



**Asian Harmonization Working Party Technical
Committee Leaders Meeting
26 – 27th Feb 2013
Bangkok Thailand**

**Mrs Joanna Koh
TC Chair
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AHWP Member Economies current status

(by Bryan)

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification	Nomenclature	Essential Principles
1	Abu Dhabi					
2	Brunei	No	No	No	No	No
3	Cambodia	Yes	Yes	Yes, GHTF	No	No
4	Chile	Yes	Yes	Yes	No	Yes
5	China	Yes	No	Yes	No	No
6	Chinese Taipei	Yes	Yes	3 risk-class, & GHTF guidelines	TMDN	Yes for Class III only
7	Hong Kong	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, AMDN	Yes, GHTF
8	India	No, moving towards GHTF	National definition & moving towards GHTF	No	No	No, moving towards GHTF
9	Indonesia	Yes, GHTF	Yes, GHTF	Yes	No	Yes, GHTF

Updates received by 27 Feb 2013

Updates by 2011

Current Regulatory Status of Member Economies (as at 2012)

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10	Jordan					
11	Korea	Yes, national definition based on GHTF	No	Yes	Yes	Yes, KFDA Medical Device Act requirements are equivalent to EPs; include the contents of EPs
12	Laos	Yes	No	Yes	No	No
13	Malaysia	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, UMDNS	Yes, GHTF
14	Myanmar					
15	Pakistan					
16	Philippines	Yes	Yes	Yes	No	No

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S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification	Nomenclature	Essential Principles
17	Saudi Arabia	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, UMDNS & GMDN	Yes
18	Singapore	Yes, GHTF	Yes	Yes, GHTF	Yes	Yes, GHTF
19	South Africa	Yes	Yes	No	Yes, UMDNS	No
16	Thailand	Yes, GHTF	No, but definition of <i>manufacture</i> in the MD Act	Presently No, but being in the procedure of reclassification	Yes, UMDNS & GMDN	Yes
21	State of Kuwait	Yes	No	No	No	Yes
22	Vietnam					
23	Yemen	YES	Yes	No	No	Yes

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Updates by 2011