

# Report by AHWP Secretariat 2016-2017

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22<sup>nd</sup> AHWP Annual Meeting  
4-8 Dec 2017, New Delhi, India

Mr Bryan SO  
AHWP Secretariat



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

# Secretariat Support to AHWP 2017



## Support to AHWP

- Strategic framework
- New applications of AHWP member economy and liaison member
- Promotion of global appearance of AHWP
- Amendment to TOR

# AHWP Strategic Framework Towards 2020

## *“The Foreseeable Harmonization Horizon”*

*Support  
to AHWP*

4 Framework Elements:



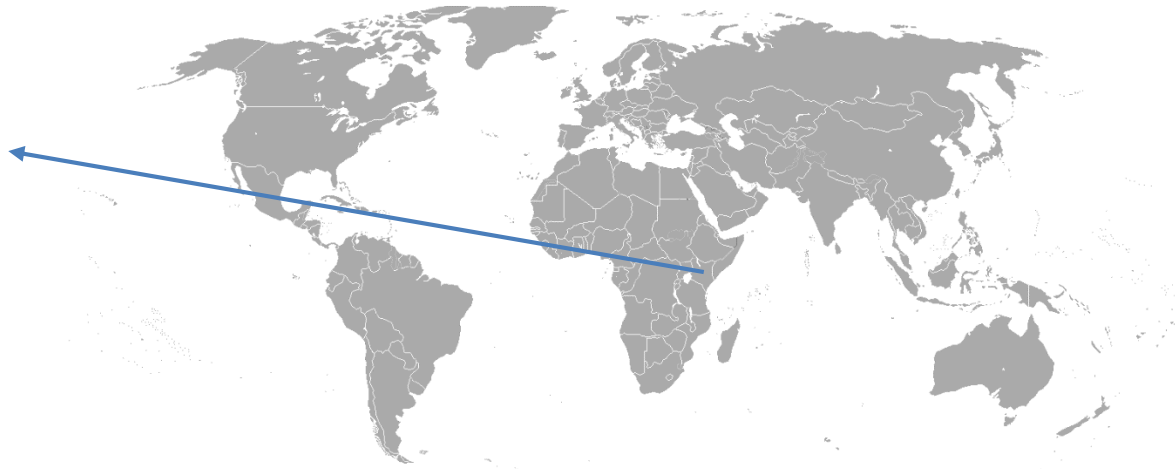
# Secretariat Support to the New Application for Joining AHWP Member Economies



- Received **new application towards endorsement in 2017:**  
Republic of Kenya



Republic of Kenya



# 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 22<sup>nd</sup> AHWP Annual Meeting, New Delhi, India, 2017
- Towards endorsement at the Annual Meeting



# Support to the AHWP Annual Meeting & Capacity Building



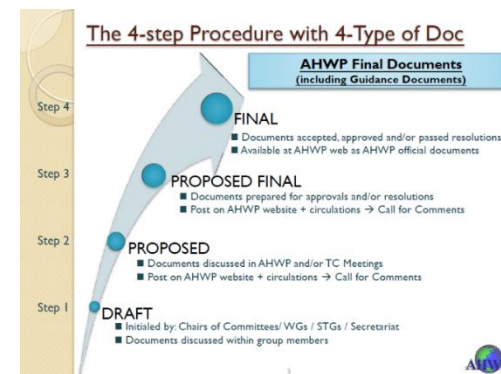
- Supported the organization of **trainings/workshops** for building capacity during the past Annual Meeting/year:
  - AHWP-DITTA Joint Session on Software as a Medical Device, Cebu, Philippines, Nov 2016
  - WG Training Sessions, Cebu, Philippines, Nov 2016
  - Capacity Building – In-country Training, Malaysia, Aug 2017
  - Capacity Building – In-country Training, Kazakhstan, Oct 2017
- Supported the logistics, communication and coordination for arranging **trainings /workshops/panel discussions** during the 22<sup>nd</sup> AHWP New Delhi Meeting, with topics:
  - AHWP Playbook Training Workshop
  - Pre-market Cases
  - Post-market Cases
  - Standards
  - Clinical Evaluation
  - Software as a Medical Device
  - Harmonization



# 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**
- 5 Working Group guidance papers to be endorsed in 2017 in the following areas:
  - Patient-matched Medical Devices Using 3D Printers
  - Regulation and treatment of e-IFU and e-Label of Medical Device
  - Consideration for Conformity Assessment of Companion IVD
  - Clinical Investigation
  - Post Market Clinical Follow-Up Studies

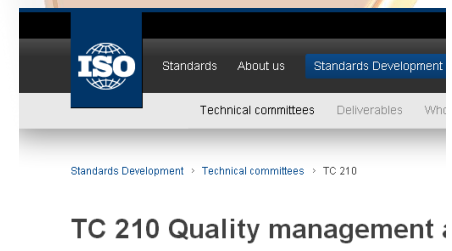




# Support to the Enhancement of AHWP's Global Partnership



- AHWP Liaison members: **DITTA**, **GS1**, **APACMed**
- AHWP is an affiliate organization to **IMDRF**
- TC Working Group collaborations with **ISO**:
  - ISO TC212 (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 22<sup>nd</sup> AHWP Annual Meeting
  - APEC, ASEAN, APACMed, DITTA



## 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](#)

# Amendment 5 to the AHWP House Rules

*Support  
to AHWP*

## Aim

To better elaborate the roles and responsibilities of AHWPTC members, and AHWPTC WGs and STG membership.

## Changes in House Rules\*

1. To propose new clause 18 on Roles and Responsibilities of Technical Committee (AHWPTC Chair, AHWPTC Co-chairs, AHWPTC WG Chairs and Co-chairs, Capacity Building Programme, AHWPTC Advisors)
2. To propose new clause 19 on AHWPTC WGs and STG Membership

\*For details, please refer to Proposed Final Document “Amendment 5 to the Asian Harmonization Working Party House Rules” in AHWP Website.

# Amendment 6 to the AHWP & AHWPTC Terms of Reference



## Aim

To revise “member economy” to “member country or region” by referencing to ICH, which has better similarity with AHWP in terms of member composition and mission.

## Updates in Terms of Reference\*

1. AHWP member economy → AHWP member country or region

\*For details, please refer to Proposed Final Document “Amendment 6 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference” in AHWP Website.

## **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, 2-3 Mar 2017, Hong Kong

# 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

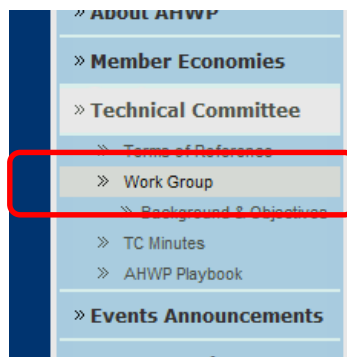
AHWP TC Working  
Group Leaders

2

AHWP TC Working  
Group Members

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 AHWPTC Representatives through electronic means and/or at AHWPTC Meetings by AHWPTC Representatives

AHWP/SECRETARIAT/P001:2017



Asian Harmonization Working Party  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED DOCUMENT

Title: Amendment 6 to the Asian Harmonization Working Party House Rules

Authoring Group: AHWP SECRETARIAT

Date: 20 November 2017

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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
- **Completion of application for tax-exemption** under Section 88 of Inland Reserve Ordinance in Hong Kong. The new AOA of ASL was endorsed in AGM in 2015. AHWP ASL has received the 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



Secretariat Meeting, 1 Mar 2017, Hong Kong

# Support to OC and Host of AHWP & TC Meetings

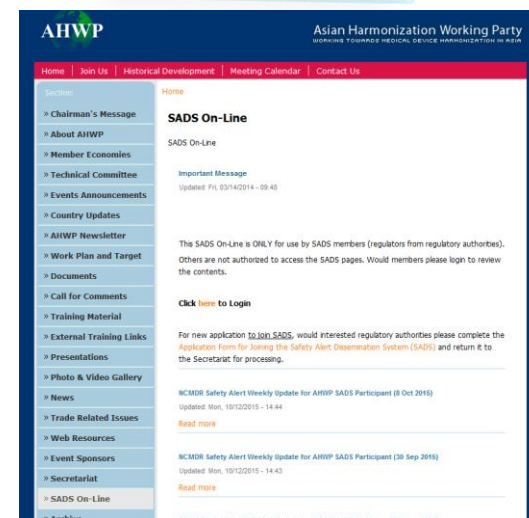
Secretariat

- **Formation and participation of Organizing Committee (OC)** of the 22<sup>nd</sup> AHWP annual meeting and 21<sup>st</sup> 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 2017**, including the Capacity Training Workshop, AHWPTC Workshops, 21<sup>st</sup> AHWPTC Meeting and the 22<sup>nd</sup> AHWP Main Meeting in New Delhi, 2017, 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



# Similar Overall Structure for Familiarity

*Secretariat*



Search bar

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



• *WG1 members*

For example



• *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

The screenshot displays the AHWP website's search results page. At the top, there is a search bar with the placeholder text "Enter your keywords:" and a red "Search" button. To the left of the search bar, there are links for "Log in" and "Register". Below the search bar, a sidebar on the left lists "MAIN SECTIONS:" including "About AHWP", "Member Economies", "Technical Committee", "News", "Events Announcements", "Events", "Documents", "SADS On-Line", and "Trade Related Issues". The main content area shows search results for "Work Group 1 (WG1) - Pre-market: General MD". The first result is titled "Work Group 1 (WG1) - Pre-market: General MD AHWP-WG1\_Regulation of Combination Products - a Review of ..." and includes a date and time stamp "admin - 11/21/2016 - 06:19". The second result is titled "Group 1 (WG1) - Pre-market: General MD" and includes a date and time stamp "admin - 11/21/2016 - 06:28 - 0 comments". The third result is titled "CALL FOR COMMENTS on the PROPOSED document 'Guidance on Regulatory Practices for Combination Products'" and includes a date and time stamp "admin - 11/06/2016 - 21:36 - 0 comments". The fourth result is titled "CALL FOR COMMENTS on the PROPOSED document 'Guidance for Minor Change Reporting'" and includes a date and time stamp "admin - 11/06/2016 - 21:35 - 0 comments". A small image of a child with a teddy bear is visible in the bottom left corner of the screenshot.

# AHWP Official Website Revamp

Secretariat

## Main Features:

- Future AHWP events' dates in calendar format

The screenshot displays the AHWP (Asian Harmonization Working Party) website. The header features the AHWP logo, which is a globe with the letters 'AHWP' overlaid, and the text 'Asian Harmonization Working Party' and 'WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA'. Below the header is a navigation bar with links: HOME, CHAIRMAN'S MESSAGE, HISTORICAL DEVELOPMENT, MEETING CALENDAR (highlighted in red), and CONTACT. A search bar is also present on the right side of the navigation bar.

The main content area is divided into two columns. The left column contains a 'MAIN SECTIONS' menu with links to About AHWP, Member Economies, Technical Committee, News, Events Announcements, Events, Documents, SADS On-Line, and Trade Related Issues. Below this is a 'USER ACCOUNT MENU' with links to My account and Log out. At the bottom of the left column is a promotional image for a book titled 'WHAT IF WE COULD ASK A DOCTOR?' with the subtitle 'IT'S OUR FUTURE'.

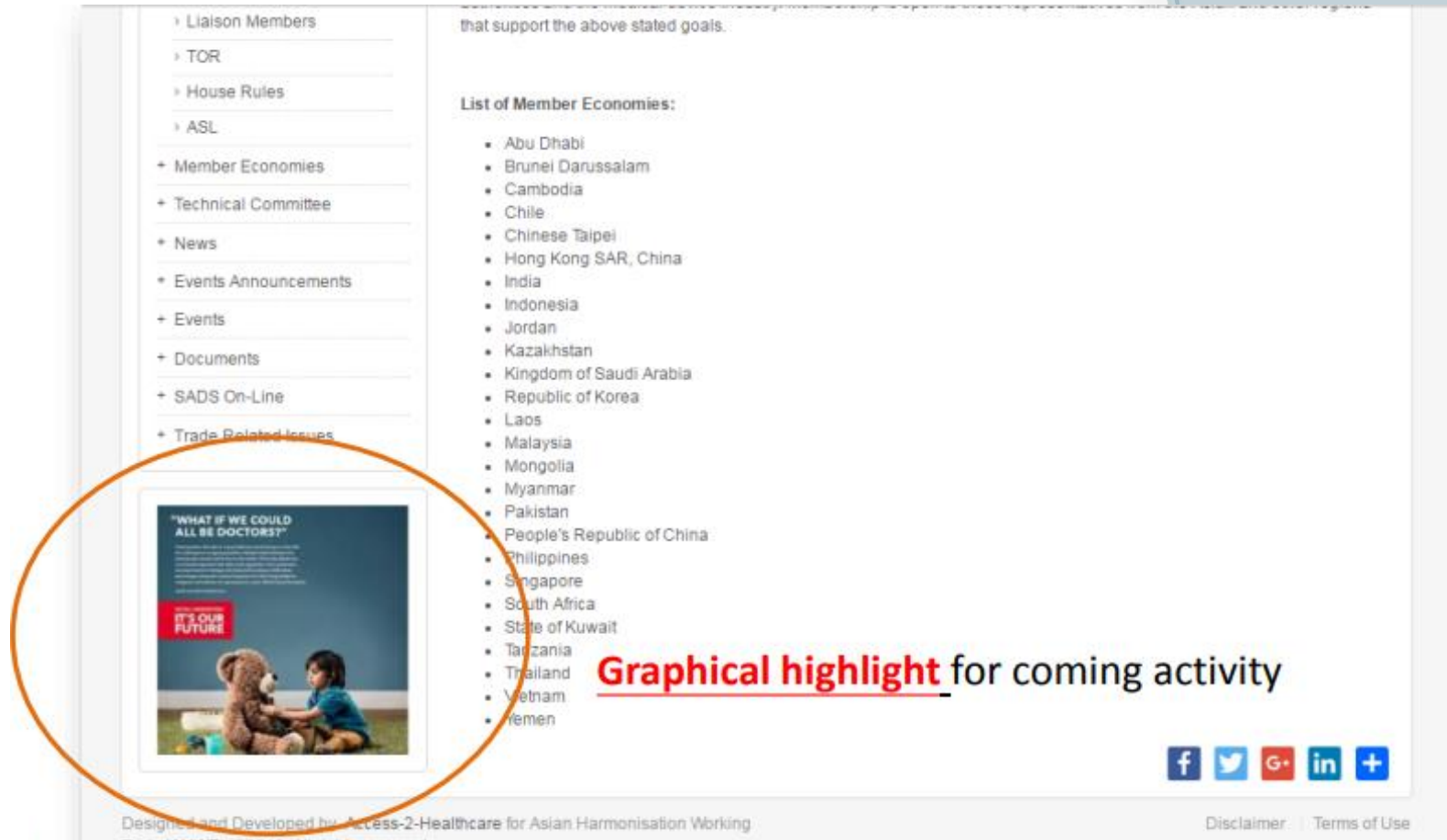
The right column features a 'Meeting Calendar' for November 2016. The calendar is a grid showing days from Sunday to Saturday. Events are listed for specific dates: November 21 (AHWP capacity building workshop), November 23 (AHWP 26th TC meeting), and November 25 (21st AHWP annual conference). The calendar includes 'Previous' and 'Next' navigation buttons.

Below the calendar, there is a section labeled 'Future Sponsor space'.

# AHWP Official Website Revamp

Secretariat

## Main Features:



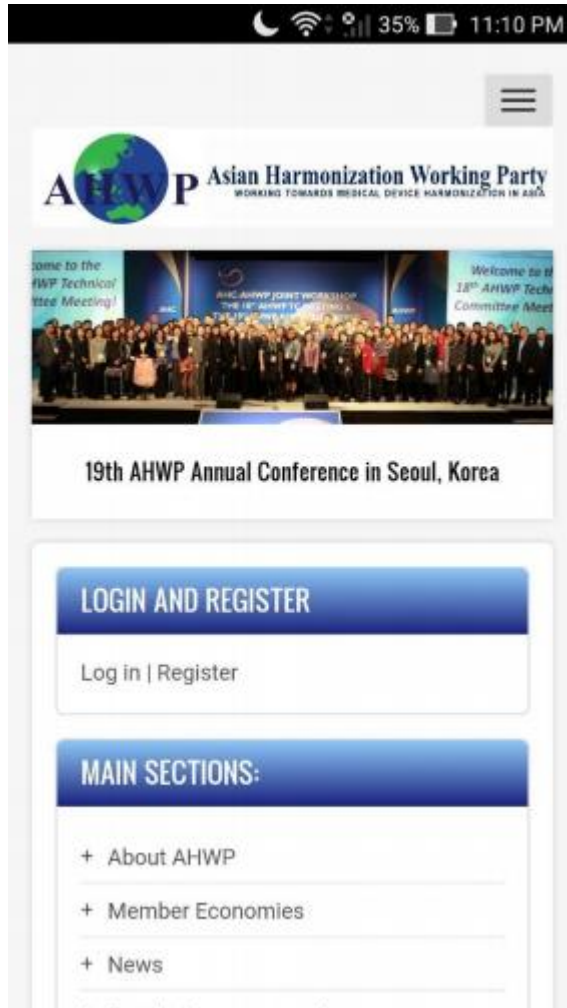


# AHWP Official Website Revamp

## Mobile View

DEMO ONLY

*Secretariat*



Mobile Responsive

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

# AHWP Official Website Revamp

## Improved Document Organization

*Secretariat*

- AHWP 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



### 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

- Migration of data available in website by the vendor (e.g., posts and attachments updated between UAT commencement till up to date)
- User Acceptance Test by AHWP leadership for final check of website

# 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

# Thank You

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