

Traditional Medicines and Health Supplements

Assuring Safety and Quality through Harmonised Technical Requirements



In support of the free flow of traditional medicines and health supplements in the ASEAN region, ASEAN Member States are working on reducing the differences in national standards, technical regulations and conformity assessment procedures that assure the safety, quality, efficacy and claimed benefits of traditional medicines and health supplements.

There are 10 ASEAN guidelines/guiding principles harmonising the technical requirements of the ASEAN Member States for traditional medicines and health supplements that have been developed. The regional guidelines/guiding principles contain common regional requirements as well as country specific requirements that vary from the existing international guidelines that are widely used in the region. Further work to separate the technical requirements for traditional medicines and health supplements on a product basis is currently underway with the

support and participation of ASEAN industry associations on traditional medicines and health supplements.

The ASEAN Agreement on Traditional Medicines and the ASEAN Agreement on Health Supplements are also being concurrently developed, and are expected to be completed in 2016. The agreements represent the commitment of the ASEAN Member States to accept and implement the harmonised technical requirements. With the agreements, the ASEAN Member States will still maintain their national regulations, but the basis of compliance on safety, quality, efficacy, and claimed benefits of the products are embodied in the harmonised technical requirements. Nonetheless, the implementation of the harmonised technical requirements will benefit the industry by providing a single reference when producing products to be marketed in the region, and will also allow regulators to issue approvals more quickly.

[TO LEARN MORE](#)

1. [Public Consultation on the Proposed ASEAN Agreement on Traditional Medicines and ASEAN Agreement on Health Supplements](#) (draft of the Agreements and the 10 guidelines/guiding principles are available for download under the section on “Consultation Documents”)

For more information, please send an email to aimo@asean.org