ASEAN AGREEMENT ON REGULATORY FRAMEWORK FOR TRADITIONAL MEDICINES

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic (Lao PDR), Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Viet Nam, of the Association of Southeast Asian Nations (ASEAN) (hereinafter collectively referred to as "Member States" or individually as "Member State");

RECOGNISING the importance of ensuring safety, quality and efficacy/claimed benefits of Traditional Medicines in order to protect consumers in the ASEAN region;

NOTING the diversity of regulatory regime in consideration of the national context, capacity, priorities and legislation;

INTENDING to harmonise and implement the technical requirements and guidelines for Traditional Medicines so as to reduce technical barriers to trade in the ASEAN region and contribute to the ASEAN Economic Integration initiatives without compromising the safety, quality and efficacy/ claimed benefits of these products.

HAVE AGREED AS FOLLOWS:

ARTICLE 1
OBJECTIVES

The objectives of the [ASEAN Agreement on Traditional Medicines] (hereinafter referred to as "Agreement") are:

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

b. to facilitate trade of Traditional Medicines through harmonised technical requirements and guidelines without compromising the safety, quality and efficacy/claimed benefits of these products.

ARTICLE 2
DEFINITION

For the purposes of this Agreement, "Traditional Medicines" mean any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) in accordance with traditional medicine principles. It shall not include any sterile preparation, vaccines, any substance derived from human parts or any isolated and characterised chemical substances.

ARTICLE 3
GENERAL PROVISIONS

Member States shall undertake necessary measures to ensure that Traditional Medicines 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 LABELING REQUIREMENTS

1. Traditional Medicines placed on the market must not be harmful to human health when consumed or applied.

2. Traditional Medicines shall comply with the conditions set out in the Annexes to this Agreement, as may be applicable:

a. Annex I – ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines;
b. Annex II – ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines;
c. Annex III – ASEAN Guidelines on Limits of Contaminants for Traditional Medicines;
d. Annex IV – ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Traditional Medicines;
e. Annex V – ASEAN Guidelines on Stability and Shelf-Life of Traditional Medicines;
f. Annex VI – ASEAN Guiding Principles on Safety Substantiation for Traditional Medicines;
g. Annex VII – ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines;
h. Annex VIII – ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines ; and

i. Annex IX – ASEAN Guidelines on Labeling Requirements for Traditional Medicines.

3. The Annexes to this Agreement shall constitute an integral part of this Agreement.

ARTICLE 5
PRODUCT PLACEMENT

Traditional Medicines should only be placed on the market upon the granting of marketing authorisation, as applicable, by the regulatory authority of the respective Member State.

ARTICLE 6
POST MARKET SURVEILLANCE

Member States shall ensure that post market surveillance is in place to handle early warning of any adverse events and/or other product safety issues that may occur and shall take appropriate measures to ensure consumer safety.

ARTICLE 7
INSTITUTIONAL ARRANGEMENTS

1. The ASEAN Traditional Medicines Committee (hereinafter referred to as "ATMC") is hereby established to be responsible for the implementation of this Agreement.

2. The ATMC shall develop and adopt its rules and procedures.

3. The ATMC, in performing its functions, shall make its decisions by consensus and shall be responsible for, amongst others, the following:

a. Coordinating, reviewing and monitoring the implementation of this Agreement.
b. Amending the Annexes to this Agreement, by reviewing and updating the Annexes to this Agreement, without recourse to the written agreement of all Member States as stated in Article 11 (1).

4. The ATMC shall consist of one official representative from each Member State's regulatory authority. The representative may be accompanied by their delegation at meetings of the ATMC.

5. The ATMC may establish any scientific body, as appropriate, to assist and provide technical or scientific advices in connection with the implementation of this Agreement. The scientific body shall develop its own rules and procedures to be approved by the ATMC.

6. The ASEAN Traditional Medicines Industry Association may be invited to meetings of the ATMC and may be consulted on matters concerning the Traditional Medicines industry.

7. The ASEAN Secretariat shall provide support to the ATMC in coordinating and monitoring the implementation of this Agreement and any other matters relating thereto.

8. The ATMC shall, with the support of the ASEAN Secretariat, report the progress of the implementation of this Agreement to the ASEAN Consultative Committee for Standards and Quality (ACCSQ) who may, as appropriate, provide policy guidance and recommendation on matters relating to the implementation of this Agreement.

ARTICLE 8
SPECIAL CASES

1. A Member State may restrict or prohibit the marketing of Traditional Medicines in its market, as it deems appropriate, for reasons specific to the protection of animal, plant life or environment and cultural or religious sensitivity.

2. A Member State that places a restriction or prohibition on specific Traditional Medicines shall notify the other Member States not later than three months after the date on which such a restriction or prohibition is placed with the reasons thereof and provide a copy of such measures to the ATMC and the ASEAN Secretariat within the same period.

ARTICLE 9
IMPLEMENTATION

Member States shall undertake appropriate measures to implement this Agreement.

ARTICLE 10
DISPUTE SETTLEMENT

The ASEAN Protocol on Enhanced Dispute Settlement Mechanism signed on 29 November 2004 in Vientiane, Lao PDR, and amendments thereto shall apply to the settlement of disputes concerning the interpretation or implementation of this Agreement.

ARTICLE 11
AMENDMENTS

1. The provisions of this Agreement may be amended by written agreement of all Member States.

2. Notwithstanding paragraph 1 of this Article, the Annexes of this Agreement may be amended by the ATMC in accordance with Article 7(3)(b) of this Agreement. Such amendments shall be administratively annexed to this Agreement and shall form an integral part of this Agreement.

3. Any amendment shall not prejudice the rights and obligations arising from or based on this Agreement prior and up to the date of such amendment.

ARTICLE 12
ENTRY INTO FORCE

1. This Agreement shall be subject to notification, ratification 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 after all Member States have notified or deposited instruments of ratification or acceptance with the Depositary upon completion of their internal requirements, or on [31 May 2023], whichever is earlier. For a Member State which notifies or deposits its instrument of ratification or acceptance with the Depositary after [31 May 2023], the Agreement shall enter into force for that Member State on the thirtieth day after the date of its notification or deposit of its instrument of ratification or acceptance.]

3. The Secretary-General of ASEAN shall promptly notify all Member States of the notifications or deposit of each instrument of ratification or acceptance referred to in paragraph 1 of this Article.

ARTICLE 13
DEPOSITARY

This Agreement shall be deposited with the Secretary-General of ASEAN who shall provide a certified copy thereof to each Member State.

IN WITNESS WHEREOF, the undersigned, being duly authorised by their respective Governments, have signed this Agreement.

DONE at …… on ……(date)……., in a single original copy in the English language.

For Brunei Darussalam:

(NAME IN BOLD AND CAPS)
(Designation)

For the Kingdom of Cambodia:

(NAME IN BOLD AND CAPS)
(Designation)

For the Republic of Indonesia:

(NAME IN BOLD AND CAPS)
(Designation)

For the Lao People's Democratic Republic:

(NAME IN BOLD AND CAPS)
(Designation)

For Malaysia:

(NAME IN BOLD AND CAPS)
(Designation)

For the the Republic of the Union of Myanmar:

(NAME IN BOLD AND CAPS)
(Designation)

For the Republic of the Philippines:

(NAME IN BOLD AND CAPS)
(Designation)

For the Republic of Singapore:

(NAME IN BOLD AND CAPS)
(Designation)

For the Kingdom of Thailand:

(NAME IN BOLD AND CAPS)
(Designation)

For the Socialist Republic of Viet Nam:

(NAME IN BOLD AND CAPS)
(Designation)