



## AHWP TC WG02 Report:

# AHWP TC WG 02

## Post-market Surveillance and Vigilance

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B&L, Hong Kong  
New Delhi, Nov 5, 08

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## WG02 Objectives

- Examine the requirements for the reporting of medical device adverse incidents
- Recommend ways to harmonize reporting requirements of medical device adverse incidents
- Work towards a harmonized regional medical device post-market surveillance and vigilance system.



## Memberships

- Chair: LAU Wah-kit, Mark, DOH, Hong Kong
- Co-Chair: TANAKASEMSUB, Miang, B&L Hong Kong
- Senior Advisor: Dr. GARCIA, Jorge, TGA, Australia
- Members (Regulators)

| <i>Family Name</i> | <i>Name</i>      | <i>From</i>                       |
|--------------------|------------------|-----------------------------------|
| CHHIENG            | Phana            | MOH, Cambodia                     |
| CHIU               | Henry            | Department of Health, Hong Kong   |
| HEANG              | SAR Kuv          | MOH, Cambodia                     |
| KWEK               | Alfred           | HSA, Singapore                    |
| SALFH              | Al Tweiir Waleed | Saudi Food & Drug Authority       |
| TANTAWIWATTANON    | Pimonvan         | FDA, Thailand                     |
| THITISATTHAYAKORN  | Suhong           | Thai-FDA                          |
| MATIENZO           | Maria Cecilia    | Department of Health, Philippines |
| PATANAWONG         | Yiwadee          | Thai-FDA                          |
| MAK                | Jennifer         | Department of Health, HKSAR       |



### •Members (Industry)

|           |                |  |
|-----------|----------------|--|
| CHAN      | Jamie          | St.Jude, Malaysia                                      |
| CHAN      | Jean           | Tyco, Singapore  |
| CHAN      | Andros         | HKMHDMA, Hong Kong                                     |
| CHANG     | Alan           | Taiwan Medical & Biotech Industry Association, Chinese |
| KIU       | Pamela         | Philips, Singapore                                     |
| LALEETHA  | Devi           | Kimberly Clark, Malaysia                               |
| LEUNG     | Terrenz        | Abbott Vascular, Hong Kong                             |
| MONTERIO  | Jacqueline     | Medtronic, Singapore                                   |
| MOORE     | Jack           | BD, Singapore  |
| ONG       | Nellie         | Johnson & Johnson, Medical Malaysia                    |
| SANDERSON | Georgina       | Cochlear, Australia                                    |
| SOENARDI  | Fiametta Sacra | Johnson & Johnson, Indonesia                           |
| TSAI      | Christine      | Boston Scientific, Hong Kong                           |
| WANG      | Ming-Che       | Center for Drug Evaluation, Chinese Taipei             |
| WONG      | Woei Jiuang    | Johnson & Johnson, Singapore                           |
| PARK      | Ho Joon        | Korea Testing Laboratory                               |
| PAN       | Ye, Brigitte   | Johnson & Johnson Medical China                        |



### Key Achievements

- Organize with GHTF SG02 the NCAR + SADS Training on 23 Oct 2007 & 4 Nov 2008
- Safety Alert Dissemination System (SADS) Final Documents issued on 23 Jan 2008
- Started the survey on Post Market Surveillance & Vigilance System on 23 Jan 2008
- Miang Tanakasemsub, Co-Chair of AHWP SG02, Join GHTF SG02 as liaison member



## Key Achievements (cont'd)

- Safety Alert Dissemination System (SADS) Launched in Jun 2008
- Draft report on survey of Post Market Surveillance & Vigilance System on 3 Nov 2008



## Development of the AHWP Safety Alert Dissemination System (SADS)



## Progress of SADS

- Final documents (23 Jan 2008)
  - [AHWP-WG2/SADS/001](#): Framework for AHWP Safety Alert Dissemination System (SADS)
  - [AHWP-WG2/SADS/002](#): Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Forms
- Launch in June 2008



## Progress of SADS

- 7 Participants
  - Hong Kong
  - Indonesia
  - Malaysia
  - Philippines
  - Singapore
  - Saudi Arabia
  - Thailand
- 2 Cases disseminated



## Training for National Competent Authority Report (NCAR) Exchange Program & SG02 documents in Asia




### Asia NCAR & SG02 Trainings

#### 2007 training:


- Chengdu, China

#### 2008 trainings:

- KL, Malaysia
- Bangkok, Thailand
- Chinese Taipei
- India
- China




## Projects and Planning & Update



## Projects Status

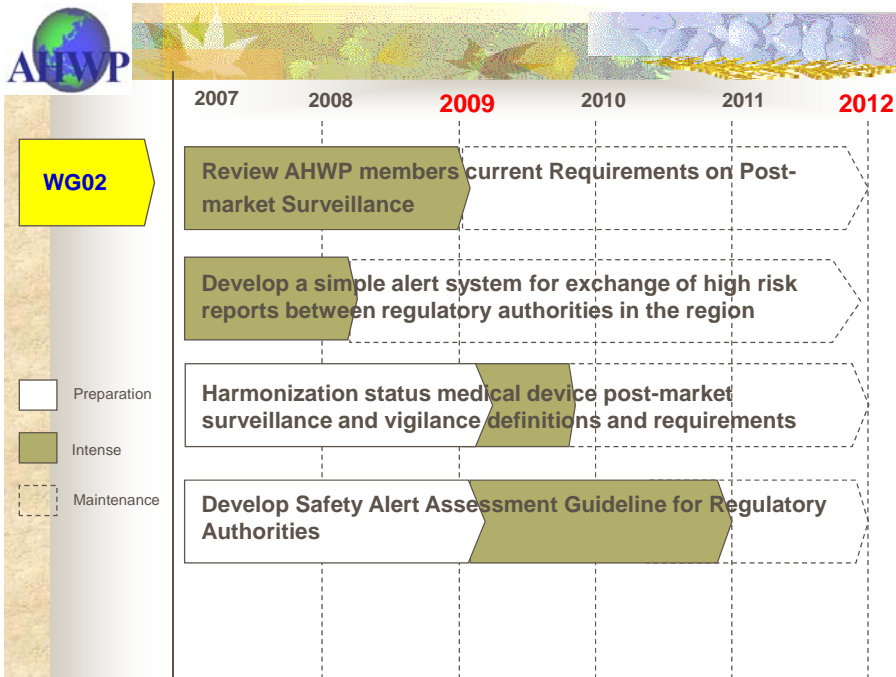


- WG-02-01: Review the Existing Post-Market Vigilance and Surveillance Systems in AHWP Economies\_Completed
- WG-02-02: Develop the AHWP Safety Alert Dissemination System (SADS)\_Completed



## Proposed working items

- Harmonized ADR reporting form
- N61: PMS Harmonization Chart
- Propose Harmonized Post-market Surveillance and Vigilance Requirements
- Develop Safety Alert Assessment Guideline for Regulatory Authorities
- PMS trainings tools







## Team work!



We will reach our harmonization goal together!

Break for  
Questions ??



James Nedock / The Monitor