AHWP TC

WG02

Post-market Surveillance and Vigilance

Content

1. Objectives and membership
2. Project plan
3. Update on GHTF SG02 invitation
4. Review of the AHWP secretariat survey on post-market surveillance system
5. NCAR Program
6. Training plan in the 12th AHWP Meeting in China
7. Hong Kong's experience in managing safety alerts and adverse incidents
8. Development of the AHWP Safety Alert system
9. Any other business

WG02 Objectives

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

Rules of WG02 Membership

- Always welcome all the Regulators participation and feedback
- For industry
  - Only one representative from one company
  - Expect full participation. Membership will be terminated automatically if no participation/delegation for 3 times.
- Communication modes
  - Regular teleconferences
  - Face to face meeting mainly in conjunction with AHWP TC meeting.

Memberships

- Chair: Mark Lau_DOH, Hong Kong
- Co-Chair: Miang Tanakasemsub_B&L Hong Kong
- Advisor: Jorge Garcia_TGA, Australia
- Members:

- Regulators

- Henry Chiu_DOH, Hong Kong
- Alfred Kwek_HSA, Singapore
- Waleed Saleh AL Twejri_ Saudi FDA, Saudi Arabia
- SAR Kuy Heang_ MOH, Cambodia
- Phana Chhieng_MOH, Cambodia

Memberships

- **Industry**

Jacqueline Monteiro_Medtronic, Singapore

Jamie Chan_St.Jude, Malaysia

Jack Moore_BD, Singapore

Wong Woei Jiuang_JNJ, Singapore

Jean Chan_Tyco, Singapore

Andros Chan_HKMHDMA, Hong Kong

Wang Ming-Che_Center for Drug Evaluation, Chinese Taipei

Devi Laleetha_Kimberly Clark, Malaysia

Pamela Kiu_Philips, Singapore

Christine Tsai_Boston Scientific, Hong Kong

Georgina Sanderson_Cochlear, Australia

Fiametta Sacra Soenardi_JNJ, Indonesia

Alan Chang_Taiwan medical and biotech industry association, Chinese Taipei

- ***Post-Market Alert System***

11. Singapore presented the proposal for post-market alert system framework which appears as **ANNEX 4**. The Meeting agreed that post-market system is important to monitor medical devices on the market and should be put in place even in the absence of pre-market activities.

    The Meeting decided AHWP TC to finalize the proposal for adoption at the next AHWP Meeting. In finalizing the proposed post-market alert system framework, AHWP TC was suggested to consider the following;

REPORT OF THE 11th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP) *Seoul, Korea 15th September 2006*

(i) Make reference to GHTF recommendations and work closely

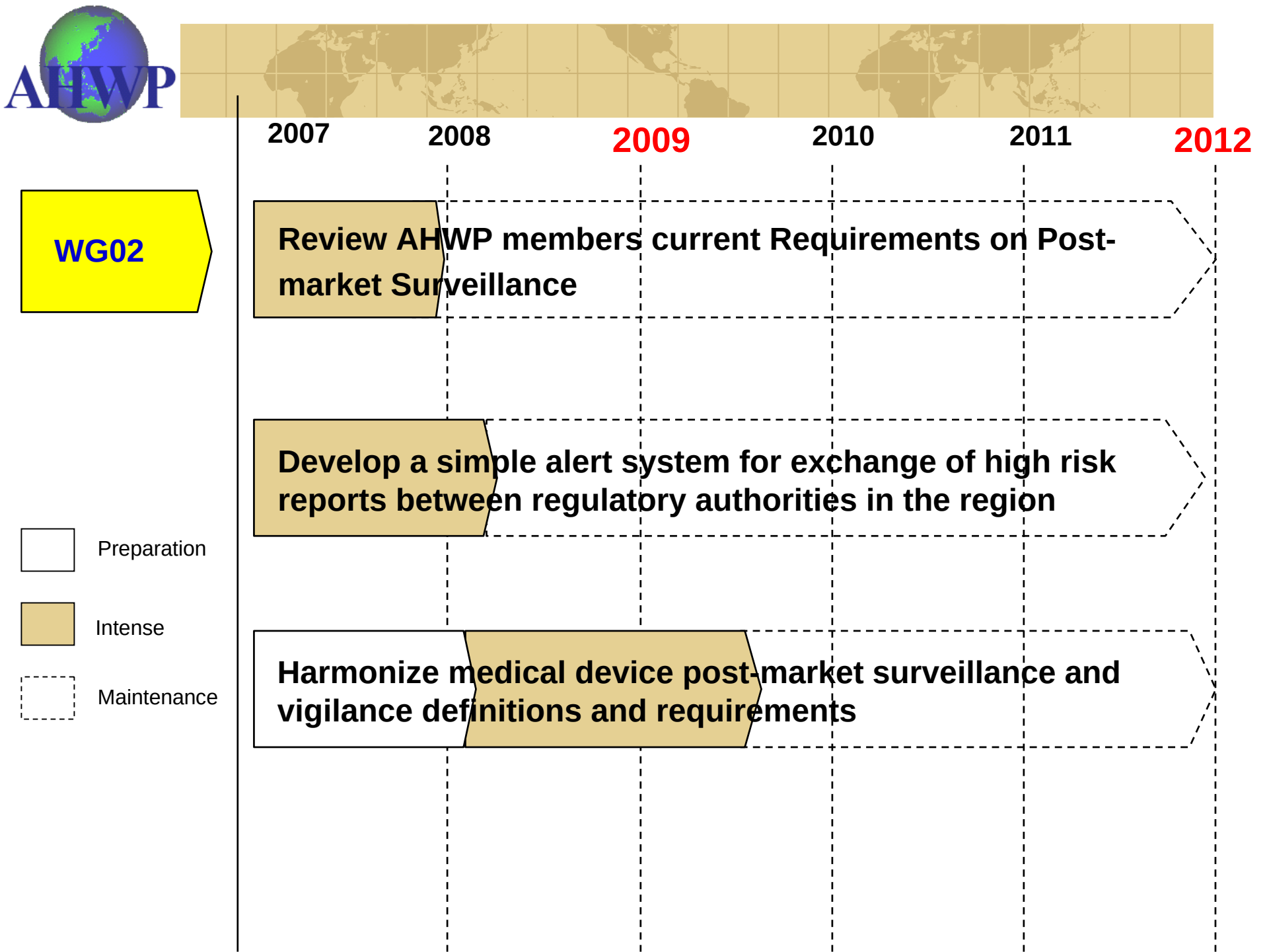
with GHTF SG2 to try to eliminate the issue of having different sets of system;

(ii) The capacity and capability of Member Economies, especially those without regulation;

(iii) Mechanism for sharing information on adverse events

Project plans

- Review AHWP members current requirements on post-market surveillance
- Develop a simple alert system for exchange of high risk reports between regulatory authorities in the region
- Harmonize medical device post-market surveillance and vigilance definitions and requirements


AHWP
2007
2008
2009
2010
2011
2012
WG02
Review AHWP members current Requirements on Post-market Surveillance
Develop a simple alert system for exchange of high risk reports between regulatory authorities in the region
Harmonize medical device post-market surveillance and vigilance definitions and requirements
Preparation
Intense
Maintenance

Update on GHTF SG02 invitation

Review of the Comparative study on the control of Medical Device in AWHP member economies on Post-Market Surveillance System

AHWP economy members post-market surveillance and vigilance system

Countries	Yes/No	Others/Comments
Brunei	N	
Cambodia	N	
China	Y	
Chinese Taipei	Y	The central competent health authority may set a specific period of time for monitoring the safety of new drugs approved and establish matters that the pharmaceutical dealers shall adhere to
Hong Kong	Y	
Indonesia	Y	Provided by administrative guidelines
Laos	N	
Malaysia	Y	Initial steps taken in a voluntary registration system, to become mandatory under the new law
Myanmar	Y	
Philippines	Y	Developing draft guidelines for adverse event reporting and vigilance reports
Singapore	Y	
South Korea	Y	
Thailand	Y	Provided by administrative guidelines/policy
Vietnam	Y	

AHWP economy members post-market surveillance and vigilance system

- China: SFDA has recently further intensified its medical device adverse event surveillance. An announcement was issued on 2 August, 2006 "*regarding the strengthening of surveillance of adverse events … to have a better surveillance of medical device adverse events, identify suspicious adverse events of medical devices in a timely manner, effectively control and take interventions against products with safety risks and ensure that medical devices on the market are safe to use.*

AHWP economy members post-market surveillance and vigilance system

- Chinese Taipei: There is a post market surveillance and vigilance system, and the regulatory authority conducts post-market surveillance. Detailed guidelines are provided in its Regulations for adverse event reporting, setting out the method, content and matters to be complied with in such reporting. Close attention is paid to information from the USFDA.

AHWP economy members post-market surveillance and vigilance system

- South Korea also has manufacturer's post market surveillance and vigilance system, and its regulatory authority (KFDA) conducts post-market surveillance, too. Guidelines are set for both adverse event reporting and vigilance reports.

AHWP economy members post-market surveillance and vigilance system

- Hong Kong has a post market surveillance and vigilance system (Guidance Note GN-01 and GN-03) with guidelines for adverse event reporting contained in Guidance Note GN-03. The voluntary listing system requires the “Local Responsible Persons” to carry out post-market surveillance. Other people could report adverse incidents by filling in the reporting form.

AHWP economy members post-market surveillance and vigilance system

- Singapore: A post-market surveillance and vigilance system covering all the components, in accordance with GHTF recommendations. Guidelines are provided on adverse event reporting and vigilance reports.

AHWP economy members post-market surveillance and vigilance system

- Thailand: A post-market surveillance and vigilance system which comprises all the components applies to manufacturers, importers and distributors

AHWP economy members post-market surveillance and vigilance system (cont)

- Malaysia: Proposed law will place responsibilities on the manufacturer, importer and distributor, covering all the components, in accordance with GHTF recommendations. The regulatory authority will also conduct post-market surveillance. Meanwhile, initial steps have been taken for the manufacturer's system in the launching of MeDVER, its voluntary registration system, in January 2006, and guidelines for adverse event reporting and vigilance reports are available on-line.

AHWP economy members post-market surveillance and vigilance system (cont)

- Myanmar: A post-market surveillance and vigilance system also covers all the components. The regulatory authority provides guidelines for adverse event reporting and vigilance reports. Myanmar's Adverse Drug Reactions Reporting System is applied to both pharmaceutical products and medical devices.

AHWP economy members post-market surveillance and vigilance system (cont)

- Indonesia: MOH conducts post-market surveillance, no tracking system and information-sharing in place.

AHWP economy members post-market surveillance and vigilance system (cont)

- Philippines: BHDT is developing guidelines for a post-market surveillance and vigilance system. Currently the Bureau of Health Devices and Technology (BHDT) monitors all the posted alerts in the websites of the US FDA, TGA, Health Canada and MHRA. If there are postings, the Bureau notifies the local distributors and inquires into what has been done about product recall. The Department of Health issues corresponding device alerts.

AHWP economy members post-market surveillance and vigilance system (cont)

- Brunei, Cambodia and Laos: No post-market surveillance and vigilance systems in place.

Product recall for the period January 2003 - June 2005

Countries	Yes/No	Others
Brunei	N	
Cambodia	N	
China	Y	
Chinese Taipei	Y	
Hong Kong	Y	
Indonesia	N	
Laos	N	Provided by administrative guideline
Malaysia	Y	
Myanmar	N	NA
Philippines	N	Monitoring of products only started in the last quarter of 2005
Singapore	Y	
South Korea	Y	
Thailand	Y	
Vietnam	Y	No records have been kept of past recalls

Enforcement power vested in regulatory authority

Countries	Yes/No	Others
Brunei	N	
Cambodia	Y	
China	Y	
Chinese Taipei	Y	
Hong Kong	N	
Indonesia	Y	
South Korea	Y	
Laos	N	NA
Malaysia	Y	
Myanmar	Y	
Philippines	Y	
Singapore	Y	
Thailand	Y	
Vietnam	Y	

Enforcement power vested in regulatory authority

- Indonesia's regulatory authority can impose fines and also issue warnings and cancel an approval.
- Myanmar's FDA can fine or imprison.
- Thailand's FDA has powers to fine or imprison, or both, and can suspend and revoke a licence with the approval of the Medical Device Committee which advises and makes recommendations to the Thai FDA and Ministry of Public Health.

Enforcement power vested in regulatory authority

- Singapore's HSA can fine or imprison, or both. For offences relating to misleading or false advertisements, HSA may require offenders to publish corrective advertisements in lieu of criminal prosecution.
- Malaysia's Medical Devices Bureau will have enforcement powers, and these are being finalised under the proposed law.
- China's laws also confer enforcement powers on the regulatory authority.

Enforcement power vested in regulatory authority

- The BPA/DOH, Chinese Taipei can withdraw a license or seize product. The law also provides for life imprisonment or imprisonment for a period, and may in addition impose a fine of not more than NT$ 250,000,000.
- Since the Hong Kong system is voluntary, there is no enforcement power vested in the authority concerned.

NCAR

National Competent Authority Report

What is NCAR?

- National Competent Authority Report (NCAR) exchange program.
- The NCAR exchange program founded by GHTF SG2.
- There are the prerequisites and commitments required from GHTF before each AHWP member economy can participate in the NCAR exchange program.

NCAR Purpose

- The purpose of a linked system incorporating adverse event reporting, and vigilance and post-market surveillance components is to improve the protection of the health and safety of patients, users and others by reducing the likelihood of repeated similar adverse events.

Scope: NCAR exchange two types of information:

- **Confidential Information:** Information that due to its nature may be unfairly prejudicial to one or more persons and that, for this reason, has been marked by the information provider as being confidential or not for general release.
- **Public Information:** For the purposes of this document, information that is regarded to be non-confidential. This information may not necessarily be widely or easily available. For example, information contained in recall notifications, safety alerts, hazard alerts, product notifications and other product advisories is considered to be public information

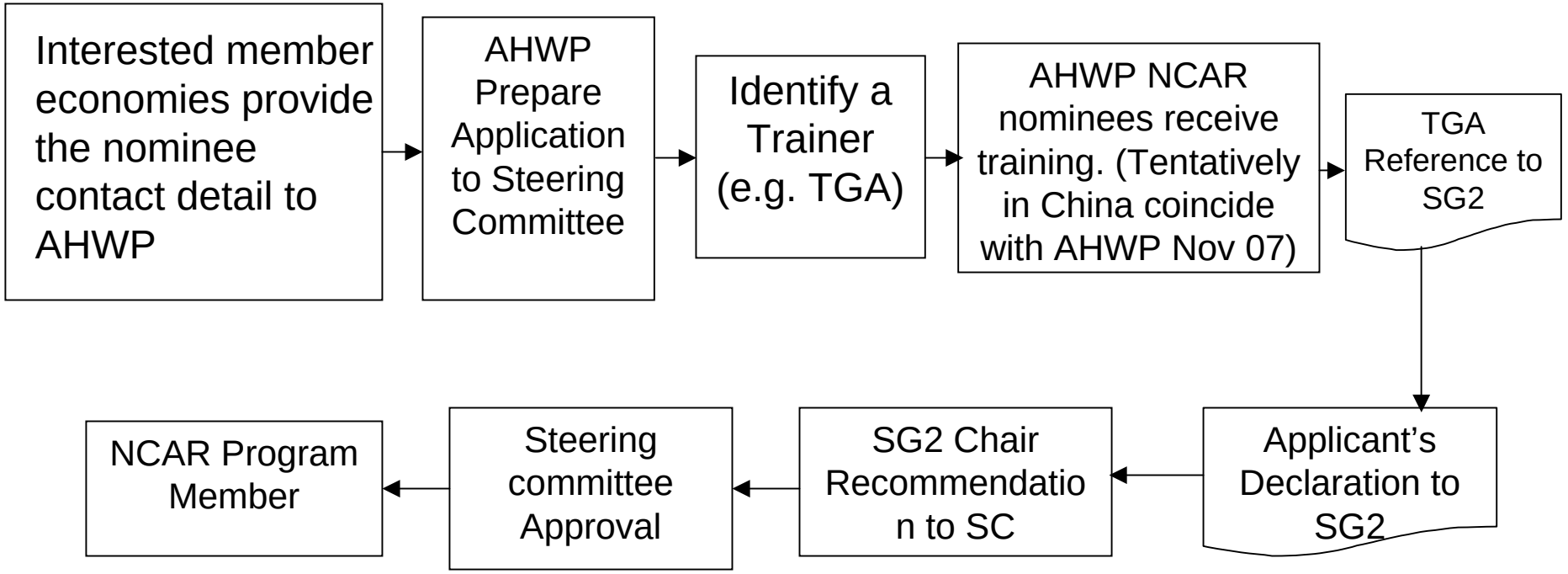
Types of Participant

- **Associate Participant:** An organization that participates in the NCAR program that receives only public information from other NCAR participants. Associate participants may contribute NCARs that contain either public or confidential information, but are not compelled to do so. An associate participant may not necessarily be a National Competent Authority.
- **Full Participant:** An organization that participates in the NCAR program that receives both public and confidential information from other NCAR participants. Full participation is open only to National Competent Authorities.

General principle

- Participants in the NCAR program will be receiving information regarding hazards associated with the use of medical devices.
- Because of the highly confidential and/or sensitive nature of some of the information being transferred, NCAs wishing to participate fully in the NCAR exchange program, **including founding members,** must meet several prerequisites and make several commitments to the other participants.

Application process for AHWP member economies as Associate Participants



Prerequisites and Commitments

- Training: For organizations wishing to participate as Associate Participants and exchange only public information, the training may be limited to document exchange procedures (GHTF SG2 N20 and GHTF SG2 N9).
- Commitments**:**

  Release of Forms:

  Agree that NCARs will be submitted only via the form entitled "Global Medical Devices NCAR Report" *(GHTF SG2 N9).*

  Single Contact Point

.

Training plan in the 12th AHWP Meeting in China

Training plan

- One day training by GHTF SG 02 for AHWP member countries representatives. (1-2 people per country)
- Examples of the manufacturer post-market surveillance process system.
- Case studies how HA handle and exchange vigilance information.