

Terms of Reference (TOR) of the Product Working Group on Traditional Medicines and Health Supplements

Background

The ASEAN Consultative Committee for Standards and Quality (ACCSQ) was formed by the ASEAN Economic Ministers in 1992 with the aim of removing technical barriers to trade without compromising safety and quality of products consumed by ASEAN peoples in order to facilitate the implementation of the Common Effective Preferential Tariff (CEPT) Agreement to realize the ASEAN Free Trade Area (AFTA).

As a follow-up to the decision of ASEAN Leaders on the establishment of the ASEAN Economic Community (AEC) by the year 2015 and to fast track the integration of the eleven priority sectors including healthcare sector, the 24th ACCSQ Meeting on 3-4 August 2004 proposed to form a Product Working Group on Traditional Medicines and Health Supplements (TMHS PWG) to implement the specific measures on Traditional Medicines and Health Supplements under the Roadmap for Healthcare Integration. The ACCSQ's proposal was approved by SEOM I/36 Meeting held on 17-19 January 2005 in Yogyakarta, Indonesia.

With the establishment of the ASEAN Economic Community (AEC) on 31 December 2015 on the facilitation of goods in ASEAN characterised as a single market and production base; highly competitive economic region; equitable economic development; and fully integrated into the global economy, the ASEAN is moving further into a greater goal under the ASEAN 2025 envisioned to be (i) a Highly Integrated and Cohesive Economy; (ii) a Competitive, Innovative, and Dynamic ASEAN; (iii) Enhanced Connectivity and Sectoral Cooperation; (iv) A Resilient, Inclusive, People-Oriented, and People-Centered ASEAN; and (v) a Global ASEAN.

The ASEAN Consultative Committee for Standards and Quality (ACCSQ), in its role as the main body responsible for the overall coordination of matters related to metrology, standards, technical regulations and conformity assessment procedures in the region, has developed the ASEAN Standards and Conformance Strategic Plan 2016-2025 in response to the ASEAN vision 2025. The TMHS PWG, in support of the realisation of the ASEAN Standards and Conformance Strategic Plan 2016-2025 has developed its action plan 2016-2025 for the traditional medicine and health supplement products.

At the 47th meeting of the ACCSQ held on 25-27 April 2017, the ACCSQ revised its terms of reference (TOR) in line with the mandate provided under the ASEAN Trade in Goods Agreement (ATIGA) and to be in line with the ASEAN Economic Community (AEC) Blueprint 2025 and ASEAN Standards and Conformance Strategic Plan 2016-2025. The ACCSQ then mandated the working group and product working groups under its purview to review their terms of references to align with the ACCSQ TOR.

Article 1: Objectives and Scope of the PWG on Traditional Medicines and Health Supplements (TMHS PWG)

1.1 Objective

The TMHS PWG shall function as the focal point in ASEAN to facilitate the development of strategies and integration initiatives to support the removal of technical barriers to trade in the traditional medicines and health supplements towards the realization of AEC without compromising the safety, quality, efficacy and claimed benefits of these products in the ASEAN market.

1.2 The scope of the TMHS PWG shall include the following:

- 1.2.1 Initiate the development of regional strategies for the harmonisation of technical requirements, guidelines and conformity assessment procedures for TMHS.
- 1.2.2 Implement the harmonised initiatives and measures and identify gaps with the view of achieving convergence.
- 1.2.3 Identify appropriate technical assistance and capacity building programmes to enhance the capability of ASEAN Member States in the implementation of harmonized approaches through close cooperation with Member States, stakeholders and Dialogue Partners within the framework for cooperation and harmonization.
- 1.2.4 Engage stakeholders and related sectoral bodies on TM and HS for consultation in the development and implementation of TMHS PWG programmes.
- 1.2.5 Implement the action plan 2016-2025 of the TMHS PWG in support of the realisation of the overall ASEAN standards and conformance strategic plan 2016-2025.

Article 2: Roles and Functions

- 2.1 Exchange, review and analyze information on the existing regulatory framework/regime including standard definition, terminologies, and technical infrastructure in Member States.
- 2.2 Study the existing regulatory frameworks/regime of selected countries and internationally accepted technical guidelines.
- 2.3 Enhance the technical infrastructure including mutual confidence in testing and conformity assessment.
- 2.4 Identify areas for further harmonization and integration.
- 2.5 Implement a joint Post Market Alert System covering traditional

medicines and health supplements, in collaboration with other healthcare product groups such as cosmetics, medical devices and pharmaceutical products, so as to have an effective alert system.

Article 3 : Structure

- 3.1 The TMHS PWG shall comprise of:
 - 3.1.1 The Chairperson and Vice-Chairperson who shall not be from the same ASEAN Member State;
 - 3.1.2 Representatives from the ASEAN Secretariat;
 - 3.1.3 Representatives from national regulatory agencies on traditional medicines and health supplements from each Member State;
 - 3.1.4 Where applicable, resource persons and experts as well as up to two (2) representatives from national traditional medicines and health supplements industry, endorsed by Heads of Delegation of respective Member States to provide technical inputs;
 - 3.1.5 Representatives from the sub-groups of TMHS PWG;
 - 3.1.6 Any ACCSQ member wishing to participate in the activities of TMHS PWG is welcome.
 - 3.1.7 Member from other ASEAN Groups as observers.
- 3.2 Representatives from government, ASEAN TMHS industry, ASEAN TMHS industry associations and other stakeholders, who are based in ASEAN and endorsed by the respective Heads of Delegations may attend the TMHS PWG Meetings as observers.
- 3.3 The representatives from ASEAN TMHS industry associations, such as the ASEAN Alliance of Health Supplements Associations (AAHSA) and the ASEAN Alliance of Traditional Medicine Industry (AATMI), will be invited to the meetings of TMHS PWG to provide inputs on matters related to the traditional medicines and health supplements industry, as appropriate.
- 3.4 The TMHS PWG may form expert committees to undertake detailed work activities and deliberation on technical issues delegated by the TMHS PWG, leading to recommendations for actions, which will be submitted to TMHS PWG for review and endorsement prior to implementation.

Article 4 : Duties and Responsibilities of Chairperson and Vice-Chairperson

- 4.1 The Chairperson shall be present at every meeting of the TMHS PWG and ensure that all decisions made are based on consensus. The Chairperson

should also ensure that interests are heard, keep discussion to the point, and the minutes are clear and precise.

- 4.2 The Vice-Chairperson shall assist the Chairperson in all Meetings. In the absence of the Chairperson, the Vice-chairperson shall assume all the duties and responsibilities of the Chairperson.
- 4.3 Prior to any TMHS PWG Meetings, the Chairperson shall consult with the members of the TMHS PWG on the agenda to be covered during the Meeting.
- 4.4 The Chairperson shall report to the ACCSQ on the proceedings and decisions made during the TMHS PWG Meetings for further consideration on policy issues and endorsement of ACCSQ.
- 4.5 In the event both the Chairperson and Vice-Chairperson, including their representatives from the regulatory authorities, are absent due to unavoidable circumstances, representative from regulatory authority of the host country shall chair the Meeting.
- 4.6 Attendance by representatives from at least six member states shall be required to constitute a quorum.

Article 5 : Meetings and Reports

- 5.1 The TMHS PWG shall meet at least once a year.
- 5.2 The decisions of the Meeting shall be achieved only through the consensus of the Heads of Delegations or their designated representatives.
- 5.3 At the conclusion of each meeting, the TMHS PWG will determine the time, date and venue of its next meeting.
- 5.4 Any ASEAN Member State can request for a meeting with the approval of the Chairperson and Vice-chairperson after consultation with the heads of delegations of the respective Member States and ASEAN Secretariat.
- 5.5 Members shall be given preferably at least three (3) months' notice of the next meeting unless there is an urgent matter that needs to be addressed by the TMHS PWG, for which a shorter notice is allowed.
- 5.6 Report of the TMHS PWG Meeting shall be adopted by its members by the end of each meeting.
- 5.7 The Chairperson of TMHS PWG shall report its recommendations and proceedings and decisions to the ACCSQ in their next Meeting.

Article 6 : Terms

- 6.1 The TMHS PWG shall function for a period of six (6) years starting from September 2016 until August 2021 and may be extended subject to the approval by ACCSQ.
- 6.2 The term of the Chairperson and Vice-Chairperson shall be for a period of one year and followed by alphabetical order. In the event an AMS cannot take up the position of Chair or Vice-Chair, the next AMS by alphabetical order will be offered the position

Chairperson of TMHS PWG

Vice-chairperson of TMHS PWG

(Ms. Marie Tham)

(Dr Htun Naing Oo)

Date: 19 April 2018