ASIAN HARMONIZATION WORKING PARTY

WG4: Post-market

(former WG2 – Post-market)

Chair: Jennifer MAK

Co-Chair: Kitty MAO

Senior Advisor: Jorge GARCIA

No. of WG members: 31

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Status of WG Items (1)

	Achievement
1	**Formal training of SG02/WG2 Guidance Document** *(Completed in May 2012)* • Already communicated to WG6
2	**Harmonized definitions of Post Market Surveillance Terms** *(Completed in Nov 2012)* •The guidance document, ***Definition and Classification of Field Safety Corrective Actions (AHWP/WG2/F002:2012)***, is available on the AHWP website
3	**Electronic AE Reporting Forms** *(Completed in Nov 2012)* •The electronic form, ***Medical Device AE Reporting Form (AHWP/WG2/F001:2012),*** is available for reference by regulators of member economies on the AHWP website

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Status of WG Items (2)

	Achievement
4	**Adoption of AE & FSCA forms across AHWP member economies** *(Completed in Nov 2012)* •Electronic AE Form is available for member economies on the AHWP website
5	**Harmonized AE Reporting** *(Completed in Dec 2013)* • The guidance document, ***Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorised Representative (AHWO/WG2/F001:2013),*** is available on the AHWP website
6	**Upgrade the SADS** *(Completed in May 2014)* •***Online Secure SADS System*** is available for use by SAD members (regulators) on the AHWP website

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Status of WG Items (3)

Work in Progress	
1	**Develop AE reporting requirements & timelines for all stakeholders** •The guidance document, ***AE Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative***, to be endorsed in the 19th AHWP Annual Meeting

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Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative

- **Scope of paper:** Adverse Event Reporting Timelines

- **Objective of paper:** To provide guidance and information to Regulatory Authorities and the Medical Device Industry on the adverse event reporting timelines

- **Summary:** The guidance suggests adverse events that resulted in
  (i) Serious public health concern shall be reported within 48 hours; and
  (ii) Death or serious injury shall be reported immediately, but not later than 10 elapsed calendar days following the awareness of the event.
  (iii) All other reportable events shall be reported as soon as possible, but not later than 30 elapsed calendar days following the awareness of the event.

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Status of WG Items (4)

Future Action Plan (Tentative)	
1	Developing guidance document for proper handling of MDs after AE and Complaints
2	Adopt new GHTF/IMDRF FSCA guidance when the IMDRF document is ready

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Thank You