ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS REGULATORY AND HARMONIZATION UPDATE

Ornsurang Teerawat
21.10.2014

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ACCSQ
(ASEAN Consultative Committee for Standard and Quality)

Standards and Conformance

WG1
(Standards and MRA)

WG2
(Accreditation and Conformity Assessment)

WG3
(Legal Metrology)

Product Working Groups
overseen by Thai FDA

ACC
(ASEAN Cosmetic Committee)

PPWG
(Pharmaceutical Product Working Group)

MDPWG
(Medical Device PWG)

PFPWG
(Prepared Foodstuff PWG)

TMHSPWG
(Traditional Medicine and Health Supplements PWG)
Content

- SEAN Agreement on Traditional Medicines and Health Supplements (TMHS)
- Technical Requirements for Traditional Medicines and Health Supplements (TMHS)
- Procedure towards the Signing of the ASEAN Agreement on TMHS
ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

ASEAN Agreement on Traditional Medicines and Health Supplements

ASEAN Agreement on Traditional Medicines

ASEAN Agreement on Health Supplements
ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

Each of Agreements consists of 14 Articles:

ARTICLE 1: Objectives
ARTICLE 2: Definition and Scope of TM/HS*
ARTICLE 3: General Provisions
ARTICLE 4: Safety, Quality, Efficacy/Claimed benefits and labelling requirements*
ARTICLE 5: Product Placement
ARTICLE 6: Post Marketing Surveillance
ARTICLE 7: Institutional Arrangements
ARTICLE 8: Special Cases
ARTICLE 9: Implementation
ARTICLE 10: Dispute Settlement
ARTICLE 11: Annexes
ARTICLE 12: Revisions, Modifications and Amendments
ARTICLE 13: Entry into Force
ARTICLE 14: Depository

Note - * Both agreements are similar, except Article 2 4 and 11
ARTICLE 1: OBJECTIVES

The objectives of the ASEAN Agreement on TM/HS are:

a) To enhance cooperation amongst Member States in ensuring the safety, quality and efficacy/claimed benefits of Traditional Medicines marketed in ASEAN region; and,

b) To facilitate trade of TM/HS through the harmonized technical requirements and guidelines without compromising the safety, quality and efficacy/claimed benefits of these products.
ARTICLE 2
DEFINITION AND SCOPE OF TRADITIONAL MEDICINES

“Traditional medicines” mean any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) used in the system of traditional practice. It shall not include any sterile preparation, vaccines, any substance derived from human parts, any isolated and characterized chemical substances.
ARTICLE 2
DEFINITION AND SCOPE OF HEALTH SUPPLEMENTS

“Health Supplements” mean any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the following:

a) Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances.

b) Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolites.

c) Synthetic sources of ingredients mentioned in (a) and (b).

It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectable, eyedrops).
ARTICLE 3
GENERAL PROVISIONS
Member States shall undertake the necessary measures to ensure that TM/HS which conform to the provisions of this Agreement and its Annexes may be placed on the market.

ARTICLE 4
SAFETY, QUALITY, EFFICACY/CLAIMED BENEFITS AND LABELLING REQUIREMENTS
1. TM/HS placed on the market must not be harmful to human health when consumed or applied.
2. TM/HS shall comply with the conditions set out in the Annexes to the Agreement, as may be applicable.
ARTICLE 14
DEPOSITORY

1. This Agreement shall be signed by all Member States and shall be subject to notification, ratification and/or acceptance by all Member States in accordance with their respective internal requirements necessary for its entry into force.

2. This Agreement shall enter into force on the thirtieth day following the date of deposit of tenth instrument of notification, ratification and/or acceptance with the Secretary-General of ASEAN, which shall be done no later than 1 December 2020.

3. ......
Content

• ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

• Technical Requirements for traditional medicines and health supplements (TMHS)

• Procedure towards the Signing of the ASEAN Agreement on TMHS
## Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

<table>
<thead>
<tr>
<th>Technical requirements</th>
<th>Status</th>
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<tbody>
<tr>
<td><strong>1. ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines and Health Supplements</strong>&lt;br&gt;A list of active substances that all MS are prohibited from being used in or being part of the composition of TMHS products (39 items for TM and 76 items for HS)</td>
<td>Adopted</td>
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<tr>
<td><strong>2. ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines and Health Supplements</strong>&lt;br&gt;Restricted and prohibited additives and excipients intended for use in TMHS, excluding flavoring agents.</td>
<td>Adopted</td>
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<td><strong>3. ASEAN Guidelines on Limits of Contaminants for Traditional Medicines and Health Supplements</strong>&lt;br&gt;Provide specifications on the limits of heavy metals and microbial contaminants and guidance notes on the control of pesticides for TMHS&lt;br&gt;  - Heavy metal: Lead ≤ 10 ppm, Arsenic ≤ 5.0ppm, Mercury ≤0.5 ppm, Cadmium ≤ 0.3ppm&lt;br&gt;  - Microbial limit: use BP as a reference except Indonesia (WHO)</td>
<td>Adopted pending Vietnam</td>
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</table>
## Technical requirements for Traditional Medicines and Health Supplements (TMHS)

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<tr>
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<tr>
<td>4. ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Traditional Medicines and Health Supplements</td>
<td>Adopted</td>
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<tr>
<td>Purpose: To minimise the risk of Transmissible Spongiform Encephalopathy (TSE) in TMHS.</td>
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<td>5. ASEAN Guidelines on Stability and Shelf-Life of Traditional Medicines and Health Supplements</td>
<td>Adopted</td>
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<tr>
<td>- Provide recommendations for conducting a stability study on TMHS and its shelf-life.</td>
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<td>6. ASEAN Guiding Principles on Safety Substantiation for Traditional Medicines and Health Supplements</td>
<td>Adopted pending Vietnam</td>
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<td>- Provide the safety data substantiation criteria.</td>
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Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

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<tr>
<td><strong>7. ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines and Health Supplements</strong></td>
<td>Adopted</td>
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<td>Provide guidance on making unbiased and truthful claims, supported by adequate evidence in order to protect the consumers from misleading claims.</td>
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<td>- Types of TM claims: • Traditional Health Use Claims</td>
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<td>• Traditional Treatment Claims</td>
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<td>• Scientifically Established Treatment Claims</td>
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<td>- Types of HS claims: • General or Nutritional Claims</td>
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<td>• Functional Claims</td>
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<td>• Disease Risk Reduction Claims</td>
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<td>This guideline also define the requirement for efficacy data submission for TM and HS claims.</td>
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</table>
### Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

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| **8. ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements**  
The ASEAN Guideline on GMP for TMHS is applicable to both TM and HS  
- ASEAN Member States who are PIC/S members will accept the ASEAN Guideline on GMP for TMHS or equivalent guidelines for product placement. | Adopted pending Vietnam |
| **9. ASEAN Guidelines on Labelling Requirements for Traditional Medicines and Health Supplements**  
- provide the information that shall appear on the label of TMHS product, for example, product name, name and strength of active ingredient etc., and should be English and/or official/national language | Adopted |
| **10. ASEAN General Principles for Establishing Maximum Levels of Vitamins and Minerals in Health Supplements**  
- provide the maximum daily intake levels of vitamins and minerals in health supplements for ASEAN. | Adopted |
## Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

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<tr>
<td><strong>11. List of restricted active ingredients</strong></td>
<td>Pending information from Member States</td>
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<td>- Contains active substances which are subject to specific restrictions for use in at least one of the ASEAN Member States.</td>
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<td>- Serves as a reference document for regulatory authorities and TMHS industry without legal binding among ASEAN Member States.</td>
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<td>- For example, Actaea racemosa, Berberis sp.</td>
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<td><strong>12. Product Dossier Submission</strong></td>
<td>Further discussed in the next ATSC Meeting</td>
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Content

• ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

• Technical Requirements for traditional medicines and health supplements (TMHS)

• Procedure towards the Signing of the ASEAN Agreement on TMHS
## ASEAN Regulatory Framework for TMHS

<table>
<thead>
<tr>
<th>Activities</th>
<th>2014</th>
<th>31/12/2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>01/01/2021</th>
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<td>• Finalisation of the Agreement</td>
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<td>• Endorsement by TMHS PWG</td>
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<td>• National consultation</td>
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<td>• Legal Scrubbing</td>
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<td>• Finalisation and endorsement of the Agreement</td>
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<td>• National approval procedures, as required</td>
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<td>• Endorsement by ACCSQ and SEOM</td>
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<td>• Signing by AEM</td>
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<td>• Deposit instruments of ratification/notification to the ASEAN Secretariat</td>
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<td>• Implementation at regional level</td>
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Ref: 21st ACCSQ TMHS PWG
A treaty which provides for a change of the territories of Thailand or the external territories that Thailand has sovereign rights or jurisdiction thereon under any treaty or an international law, or requires an enactment of an Act for its implementation or has wide scale effects on economic or social security of the country, shall be approved by the National Legislative Assembly. In this case, the National Legislative Assembly shall complete its deliberation within sixty days as from the date of receipt of such matter.

The treaty with wide scale effects on economic or social security of the country under paragraph two means a treaty related to free trade or customs cooperation area, to the use of natural resources, to waive the rights in any natural resources of the country, wholly or partly, or other matters as prescribed by law.”

This Agreements shall be approved by Cabinet and the National Legislative Assembly, respectively before implementation.
The Government sector should do:

- Compare and update rules and regulations to comply with the ASEAN requirements and guidelines, concerning the safety of consumers.

- Promote entrepreneurs in the country, particularly SMEs to be ready for the ASEAN Economic Community by disseminating information to have a better understanding and recognizing the importance of adaptation as well as developing the capacity and capability to comply with the regulations.

- Provide necessary measures or ways to promote and help the SMEs in order to improve, develop and enhance the standards of production in accordance with the ASEAN requirements as well as international standards.
Thank you for your attention

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