



AHWP WG2: PMS & Vigilance

Report & Work Plan

AHWP main meeting
Bali
November 2011



Agenda

- Key achievements
- AHWP TC WG2 key activities updates
- Collaboration programs between SG2 & AHWP TC WG2
- AHWP TC WG02 work plans



Key Achievements

SADS update:

In November 2011, we asked all the AHWP TC members to re-apply the SADS members. As a result, 15 AHWP countries economy members as follows have been join SADS,

- Saudi Food and Drug Authority
- Department of Health, Hong Kong
- Medical Device Bureau, Ministry of Health, Malaysia



Key Achievements

- Bureau of Health Device & Technology, Department of Health, Philippines
- Health Sciences Authority, Singapore
- Medical Device Control Division, Food and Drug Administration, Thailand
- Ministry of Health, Indonesia
- Health Authority, Abu Dhabi
- State Food and Drug Administration, China
- Jordan Food & drug Administration, Jordan
- Chinese Taipei



Key Achievements

- Ministry of Health, South Africa
- Ministry of Health, Yemen
- Ministry of Health, Pakistan
- Chile

Saudi Arabia FDA has reviewed all the safety alert of GHTF founder members website and disseminated to all relevant organizations in Saudi Arabia therefore we asked SFDA to extend the list to all the SADS members.

Currently WG02 successfully disseminate these safety alerts information in weekly basis.



Key Achievements

- Harmonized AE form across AHWP economy members
 - Proposed AE form for AHWP approval
 - Post the electronic AE form on the AHWP website
- Harmonized FSCA form across AHWP economy members
 - Proposed FSCA form for AHWP approval
 - Post the electronic FSCA form on the AHWP website

WG2 Update

- Review AHWP TC WG02 membership
 - New AHWP TC WG02 chair: Mr. Yorkie Chow, Hong Kong DOH
 - Nominated AHWP TC WG02 secretariat: Eric Chin, 3M Singapore
 - Renewed all the membership
 - Jorge Garcia and Mark Lau are nominated as WG02 senior consultants

WG2 Update

- Improve communication among AHWP TC WG02 members
 - Set up a fix schedule meetings for AHWP TC WG02
 - Meeting face to face with telecon concurrently
 - 1 day prior TC meeting (Attach with TC meeting)
 - 1-2 months prior to the Annual meeting
 - 1 day prior to the Annual meeting (Attach with Annual meeting)
 - Location: Rotating among AHWP economy members

WG2 Update

- Attended GHTF SG 2 meeting in Madrid.
 - SG 2 & 5 joint guidance documents: AE reporting during premarket Clin. Investigat has been up for comment and feedback.
 - Major work items
 - N111 (Definition and classification of Field Safety Corrective Actions -FSCA- , including recalls)
 - Finalization of N87 (electronic transfer of AE between manufacturers and NCAs)
 - SG2 input as ISO liaison for the possible revision of ISO13485 (incl. Post market surveillance section)
 - Future of SG 2
 - Complete Work Items by December 2012.
 - The National Competent Authorities Reports (NCAR) Exchange Program will be maintained.

WG2 Update

- 2nd face to face meeting in Hong Kong, November 3-4, 11.
- PMS Survey:
 - Final Report on Current Requirements for Post Market Surveillance & Vigilance System is completed and up on AHWP website
 - No plan to conduct the additional survey
 - Key finding: No harmonization across AHWP economy members

WG2 Update

- Review of Implementation of GHTF SG2 Documents status is completed for 7 AHWP economy members.
 - 2 from 7 economy members fully implemented GHTF SG02 documents
 - 2 from 7 economy members have their own guidelines and implemented GHTF SG2 documents less than 10%
 - Across 7 economy members, the timing of AE reporting guideline is the most adopted
 - Plan to use it as an AHWP TC WG02 dashboard to measure WG02 performance
 - Will follow up the rest economy members to complete the survey



WG2 Update

- Merge Safety Alert Dissemination System (SADS) and NCAR members
 - 8 AHWP economy members are SADS members
 - 4 AHWP economy members are NCAR members
 - Simplified SADS form (HA need to notify manufacturer prior to dissemination)
 - [Create "SADS Online" under http://www.ahwp.info](http://www.ahwp.info)
 - user: sadsonline
 - password : sads123
 - No feedback from economy with regards to the format so we decided to go live in 2012.



Collaboration with GHTF SG2

- GHTF SG02 training pool
 - SG02 agreed for AHWP liaisons (Miang & Essam) to be the qualify trainers for SG02 guidance documents.



Work Plans

- Training
 - Create the folder under AHWP WG02 & post all the trainings + VDO that need consent form from all the trainers to upload on the folder.
 - Proposed structure the trainings
 - ❖ Basic training
 - SG02 guidance documents
 - Manufacturers Trend Reporting of Adverse Events
 - Guidance of How to handle information concerning Vigilance Reporting Related to Medical Devices
 - FSCA

Work Plans

- Training (Cont)
 - ❖ Advance program
 - Mark Bruley (ECRI)_AE investigation program
 - Provided DVDs to the regulators and industries group for each economy
 - Long term_Propose WG06 to take care all these materials distribution

Future Collaboration with GHTF SG2

- Building regulatory capacity in post-market areas
 - Mentoring programs
 - Risk assessment capability
- Safety information Handling guidance documents for health authorities
- Merge NCAR/SADS: Exchange the non-confidential safety information
- Training on new FSCA guidance document



THANK YOU!