



Association of South East Asian Nations (ASEAN)

# ANNEX VII

## ASEAN GUIDELINES ON CLAIMS AND CLAIMS SUBSTANTIATION FOR TRADITIONAL MEDICINES

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*Disclaimer:*

*This document is provided for information purpose only and subject to changes, pending the finalisation of the ASEAN Agreement on Regulatory Framework for Traditional Medicines. Official references to this document can only be made once the said Agreement has been finalised.*

Version 2.0



## DOCUMENT INFORMATION

This version is adopted at the 22<sup>nd</sup> ACCSQ TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS SCIENTIFIC COMMITTEE MEETING (ATSC) 3-6 March 2014, Kuala Lumpur, Malaysia and endorsed at the 21<sup>st</sup> ACCSQ TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS PRODUCT WORKING GROUP (TMHSPWG) MEETING 27-28 June 2014, Siem Reap, Cambodia.

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## 1. INTRODUCTION

The ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines (TM) is developed by taking into consideration similar guidelines that exist internationally (WHO, EU, US, Canada, Australia) and the regulatory situation and stakeholders' interests in the ASEAN region.

The TM claims refer to any message that states, suggests, or implies that a TM ingredient/product has positive contribution and benefit to human health. A balanced approach between consumer protection and encouraging science and innovation is important in implementing the harmonised ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines.

It should also be underlined that this document deals with the guidance of allowable claims and their corresponding levels of literature and scientific substantiation. Certain TM claims need to be substantiated by efficacy data, and these data requirements are defined in the guidelines.

## 2. OBJECTIVE

This document aims to provide guidance on making unbiased and truthful claims, supported by adequate evidence in order to protect the consumers from misleading claims. This will enable consumers to make informed choices in taking care of their health. Furthermore, this document will facilitate the product placement of TM products and set up requirements for efficacy data submission for certain TM claims.

## 3. KEY PRINCIPLES OF ASEAN TM CLAIMS AND CLAIMS SUBSTANTIATION

All claims made for TM should:

- Be consistent with the ASEAN definition of TM
- Support the safe, beneficial and appropriate use of the products
- Maintain the level of traditional usage and/or scientific evidence which is proportionate to the type of claim
- Meet the dosing recommendations stated in the evidence or references for the claimed intended effects, unless otherwise justified



- Not be misleading or false
- Enable consumers to make an informed choice regarding products
- Be for health maintenance or treatment of disease in accordance with traditional principles and practice
- Be substantiated by good quality evidence that is relevant to the claim

The claimed benefit/efficacy of a product and/or its ingredient(s) shall be based on the totality of the substantiation evidence provided including human, non-clinical and empirical or historical data, as well as other documented evidence, where applicable. Please refer to Table 2

## 4. GUIDANCE FOR TM CLAIMS SUBSTANTIATION

TM claims refer to the beneficial effects of consuming TM to promote the maintenance of health, to relieve symptoms, or prevent or treat a disease, disorder or medical condition in the context of the respective traditional medicine principles and theories.

### 4.1 Types of TM claims

The 3 types of TM claims are stated in Table 1.

- Traditional Health Use Claims
- Traditional Treatment Claims
- Scientifically Established Treatment Claims

Scientifically Established Treatment Claims shall be substantiated by the proportional degree of data from efficacy studies and relevant documentation.

**Table 1. Scope and examples of the 3 types of TM claims**

Type of TM claim	Scope	Examples to illustrate the scope <i>(as determined by the regulatory authority of each Member State)</i>
Traditional Health Use	Traditionally used for general health maintenance or enhancement	<ul style="list-style-type: none"><li>• Traditionally used to maintain health for people above 40 yrs old</li><li>• Tonic traditionally used to restore energy and health in women after childbirth/puerperium</li><li>• Tonic traditionally used to strengthen body by nourishing blood and invigorating vital energy</li></ul>



Traditional Treatment	<p>Traditionally used to relieve or alleviate a symptom, or treat a disease or medical condition according to the principles of traditional medicine, with the exception of the prohibited diseases according to each Member State</p> <p>To prevent/stop/slow down the progress of a mild or self-limiting disease or medical condition, based on principles of traditional medicine</p>	<ul style="list-style-type: none"><li>• A Traditional medicine for dizziness/vomiting during travel in car, boat and airplane</li><li>• Traditionally used to prevent cold or flu</li><li>• Traditionally used to relieve cold and sore throat</li><li>• Traditionally used to treat stomachache</li><li>• Traditionally used to treat constipation</li><li>• A traditional medicine to relieve itchiness</li></ul>
Scientifically Established Treatment	<p>To relieve a symptom or treat a disease, disorder or medical condition substantiated by scientific evidence, which corroborates TM principles*</p> <p><i>*as determined by the regulatory authority of each Member State</i></p>	<ul style="list-style-type: none"><li>• For treatment of hypertension</li><li>• To treat or relieve arthritis</li><li>• Used to lower blood pressure</li><li>• Used to reduce blood sugar</li></ul>

## 4.2. Principles of TM Claims Substantiation

TM claims must be in line with the respective TM principles (such as Jamu, Traditional Chinese Medicine, Ayurvedic Medicine) and supported by adequate evidence from TM based document.

As the usage of traditional medicine is based on accumulated experience and historical knowledge, the TM claims and rationale of ingredient or formulation should be based on the specific TM disciplines.

## 4.3. Substantiation of TM Claims

The substantiation of TM claims shall follow Table 2 and be based on finished product, or ingredient(s) with justification as required by the regulatory authority. It is the responsibility of the company to provide the required evidence in order to comply with the criteria to make TM Claims.

Efficacy data to support Scientifically Established Treatment Claims shall be generated from studies on the finished product, or ingredient(s), with justification as required by the regulatory authority. Efficacy data should be obtained from human studies; this may be



supplemented by data from non-clinical studies. In addition, summary of empirical or historical and raw data should be submitted if required by the regulatory authority.

#### Human studies

Scientific data could be derived from observational or intervention human studies, that are well designed in accordance with recognized scientific principles, with statistically and clinically significant outcomes addressing the specific TM claim. The acceptable principles for human studies can be referred to internationally accepted guidelines, for example, ICH-GCP Guidelines.

#### Non-clinical (animal and in vitro) studies

In vitro studies as well as animal studies are intended to generate the non-clinical data. Data from animal study should be derived from animal model which can represent human condition related to claim. The methodology should be an acceptable and valid procedure to measure the parameter. Data from animal studies are important to give the preliminary efficacy data prior to the conduct of human study. When data from animal and in vitro studies are submitted as substantiation of claims, an explanation on its relevance to humans should be included.

### **Summary of total available scientific data**

The total available published and/or unpublished scientific data should be summarised as part of the substantiation documentation. It should contain the following information:

- a) Product/Ingredient Studied
- b) Indication
- c) Type of Claim
- d) Dosage and Administration
- e) Type of Study (example, Human or Animal)
- f) Study Design (example, Observation or Experimental)
- g) Study population
- h) Duration of the Study
- i) Study End points
- j) Limitation of the Study
- k) Study Results



l) Source of Evidence

- i. Author
- ii. Title
- iii. Publication Details (year)
- iv. Type

m) Other information, if any

- i. Ethics Committee approval

For Scientifically Established Treatment Claims, a company wishing to use the same approved claim for a similar product should provide adequate scientific evidence/data to ensure adequate substantiation.

**Table 2. Degree of evidence required to support different types of TM claims**

Type of TM claim	Level of evidence	Criteria for Well-documented TM Claim	Evidence to substantiate TM Claim
Traditional Health Use	Evidence from documented traditional use and knowledge	- Claims for general health maintenance or enhancement are documented in TM references  - In accordance with TM principles and practice	Evidence of documented traditional use or history of use that may be found in the following: <ul style="list-style-type: none"> <li>• Classical TM Texts</li> <li>• Pharmacopoeias and Monographs</li> <li>• Reference Textbooks/Journals</li> </ul>
Traditional Treatment	Evidence from documented traditional treatment	- Claims for treatment and prevention are documented in TM references  - In accordance with TM principles and practice	Evidence of documented history of traditional treatment that may be found in the following: <ul style="list-style-type: none"> <li>• Classical TM Texts</li> <li>• Pharmacopoeias and Monographs</li> <li>• Reference Textbooks/Journals</li> </ul>
Scientifically Established Treatment	Scientific data and TM principles	- Claims for treatment supported by scientific data (such as <i>in vitro</i> , <i>in vivo</i> , epidemiological and/or human intervention	<b>Compulsory evidence:</b> Substantiation of TM claims based on scientific data as required by the regulatory authority to be conducted on finished product or ingredient(s). Justification will have to be provided to the regulatory authority if evidence provided is based on ingredient





		studies)  - In accordance with TM principles and practice	<b>At least 1 additional evidence:</b> Evidence of documented history of traditional treatment that may be found in the following: <ul style="list-style-type: none"><li>• Classical TM Texts</li><li>• Pharmacopoeias and Monographs</li><li>• Reference Textbooks/Journals</li></ul>
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**Note:** References that are used to substantiate a TM claim include ASEAN Member States' official pharmacopoeias and monographs.

Decision tree on the evidence required to support TM claims appears as Figure 1. Please note that Figure 1 below should be read in conjunction with the details in Table 2 for full information.

Figure 1. Decision tree on the evidence required to support the different types of TM claims

