WG4 – Post-market

Chair: Ms Jennifer MAK (Dept of Health, HKSAR)

Co-Chair: Ms Kitty MAO (GE Healthcare, Singapore)

Advisors: Dr Jorge GARCIA (TGA, Australia)
Ms Joanna KOH (HSA, Singapore)

Secretary: N.A.

AHWP 19th TC Meeting
5 Nov 2015, Bangkok

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Updates (1)

- No. of WG members: 24 (excluding chair and co-chair)
  - 6 from Regulatory Authorities (Hong Kong, Indonesia, Korea, Saudi, Thailand and Tanzania)
  - 18 from Industry (China, Chinese Taipei, Hong Kong, Indonesia, Korea, Malaysia and Singapore)

Updates (2)

- **Activities**
  - Formulation of WG4 work plan 2015-2107
  - WG members grouped into 4 teams each working on a 2015 work task
  - Intra-team collaboration preparing draft document or taking forward the work task
  - WG telecons held on 4 Mar and 23 Sep 2015 discussing various WG4 matters
  - 6 progress summary on WG4 matters distributed to all WG members (21 Jan, 26 Mar, 26 Jun, 13 Aug, 13 Oct and 28 Oct 2015)

Proposed Work Plan 2015 – 2017 (1)

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	Revised Guidance Document	2015
2	Review the Safety Alert Dissemination System (SADS)	Review Report	2015
3	Post-market Surveillance (PMS) Training (subject to TC approval)	Training Sessions	2015
4	Develop guidelines on Adverse Events (AE) reporting details for specific devices, e.g. a) Intraocular Lenses (IOL) b) Joint replacement Implants	Guidelines	2016/2017

Proposed Work Plan 2015 – 2017 (2)

Priority	Work Item	Deliverables	Action Plan and Timeline
5	Review and update the existing WG4 guidance documents on a) Field Safety Correction Actions (FSCAs) b) SADS (if needed)	Revised Guidance Documents	2016/2017
6	Develop guidance document for Adverse Event Trending based on GHTF documents	Guidance Document	2016/2017
7	Develop guidelines on proper handling of medical devices after complaint and AEs	Guidelines	2016/2017
8	Conduct survey on the post-market status (include both reportable AEs and FSCAs) and challenges of AWHP member economies	Survey Report	2016/2017

WG Progress Update (1)

since last AHWP Seoul TC Meeting in 2014

No.	Work Item	Status	Achievements	Timeline
1	Review and update the existing WG4 guidance documents on Adverse Events (AE) Reporting	**Pending**	• Revised proposed document be endorsed in the 20th AHWP Annual Meeting and finalized version be uploaded to the AHWP website	• 2015
2	Review the Safety Alert Dissemination System (SADS)	**Completed (with actions to follow)**	• Preliminary review conducted and reported at the AHWP TC Leaders Meeting in Mar 2015 • Messages sent to AHWP members to encourage participation and use of SADS On-line in June 2015 • Survey on SADS to AHWP members conducted and results reported in the 19th AHWP TC Meeting	• 2015

WG Progress Update (2)

since last AHWP Seoul TC Meeting in 2014

No.	Work Item	Status	Achievements	Timeline
3	Arrange post-market surveillance (PMS) training	**Completed**	• PMS Training Proposal for AHWP meeting submitted • Supported the PMS training at the 20th AHWP meeting	• 2015
4	Develop guidelines on Adverse Events (AE) reporting details for specific devices	**In progress**	• Percutaneous transluminal coronary angioplasty (PTCA) devices selected • Proposed contents of guidelines including summary, checklist and examples being worked on	• 2016/2017

Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorised Representative (AHWP/WG4/D001:2015) (1)

- **Scope of paper:**
  - Adverse event (AE) reporting guidance for medical device manufacturer or its authorised representative

- **Objective of paper:**
  - To provide a complete guidance to Regulatory Authorities (RAs) and the industry on AE reporting
  - To incorporate more advice on AE reporting involving in-vitro diagnostic medical devices (IVDMDs)
  - To update definitions of the terminologies used by referencing international standards, IMDRF documents and post-market guidelines issued by RAs

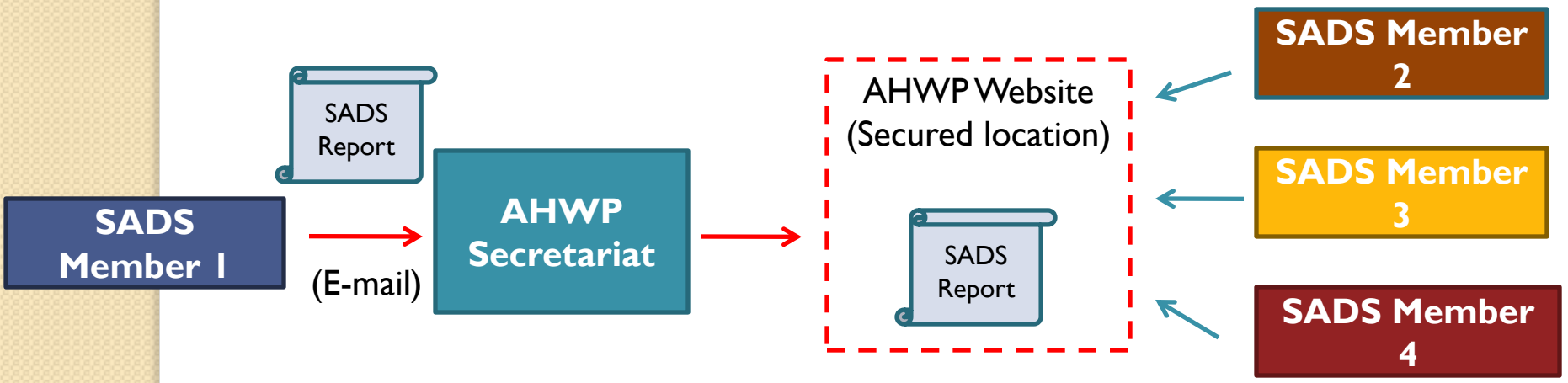
Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorised Representative (AHWP/WG4/D001:2015) (2)

- **Summary:**
  - The document is a combined version of the following AHWP guidance on Adverse Event Reporting:
    (a) Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative (AHWP/WG2/F001:2013)
    (b) Medical Device Adverse Event (AE) Report Form (AHWP/WG2/F001:2012) ; and
    (c) Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative (AHWP/WG4/F001:2014).
  - Contents covering definitions, reporting criteria, exemption rules, use errors and timelines in relation to AE reporting are updated.
  - New AE reporting requirements and examples on IVDMDs are added.

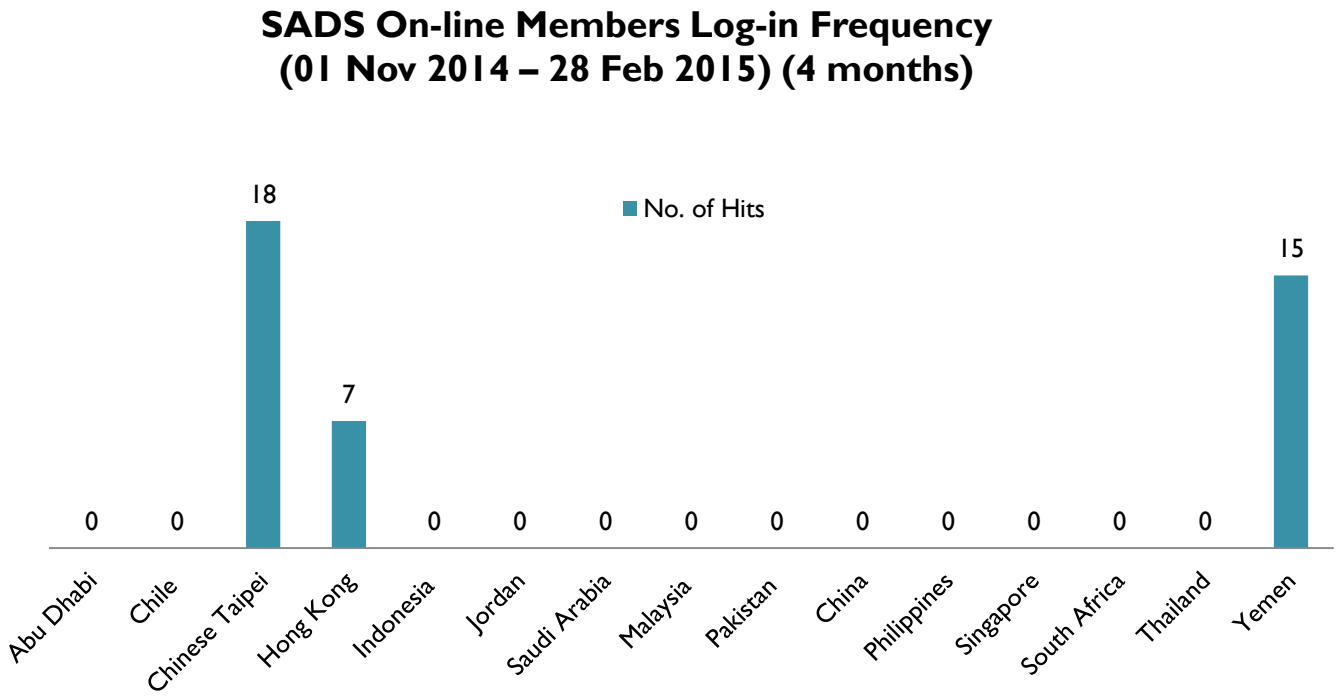
Safety Alert Dissemination System (SADS)

- **SADS On-line** introduced and launched since May 2014, providing a secured location at AHWP website for sharing by regulators
- As at 1 Mar 2015, 15 SADS On-line members, each having 2 log-in accounts:

  Abu Dhabi, Chile, Chinese Taipei, Hong Kong, Indonesia, Jordan, Saudi Arabia, Malaysia, Pakistan, China, Philippines, Singapore, South Africa, Thailand, Yemen



Safety Alert Dissemination System (SADS) - Utilization (01 Nov 2014 – 28 Feb2015)



Safety Alert Dissemination System (SADS) Review

- **Finding**
  - Access to SADS On-line for most SADS members is quite low

- **Actions taken**
  - Messages sent to representatives of ALL AHWP members to encourage usage, as well as introducing the system to non-SADS members
  - Powerpoint explaining the operation of the SADS On-line developed and sent out to both current and old SADS members
  - A survey questionnaire on SADS On-line sent to ALL AHWP economy members seeking comments and views for improvement

Safety Alert Dissemination System (SADS) – Survey Report (1)

- **Survey objectives**
  - To study why the utilization of the SADS On-line is low
  - To explore what information SADS members would like to get and how to make better use of the system

- **Survey target respondents**
  - 24 SADS/ AHWP representatives of AHWP economy members – including 9 current SADS members, 6 old SADS members and 9 non-SADS members
  - Survey questionnaires sent on 24 Jun 2015 and reminders sent on 5 Aug 2015
  - So far, 8 survey questionnaires returned from
    - 5 current SADS members – Chinese Taipei, HK, Saudi Arabia, Malaysia and Thailand
    - 3 non-SADS members – Korea, Kuwait and Tanzania

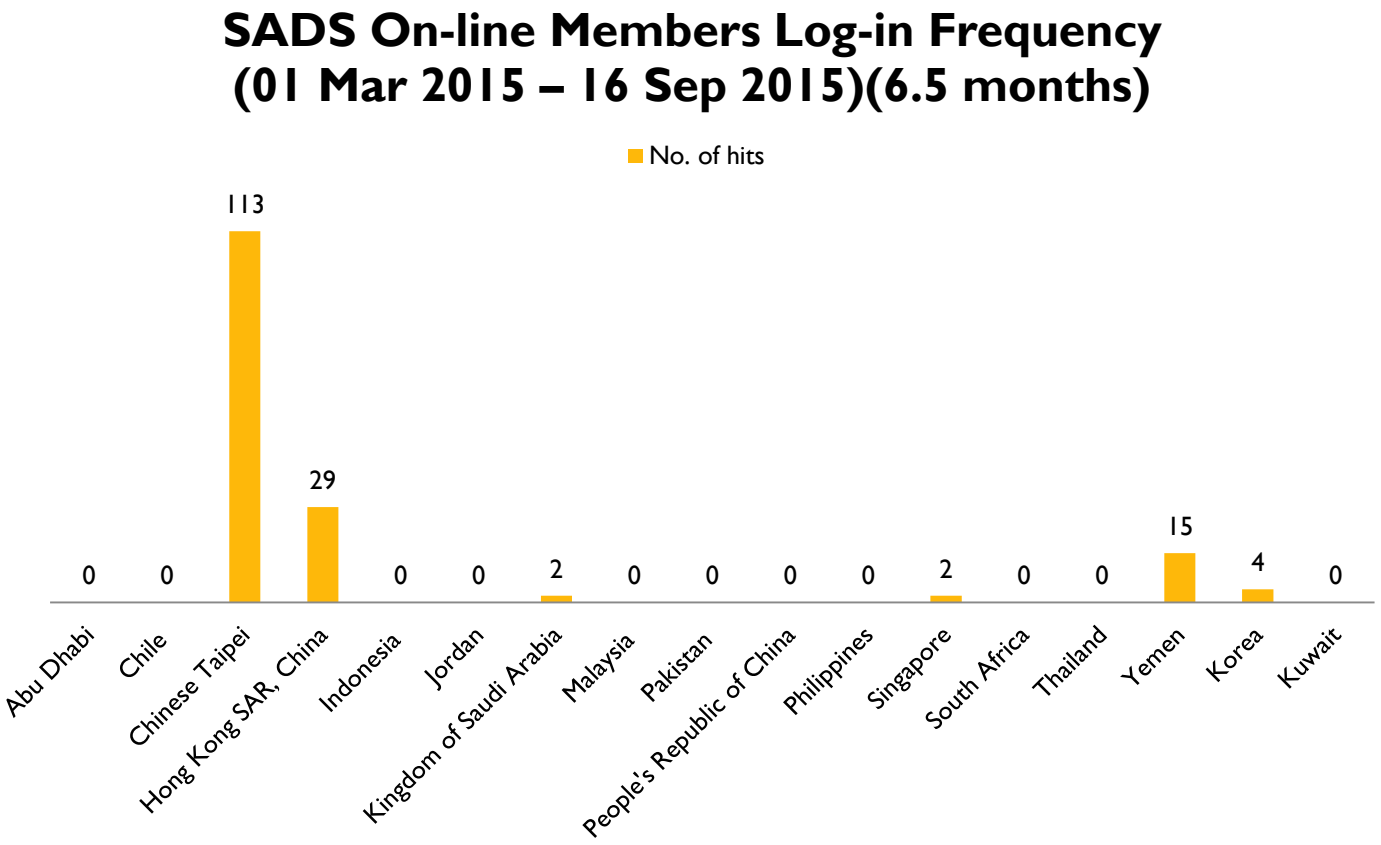
Safety Alert Dissemination System (SADS) – Survey Report (2)

- **Survey results**
  - Frequency of usage of SADS On-line
    - 1 current SADS member use SADS on-line regularly (once per week)
    - 2 current SADS members use SADS on-line on a needed basis
  - Purpose(s) of gaining access to the SADS On-line
    - To get safety information, without sharing any safety information (due to no specific post-market information to share with other RAs)
  - Reason(s) for not using SADS On-line
    - Not familiar with the operation of secured SADS On-line
    - No post-market system in the country / person in-charge was not directly involved in post-market activities
    - The contact person has been changed
    - Never heard of SADS

Safety Alert Dissemination System (SADS) – Survey Report (3)

- **Survey results**
  - Information expected to be found in SADS On-line
    - SADS Report
    - Safety information / inquiry on performance of certain life support or high risk medical devices
    - Some post-market guidance / guidelines issued by other RAs
  - In general, responded members find the SADS On-line useful
- **SADS membership**
  - New applications: Korea, Kuwait and Tanzania
  - 18 SADS On-line members (12 with updated contacts & 6 with no recent response)

Safety Alert Dissemination System (SADS) Utilization (01 Mar 2015 – 16 Sep 2015)



Safety Alert Dissemination System (SADS) – Way Forward

- **Utilization of SADS On-line**
  - Comparing with that during the period (Nov 2014 - Feb 2015), the average monthly hit rate to SADS On-line increased by about 90% in the past 6 months
  - More SADS members tried logging into the SADS On-line in the past 6 months
- **Recommendations**
  - To maintain the current operation of the SADS On-line;
  - To review the existing AHWP SADS guidance documents and update if needed; and
  - To explore additional information to be put into the SADS On-line e.g. links of some post-market guidance / guidelines issued by other RAs

ASIAN HARMONIZATION WORKING PARTY

Thank you