



WGI - Pre-Market Submission and CSDT

Chair: BAI Huifen

Co-Chair: KWEK, Alfred

Proposed Work Plan 2012 - 2014

Priority	Work Item	Deliverables	Action Plan and Timeline
1	Definition of medical device	<ul style="list-style-type: none"> (i) Survey on extent of adoption of GHTF's MD definition (ii) Identify and promote awareness of the potential gaps of the definition 	<p>Mid-2012 TC meeting: Send survey to AHWP economies</p> <p>End 2012: Study the revision in GHTF definition</p> <p>End 2012: compile survey findings and present the gaps identified</p> <p>Mid 2013: Publish the findings</p>
2	Combination products	<ul style="list-style-type: none"> (i) Publish survey findings on combination products (ii) Guidance document on registration pathway 	<p>End-2012 TC meeting: Publish survey results</p> <p>Mid-2013: publish draft registration guidance document.</p>
3	Software	Guidance document on what is standalone SW, what is not a standalone SW, what is (and not) the criteria for determining SW as a medical device.	<p>Mid-2012 TC meeting: Send survey to AHWP economies</p> <p>End 2012: compile survey findings and environment scan SW.</p> <p>Mid 2013: publish findings</p>