

AHWP Technical Committee

Special Task Group (Legal Entity) – Progress Report

Asian Harmonization Working Party WORKING TOWARDS MEDICAL DEVICE HARMONIZATION



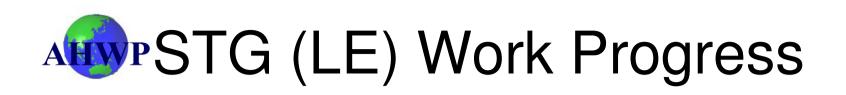
Background

- The existing AHWP Terms of Reference (ToR) has been established for many years. There is a call for review of the existing ToR so that:
 - the mission, goals and organization of the AHWP are updated (if required); and
 - the selections of office bearers are made in a more systematic way.
- Revenue is anticipated to be generated from the regulatory training course developed by WG06. To open a bank account for the revenue and any donated funds, a legal entity for AHWP is to be set up.



Background

- In mid 2008, the AHWPTC began to work on the revision of the ToR and the draft documents for setting up AHWP as a legal entity.
- At the AHWPTC meeting in November in India,
 - some proposed versions of the ToR and Memorandum & Articles of Association (M&A) documents were discussed, but no consensus was reached; and
 - the Special Task Group (Legal Entity) was set up targeted to follow up on the ToR and Legal Entity issues



- 20 December 2008:
 - In the AHWP Planning Meeting, STG(LE)'s work targets are to:
 - Consolidate ideas and propose a revised ToR for members' agreement in the 14th AHWP Meeting
 - Prepare for establishment of AHWP as a legal entity in HK
- 26 February 2009
 - Circulate the first draft of ToR among STG members for comments
- 23 March 2009
 - Circulate the first draft of M&A of the AHWP Ltd among STG members for comments

STG (LE) Work Progress

- 7 May 2009:
 - Arrange a STG(LE) meeting to discuss the M&A
- 20 July 2009:
 - Arrange a STG(LE) teleconference to discuss the M&A
- 14 August 2009:
 - Upload the draft ToR onto the AHWP Website and call for comments message sent to AHWP & AHWP TC Representatives
- 9 October 2009:
 - Call for Comments on the draft ToR message sent to AHWP TC Core Team and WG Leaders



- 28 October 2009:
 - Upload the proposed ToR (STGLE001) and the draft M&A (STGLW002) documents onto the AHWP
 - Call for comments message regarding the proposed resolutions on ToR and Legal Entity issues sent to AHWP & AHWPTC Representatives
- 4 November 2009:
 - deliver presentations on ToR & Legal Entity at AHWPTC
 - seek AHWPTC representatives' support to
 - Adopt the proposed ToR; and
 - Set up the Legal Entity (AHWP Administration Services Limited) in Hong Kong



Thanks !!

End of STG(LE) Session

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