Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Post-market Surveillance and Vigilance

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13th AHWP Meeting

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YTD Key Achievements

- Commence Safety Alert Dissemination System – Mar 08
- Join GHTF SG02 as one of the liaison members. Miang Tanakasemsub, Co-Chair of AHWP SG02
- Worked with GHTF SG02 to organize numbers of the NCAR & SG02 documents Training
- Complete First Draft on the control of Medical Device in AWHP member economies on Post-Market Surveillance System

Review of the survey on Post-Market Surveillance System

Review of the first draft of the survey on the control of medical device in AWHP member economies on Post-Market Surveillance System

Objectives of this document

- To review current Post Market Surveillance System among AHWP member economies
  - Organization and infrastructure
  - Scope and requirements
  - Post Market Surveillance & Vigilance system
  - Withdrawal and Recall
- To define the differences in the systems among AHWP member economies

Review of the survey on Post-Market Surveillance System

Current requirements

- 13 out of 15 AHWP member economies participated in the survey as follows;
- Cambodia, China, Hong Kong, India, Indonesia, Korea, Laos, Malaysia, Philippines, Saudi Arabia, Singapore, Chinese-Taipei, Thailand
- 11 have established medical device regulatory systems. To date only Laos and Cambodia don't have medical device regulatory system in place.

Review of the survey on Post-Market Surveillance System

Current requirements

- The following 7 member economies implement mandatory medical devices regulatory systems: China, India, Indonesia, Korea, Chinese Taipei, Singapore and Thailand.
- Saudi Arabia and Philippines are under both mandatory and voluntary phases.
- Malaysia and Hong Kong are still under voluntary however Malaysia's draft Act is going to Parliament in Q1 2009
- Medical devices regulation was developed in the later stage, therefore medical devices in the following markets are controlled under pharmaceutical law: India & Philippines.

Review of the survey on Post-Market Surveillance System

Current requirements

- Chinese Taipei is only member economy for which its regulation is under both medical devices and pharmaceutical laws.
- All 11 established medical device regulatory systems have post market surveillance (System that enables manufacturer to gain and review experience about their product) and vigilance system (Activities undertaken once manufacturer becomes aware of adverse events, malfunctions)
- Only Hong Kong, India and Malaysia are still under voluntary phase.

AE reporting requirements including reporting timelines

AHWP AE Reporting Requirements		Device malfunction Related		Serious injury or Related		Near Adverse event Related		Serious public Related		
Country	Origin of Cases	Exp	Unexp	Exp	Unexp	Exp	Unexp	Exp	Unexp	Website & Reporting Form
Singapore	Local			10d	10d	30d	30d	48h	48h	http://www.hsa.gov.sg
	Foreign							48h	48h	
Malaysia	Local	30d	30d	30d	30d	30d	30d	7d	7d	www.mdb.gov.my
	Foreign									
Thailand	Local	30d	30d	24h	24h	15d	15d	24h	24h	http://www.fda.moph.go.th/fda%2Dnet/html/product/mdcd/eng/
	Foreign	30d	30d	24h	24h	15d	15d	24h	24h	
India	Local			x	x			x	x	www.cdsco.nic.in
	Foreign									
Indonesia	Local	30d	30d	24h	24h	30d	30d	24h	24h	
	Foreign									
Hong Kong	Local			10d	10d	30d	30d	10d	10d	www.mdco.gov.hk
	Foreign									..\Adverse Event Forms\Hong Kong.pdf
Taiwan	Local	30d	30d	10d	10d	30d	30d	48h	48h	www.doh.gov.tw/EN2006
	Foreign									
Saudi Arabia	Local	30d	30d	10d	10d	30d	30d	10d	10d	http://mdprc.sfda.gov.sa
	Foreign	30d	30d	10d	10d	30d	30d	10d	10d	
Korea	Local	10d	10d	15d	15d	30d	30d	7d	7d	http://www.emed.kfda.go.kr
	Foreign									
China	Local			Death_Immediately / Serious AE_10 Days	Death_Immediately / Serious AE_10 Days	15d	15d	24 h	24 h	www.sfda.gov.cn/eng
	Foreign			Death_Immediately / Serious AE_10 Days	Death_Immediately / Serious AE_10 Days	15d	15d	24 h	24 h	..\Adverse Event Forms\CHINA.doc

Withdrawal and Recall

- Identified definition of recall of all member economies
- Almost all member economies required manufacturers/representative to report recalls/corrective actions that happen inside and outside their jurisdictions; except Korea, Hong Kong SAR and Chinese Taipei that require only the report inside their jurisdiction.
- Philippines encourages manufacturers/representative to report recalls/corrective actions that happen inside their jurisdiction however it is not imposed by law.

Summary

- Current requirements, definitions and understanding of Post-Market Surveillance (PMS) activities among AHWP member economies are still **not harmonized.**
- We believe that harmonization of some aspects of GHTF SG02 framework may benefit regulatory authorities and industry of AHWP member economies'.

Training on NCAR Exchange Program & SG02 documents in Asia

Asia NCAR & SG02 Trainings

- 2007:
  - Chengdu, China
- 2008:
  - KL, Malaysia
  - Bangkok, Thailand
  - Chinese Taipei
  - India
  - China

Training on NCAR Exchange Program & SG02 documents in Asia

NCAR Training on 23 Oct 2007

- Speakers:
  - Dr Jorge Garcia, GHTF SG2 Chair;
  - Dr Philippe Auclair, Abbott Vascular
- Attendance:
  - 40 people
  - 13 from 15 AHWP member economies (90%) attended (except Vietnam & Indonesia)
- Result:
  - Satisfied the training requirement for joining NCAR as Associate Participant
  - 30 participants provided feedback through the Quiz

AHWP NCAR membership update

- Hong Kong: Prior NCAR training
- Saudi Arabia: After Chengdu training
- Burning question: Efficiency of NCAR trainings???

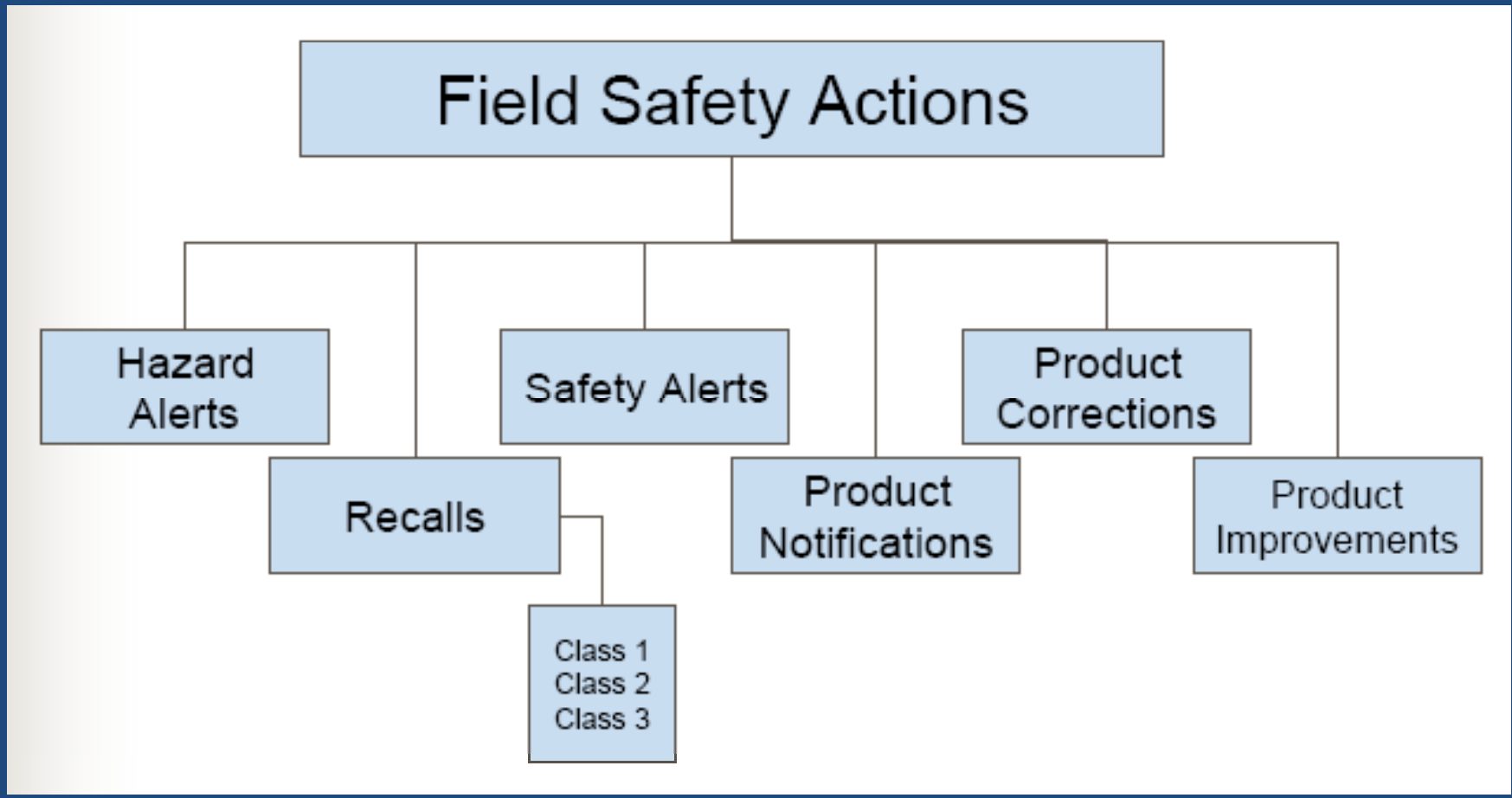
GHTF SG02 update

- New Chair: Isabelle Demade from European Commission
- New GHTF NCAR Secretary : TGA, Australia
- Meetings in 2008
  - Lisbon, Portugal_Feb 08
  - Ottawa, Canada_Oct 08
- Next year meeting: Brussels, Belgium, Feb 09

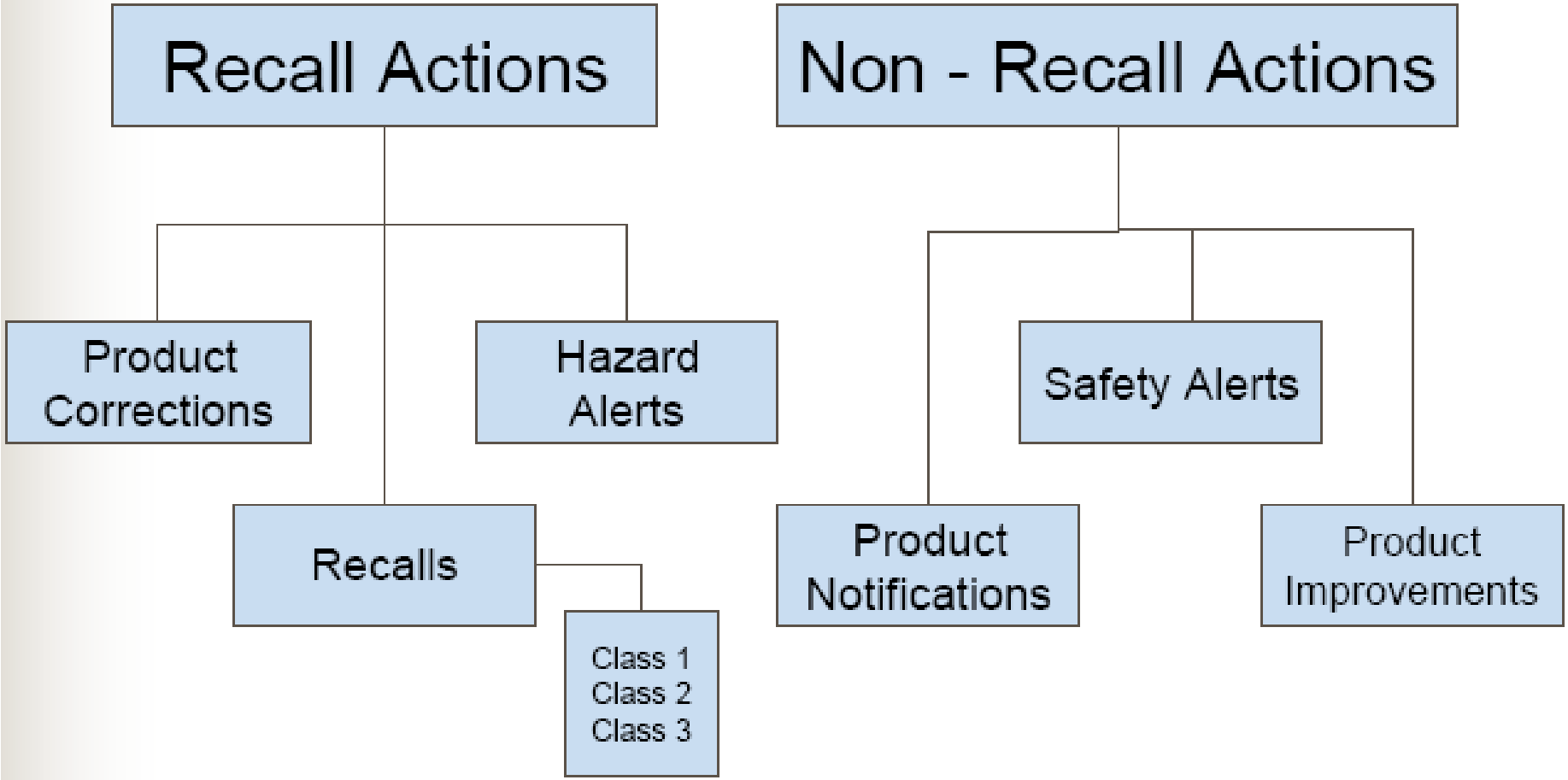
Working items

- Adverse Event Coding and ISO 19218: Discussion developments - USFDA mapping and 2 levels code
- Pilot of N87PD: Pilot project for electronic adverse event reporting using the XML format: Health Germany plan to commence in Q1 09
- Definition and Classification of Product Safety Corrective Actions, Including Recalls: Harmonization status chart

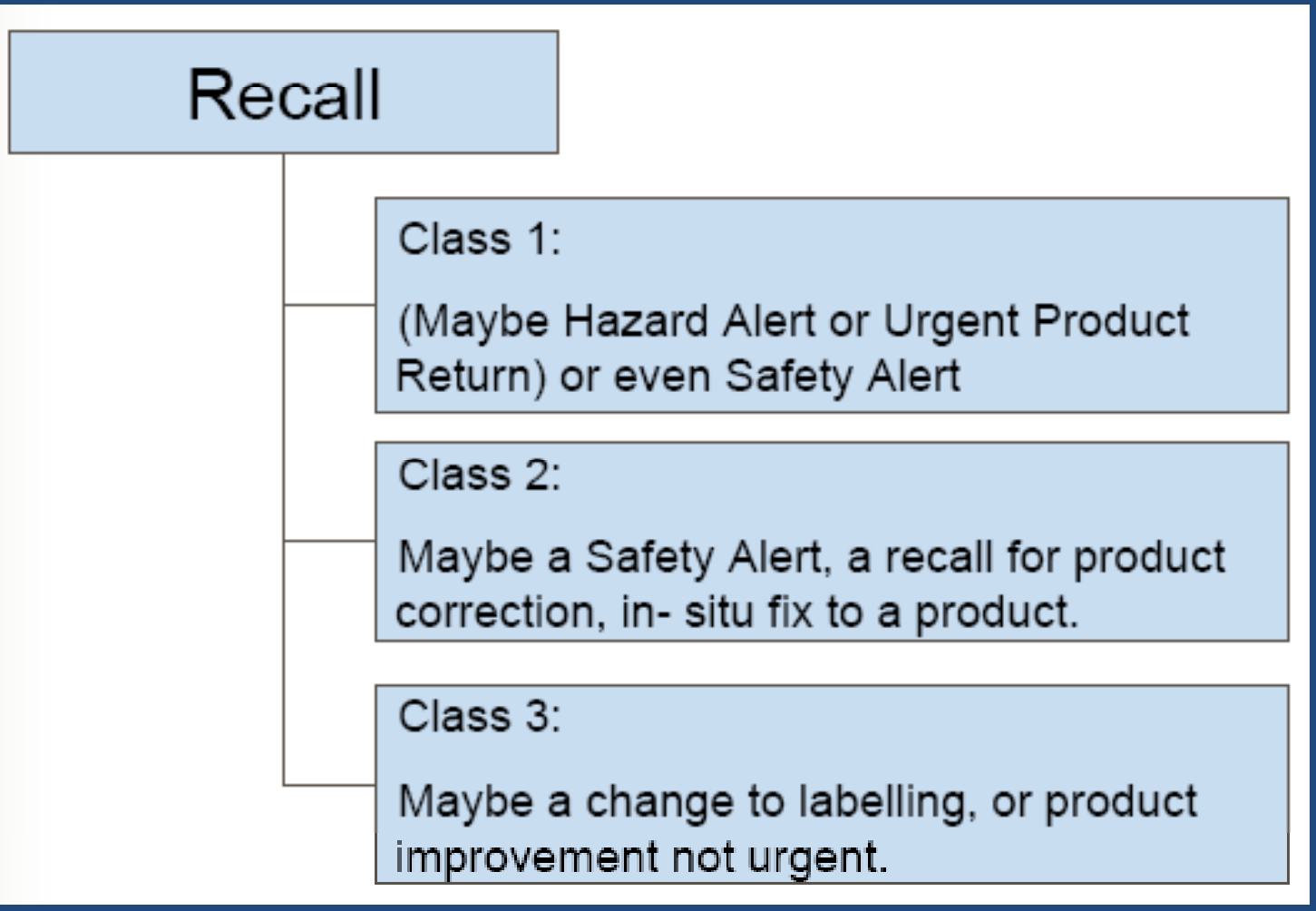
Family Tree for FSCAs (notional)



FSCAs: alternative naming schemes



FSCAs: alternative naming schemes (2)

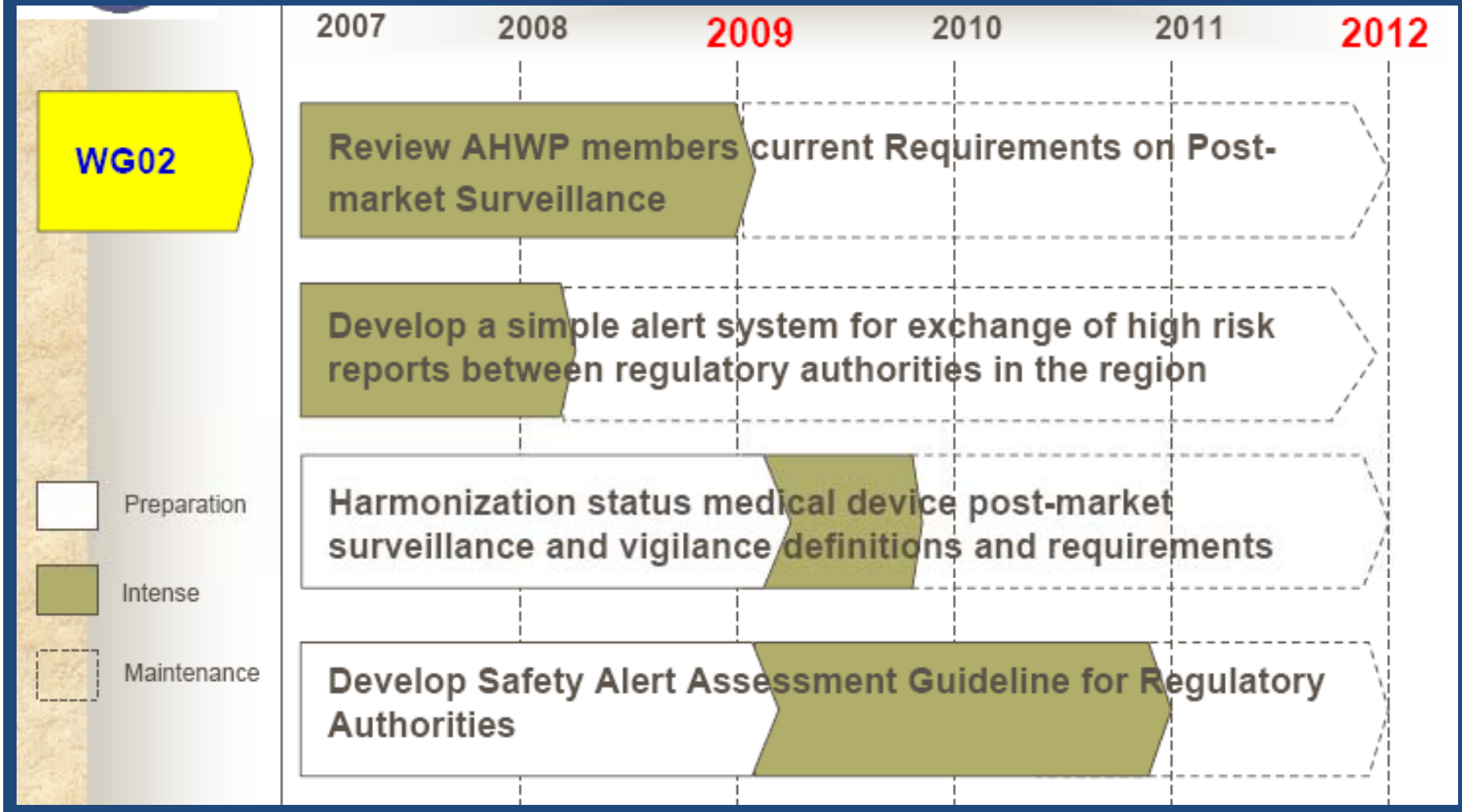


Projects and Planning & Update

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
- WG-02-03: Propose Harmonized Post-market Surveillance and Vigilance Requirements – On-going
- WG-02-04: Develop Safety Alert Assessment Guideline for Regulatory Authorities – On-going
- N61: PMS Harmonization Chart – Started

Projects and Planning & Update



Projects and Planning & Update

- **Upcoming Activities**
- Complete an update survey on post-market surveillance systems in AHWP member economies
- Facilitate AHWP economy members SADS & NCAR program participation
- Propose medical devices post-market surveillance and vigilance definitions and requirements
- Facilitate TGA best practices sharing (How TGA handle AE and field corrective action): KL 5th of Mar


Break for
Questions ??

Thank you for your attention!