



WG2 – Post Market Surveillance

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Proposed Work Plan 2012 - 2014

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Set up Harmonized definitions for the PMS Terminologies i.e. AE, PMS etc,	Guidance document	Review N 54, ISO TC 210 Consensus Adoption & Acceptance Nov. 2012
2	Set up the electronic AE reporting forms in Acrobat template	Electronic AE reporting system	Telecon/meeting of the WG02 in May 2012 to seek feedback from members Action the feedback
3	Implement adoption to use the common AE and FSCA forms across AHWP member economies.	Acceptance by each economy •Adoption by the economy (Not yet implemented MD regulations) HK, SQ •Acceptance by economy (Have implemented the MD regulations)	Appeal by TC Chair/WG02 Chair to Member economies - Jun 2012 Organize one session in AHWP meeting for understanding/feedback from Regulators - End 2012

Proposed Work Plan 2012 - 2014

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4	Upgrade the SADS secretariat (Attach with WG02 Chair)	Secure SADS system	<p>Communication from TC Chair/WG02 Chair on availability of SADS – June 2012</p> <p>After acceptance by member economies issue user name & PW to regulators September 2012</p> <p>Work with AHWP Secretariat to ensure security of the site. June 2012</p>
5	Develop AE reporting requirements and Timelines for all stakeholders -Manufacturers, HCPs, Distributors	Guidance Document	<p>Review GHTF documents</p> <p>Gap assessment</p> <p>Adoption/Acceptance</p> <p>Nov 2012</p>
6	Adopt new GHTF FSCA guidance documentation	Guidance Document	<p>Review GHTF document</p> <p>Gap assessment</p> <p>Adoption/Acceptance Mid 2013</p>

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7	Developing Guidance Doc for proper disposal of MDs	Guidance Document	Gap analysis WW and AP Review/update/adopt. End 2013
8	Formal training of SG02 /WG2 guidance document	Training by WG 6	The training needs to be discussed in the WG telecom May 2012 Training needs to be conveyed to WG06 July 2012