serif font. Below the header is a navigation menu with five items: 'HOME', 'CHAIRMAN'S MESSAGE', 'HISTORICAL DEVELOPMENT', 'MEETING CALENDAR', and 'CONTACT'. To the right of the navigation menu is a search bar with the placeholder text 'Search the AHWP website.'. Below the navigation menu is a large, high-angle photograph of a large group of people, mostly men in suits, posing for a group photo. The photo is framed by a dark blue border with white navigation arrows on the left and right sides. Below the photo is a dark blue banner with the text '20th AHWP annual meeting in Bangkok, Thailand' in white. At the bottom left of the screenshot is a blue button with the text 'LOGIN AND REGISTER'. To the right of the button is the text 'Chinese Taipei'. At the bottom right of the screenshot is the text 'Submitted by admin on Wed, 11/22/2016 - 18:24'.

Similar Overall Structure for Familiarity



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

- HOME
 - CHAIRMAN'S MESSAGE
 - HISTORICAL DEVELOPMENT
 - MEETING CALENDAR
 - CONTACT
-

Search bar



20th AHWP annual meeting in Bangkok, Thailand

MAIN SECTIONS:

- + About AHWP
- + Member Economies
- + Technical Committee
- + News
- + Events Announcements
- + Events
- + Documents
- + SADS On-Line
- + Trade Related Issues

USER ACCOUNT MENU

19th AHWP Meeting Photos, Seoul, 18-21 Nov 2014

Submitted by admin on Wed, 11/23/2016 - 14:55

test

[+ Read more](#) [Add new comment](#)



Post Comments on News

STG (U&N) - Special Task Group on UDI & Nomenclature

Submitted by admin on Mon, 11/21/2016 - 06:55

STG membership status

[+ Read more](#) [Add new comment](#)



Work Group 8 (WG8) - Standards

Submitted by admin on Mon, 11/21/2016 - 06:50

Read and Social Share

AHWP Official Website Revamp

Secretariat

Main Features:

- Work Group documents in individual Work Group Page for categorization
- Connected to Social Networking Media

Work Group 1 (WG1) - Pre-market: General MD
Submitted by admin on Wed, 09/28/2016 - 22:48
AHWP-WG1_Regulation of Combination Products - a Review of International

Chair:
Mr. Essam Mohammed Al Mohandis
Executive Director
Surveillance and Biometrics
Saudi Food and Drug Authority
Kingdom of Saudi Arabia
Regulatory Authority

Acting Co-Chair:
Ms. Kate HyeongJoo KIM
NA Professional Affairs Director

• *WG1 members*

for example

Guidance Documents
(links to guidance documents section)

File
AHWP-WG1_Regulation of Combination Products - a Review of International Practice_FINAL.pdf

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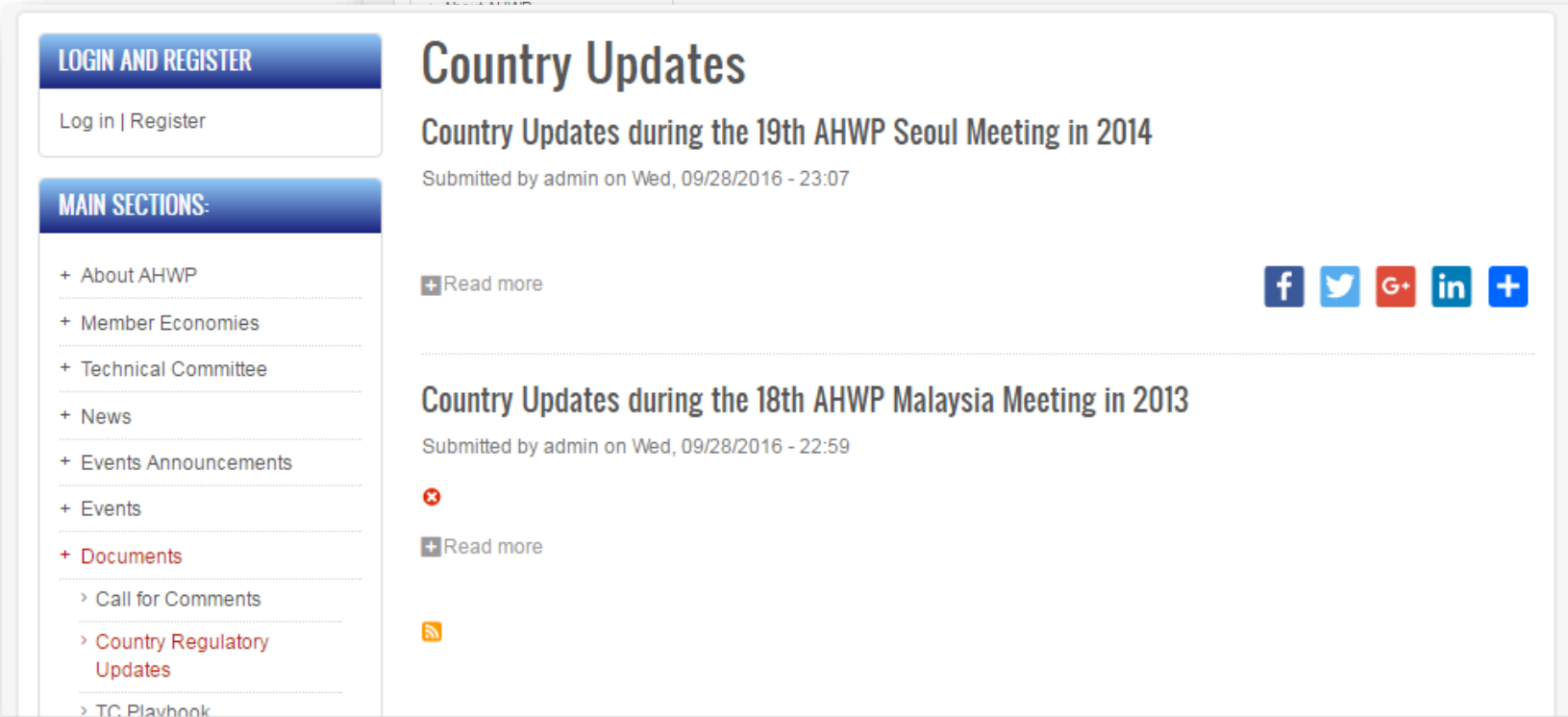
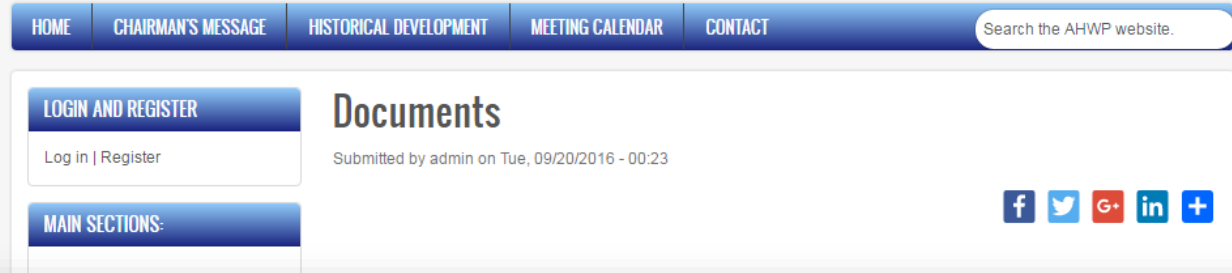
• *WG1 documents*

AHWP Official Website Revamp

Secretariat

Main Features:

- **Country Updates** separately grouped



AHWP Official Website Revamp

Secretariat

Main Features:

- Search Function Enhancement for identification of information location

Log in | Register

Enter your keywords:

WG1

MAIN SECTIONS-

- + About AHWP
- + Member Economies
- + Technical Committee
- + News
- + Events Announcements
- + Events
- + Documents
- + SADS On-Line
- + Trade Related Issues

Search help

Search results

Work Group 1 (WG1) - Pre-market: General MD

Work Group 1 (WG1) - Pre-market: General MD AHWP-WG1_Regulation of Combination Products - a Review of ... File AHWP-WG1_Regulation of Combination Products - a Review of ...

admin - 11/21/2016 - 06:19

Group 1 (WG1) - Pre-market: General MD

Group 1 (WG1) - Pre-market: General MD ... File AHWP-WG1_Regulation of Combination Products - a Review of ...

admin - 11/21/2016 - 06:28 - 0 comments

CALL FOR COMMENTS on the PROPOSED document "Guidance on Regulatory Practices for Combination Products"

...) with the template below and copy to the AHWP WG1 Chair, Mr. Essam Mohammed Al Mohandis (EMMohandis@sfd.gov.sa) and WG1 Co-chair, Ms Kate KIM (hkim55@its.jnj.comm) on or ...

admin - 11/06/2016 - 21:36 - 0 comments

CALL FOR COMMENTS on the PROPOSED document "Guidance for Minor Change Reporting"

...) with the template below and copy to the AHWP WG1 Chair, Mr. Essam Mohammed Al Mohandis (EMMohandis@sfd.gov.sa) and WG1 Co-chair, Ms Kate KIM (hkim55@its.jnj.comm) on or ...

admin - 11/06/2016 - 21:35 - 0 comments

"WHAT IF WE COULD ALL BE DOCTORS?"

IT'S OUR FUTURE

AHWP Official Website Revamp

Secretariat

Main Features:

- Future AHWP events' dates in **calendar** format

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

HOME CHAIRMAN'S MESSAGE HISTORICAL DEVELOPMENT **MEETING CALENDAR** CONTACT Search the AHWP website.

MAIN SECTIONS:

- + About AHWP
- + Member Economies
- + Technical Committee
- + News
- + Events Announcements
- + Events
- + Documents
- + SADS On-Line
- + Trade Related Issues

USER ACCOUNT MENU

- + My account
- + Log out

November 2016

Previous « Next »

Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	1	2	3	4	5
6	7	8	9	10	11 TOR Fil, 11/11/2016 - 13:00	12
13	14	15	16	17	18	19
20	21 AHWP capacity building workshop Mon, 11/21/2016 - 13:00 Wed, 11/23/2016 - 13:00	22	23 AHWP capacity building workshop Mon, 11/21/2016 - 12:00 Wed, 11/23/2016 - 12:00	24 AHWP 20th TC meeting Thu, 11/24/2016 - 13:00	25 21st AHWP annual conference Fri, 11/25/2016 - 13:00	26
27	28	29	30	1	2	3

Previous « Next »

Future Sponsor space

Meeting Calendar

AHWP Official Website Revamp

Secretariat

Main Features:

> Liaison Members
> TOR
> House Rules
> ASL
+ Member Economies
+ Technical Committee
+ News
+ Events Announcements
+ Events
+ Documents
+ SADS On-Line
+ Trade Related Issues

that support the above stated goals.

List of Member Economies:

- Abu Dhabi
- Brunei Darussalam
- Cambodia
- Chile
- Chinese Taipei
- Hong Kong SAR, China
- India
- Indonesia
- Jordan
- Kazakhstan
- Kingdom of Saudi Arabia
- Republic of Korea
- Laos
- Malaysia
- Mongolia
- Myanmar
- Pakistan
- People's Republic of China
- Philippines
- Singapore
- South Africa
- State of Kuwait
- Tanzania
- Thailand
- Vietnam
- Yemen

Graphical highlight for coming activity

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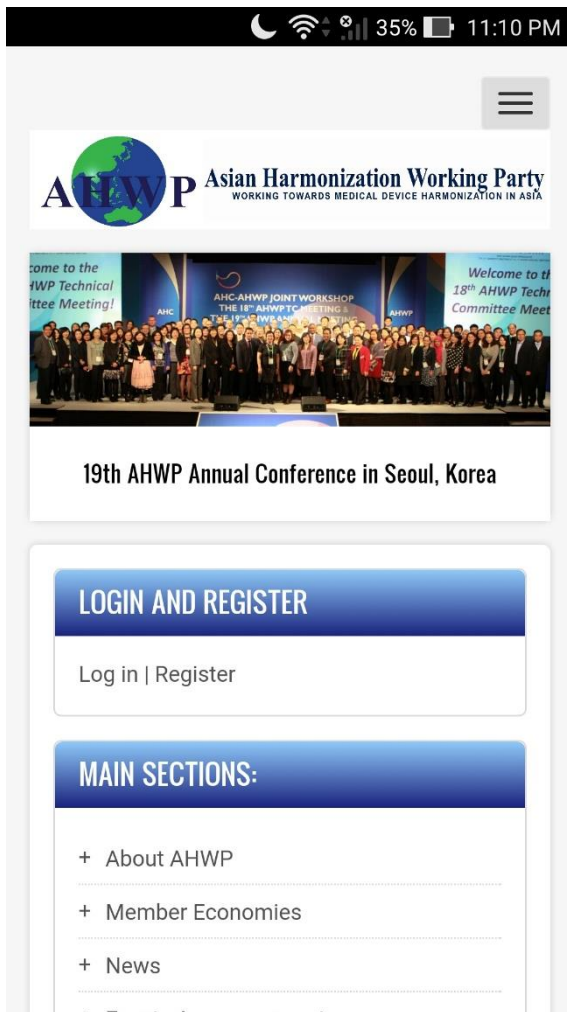
Disclaimer | Terms of Use

AHWP Official Website Revamp

Mobile View



DEMO ONLY



Mobile Responsive

Completely separate login for visitors, TC members, Member Economies, and SADS Online for improved security



AHWP Official Website Revamp

Improved Document Organisation

Secretariat

- TOR, house rules, strategic framework
- Documents
 - Country Regulatory updates
 - Call for Comments
 - Guidance documents
- Events
 - Presentations
 - Photos
- Document Endorsement Workflow – utilizing authorized views and commenting features

AHWP Official Website Revamp

What's left



- Finishing up – last features
- Transfer to actual server
- Populate full website content
- Provide Instructions for Use
- Hand over to Secretariat ~Jan 2017

AHWP Official Website Revamp

Secretariat

Main features in summary:

- Work Group documents in individual Work Group Page for categorization
 - Country Updates separately grouped
 - Categorized users
 - Connected to Social Networking Media
 - Search Function Enhancement for identification of information location
 - Future AHWP events' dates in calendar format
 - Graphical highlight for coming activity
- Website sponsorship opportunity open

Thank You

AHWP Secretariat Contact:
Mr. Bryan SO / Ms. Carol LIU
secretariat@ahwp.info