ภาคผนวก ก
ความตกลงของอาเซียนว่าด้วยกรอบการกำกับดูแล
ด้านยาแผนโบราณ และผลิตภัณฑ์เสริมอาหาร

ข้อตกลงอาเซียนว่าด้วยกรอบกฎระเบียบสำหรับยาแผนโบราณ

(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, 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, Member States 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 or claimed benefits of Traditional Medicines in order to protect consumers in the ASEAN region;

NOTING the diversity among the Member States' regulatory regimes taking into consideration their respective national context, capacity, priorities, and legislation;

RECALLING the ASEAN Trade in Goods Agreement signed on 26 February 2009 in Cha-am, Thailand;

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 or claimed benefits of these products,

HAVE AGREED AS FOLLOWS:

ARTICLE 1

DEFINITION

For the purposes of the ASEAN Agreement on Regulatory Framework for Traditional Medicines (hereinafter referred to as "Agreement"), **Traditional Medicines** means any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals, 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 2

OBJECTIVES

The objectives of this Agreement are:

(a) to enhance cooperation amongst Member States in ensuring the safety, quality, and efficacy or 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 or claimed benefits of these products.

ARTICLE 3

GENERAL PROVISIONS

Each Member State shall undertake necessary measures to ensure that Traditional Medicines, that conform to the provisions of this Agreement and its Annexes, may be placed on its market.

ARTICLE 4

SAFETY, QUALITY, EFFICACY OR CLAIMED BENEFITS, AND LABELLING REQUIREMENTS

1. Traditional Medicines placed on a Member State's 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 thisAgreement, 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 Labelling Requirements for Traditional Medicines.

3. Notwithstanding paragraph 2, any Member State may defer its implementation of Annexes V and VIII by notifying in writing to the Secretary-General of ASEAN when it notifies or deposits its instruments of ratification or acceptance with the Depositary for the entry into force of this Agreement in accordance with paragraphs 2 and 3 of Article 13. The Secretary-General of ASEAN shall thereafter notify the rest of the Member States of such deferral. The deferral shall be effective upon the entry into force of the Agreement for the deferring Member State. For the avoidance of doubt, the absence of such notification to defer shall be considered that all Member States are ready to implement Annexes V and VIII.

4. After seven years of the date of entry into force of this Agreement for a deferring Member State, the ASEAN Traditional Medicines Committee (hereinafter referred to as "ATMC") shall conduct a review regarding that Member State's deferral. Where appropriate, the ATMC may decide to conduct further such reviews every five years thereafter or any other period as may be agreed by the ATMC.

5. Any deferring Member State may at any time withdraw its notification to defer the implementation of Annexes V and VIII by notifying in writing the Secretary-General of ASEAN of its intention to do so. The Secretary-General shall thereafter notify the rest of the Member States of the withdrawal. Such withdrawal shall be effective upon notification by the Secretary-General of ASEAN to the other Member States.

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

7. Notwithstanding Article 3, in case of a Member State that is a member of an international body whose aim is the international harmonisation of Good Manufacturing Practice (GMP) standards, such Member State may also require that Traditional Medicines conform to the GMP Guide of that international body implemented under the laws and regulations of such Member State.

ARTICLE 5

PRODUCT PLACEMENT

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

ARTICLE 6

POST MARKET SURVEILLANCE

Each Member State shall ensure that post market surveillance is in place to detect early warnings of any adverse events or other product safety issues that may occur and shall take appropriate measures to ensure consumer safety.

ARTICLE 7

INSTITUTIONAL ARRANGEMENTS

1. The ATMC is hereby established and shall 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; and

(b) amending the Annexes to this Agreement, by reviewing and updating the Annexes to this Agreement, without requiring the written agreement of all Member States as set out in paragraph 1 of Article 11.

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

5. The ATMC may establish any scientific body, as appropriate, to assist and provide technical or scientific advice in connection with the implementation of this Agreement. The scientific body shall develop its own rules and procedures, which are subject to approval 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 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, as it deems appropriate, restrict or prohibit the marketing of Traditional Medicines in its market for the protection of human, animal, plant life or health, the environment, or cultural or religious sensitivity.

2. A Member State that places a restriction or prohibition on specific Traditional Medicines shall notify the other Member States with the reasons thereof not later than three months after the date on which such restriction or prohibition is placed. That Member State shall provide a copy of such notification 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, or its successor 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, the Annexes of this Agreement may be amended by the ATMC in accordance with subparagraph 3 (b) of Article 7. Such amendments shall be administratively annexed to this Agreement by the ASEAN Secretariat 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

DEPOSITARY

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

ARTICLE 13

ENTRY INTO FORCE

1. This Agreement shall be subject to notification or 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 December 2024], whichever is earlier.

3. In the event that a Member State notifies or deposits its instrument of ratification or acceptance with the Depositary after [31 December 2024], 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.

4. 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.

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

DONE at [City], [Country], this [Day] of [Month] in the Year [spelt out with Title case], in a single original copy in the English language.

ข้อตกลงอาเซียนว่าด้วยกรอบกฎระเบียบสำหรับผลิตภัณฑ์เสริมอาหาร

(ASEAN Agreement on Regulatory Framework for Health Supplements)

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, 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, Member States 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 or claimed benefits of Health Supplements in order to protect consumers in the ASEAN region;

NOTING the diversity among the Member States' regulatory regimes taking into consideration their respective national context, capacity, priorities, and legislation;

RECALLING the ASEAN Trade in Goods Agreement signed on 26 February 2009 in Cha-am, Thailand;

INTENDING to harmonise and implement the technical requirements and guidelines for Health Supplements 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 or claimed benefits of these products,

HAVE AGREED AS FOLLOWS:

ARTICLE 1

DEFINITION

For the purposes of the ASEAN Agreement on Regulatory Framework for Health Supplements (hereinafter referred to as "Agreement"), **Health Supplements** means any product that is used to supplement a diet and to maintain, enhance, and improve the healthy function of the 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; and

(c) synthetic sources of ingredients referred in (a) and (b).

Health Supplements are presented in dosage forms and administered in small unit doses such as capsules, tablets, powder, and liquids and shall not include any sterile preparations such as injectables or eye drops.

ARTICLE 2

OBJECTIVES

The objectives of this Agreement are:

(a) to enhance cooperation amongst Member States in ensuring the safety, quality, and efficacy claimed benefits of Health Supplements marketed in the ASEAN region; and

(b) to facilitate trade of Health Supplements through harmonised technical requirements and guidelines without compromising the safety, quality, and efficacy or claimed benefits of these products.

ARTICLE 3

GENERAL PROVISIONS

Each Member State shall undertake necessary measures to ensure that Health Supplements, that conform to the provisions of this Agreement and its Annexes, may be placed on its market.

ARTICLE 4

SAFETY, QUALITY, EFFICACY OR CLAIMED BENEFITS,

AND LABELLING REQUIREMENTS

1. Health Supplements placed on a Member State's market must not be harmful to human health when consumed or applied.

2. Health Supplements 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 Health Supplements;

(b) Annex II – ASEAN Guiding Principles for the Use of Additives and Excipients in Health Supplements;

(c) Annex III – ASEAN Guidelines on Limits of Contaminants for Health Supplements;

(d) Annex IV – ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Health Supplements;

(e) Annex V – ASEAN Guidelines on Stability and Shelf-Life of Health Supplements;

(f) Annex VI – ASEAN Guiding Principles on Safety Substantiation for Health Supplements;

(g) Annex VII – ASEAN Guidelines on Claims and Claims Substantiation for Health Supplements;

(h) Annex VIII – ASEAN Guidelines on Good Manufacturing Practice for Health Supplements;

(i) Annex IX – ASEAN Guidelines on Labelling Requirements for Health Supplements; and

(j) Annex X – ASEAN General Principles for Establishing Maximum Levels of Vitamins and Minerals in Health Supplements.

3. Notwithstanding paragraph 2, any Member State may defer its implementation of Annexes V and VIII by notifying in writing to the Secretary-General of ASEAN when it notifies or deposits its instruments of ratification or acceptance with the Depositary for the entry into force of this Agreement in accordance with paragraphs 2 and 3 of Article 13. The Secretary-General of ASEAN shall thereafter notify the rest of the Member States of such deferral. The deferral shall be effective upon the entry into force of the Agreement for the deferring Member State. For the avoidance of doubt, the absence of such notification to defer shall be considered that all Member States are ready to implement Annexes V and VIII.

4. After seven years of the date of entry into force of this Agreement for a deferring Member State, the ASEAN Health Supplements Committee (hereinafter referred to as "AHSC") shall conduct a review regarding that Member State's deferral. Where appropriate, the AHSC may

decide to conduct further such reviews every five years thereafter or any other period as may be agreed by the AHSC.

5. Any deferring Member State may at any time withdraw its notification to defer the implementation of Annexes V and VIII by notifying in writing the Secretary-General of ASEAN of its intention to do so. The Secretary-General shall thereafter notify the rest of the Member States of the withdrawal. Such withdrawal shall be effective upon notification by the Secretary-General of ASEAN to the other Member States.

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

ARTICLE 5

PRODUCT PLACEMENT

Health Supplements should only be placed on a Member State's market upon the granting of marketing authorisation, as applicable, by the regulatory authority of that Member State.

ARTICLE 6

POST MARKET SURVEILLANCE

Each Member State shall ensure that post market surveillance is in place to detect early warnings of any adverse events or other product safety issues that may occur and shall take appropriate measures to ensure consumer safety.

ARTICLE 7

INSTITUTIONAL ARRANGEMENTS

1. The AHSC is hereby established and shall be responsible for the implementation of this Agreement.

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

3. The AHSC, 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; and

(b) amending the Annexes to this Agreement, by reviewing and updating the Annexes to this Agreement, without requiring the written agreement of all Member States as set out in paragraph 1 of Article 11.

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

5. The AHSC may establish any scientific body, as appropriate, to assist and provide technical or scientific advice in connection with the implementation of this Agreement. The scientific body shall develop its own rules and procedures, which are subject to approval by the AHSC.

6. The ASEAN Health Supplements Industry Association may be invited to meetings of the AHSC and may be consulted on matters concerning the Health Supplements industry.

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

8. The AHSC 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 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, as it deems appropriate, restrict or prohibit the marketing of Health Supplements in its market for the protection of human, animal, plant life or health, the environment, or cultural or religious sensitivity.

2. A Member State that places a restriction or prohibition on specific Health Supplements shall notify the other Member States with the reasons thereof not later than three months after the date on which such restriction or prohibition is placed. That Member State shall provide a copy of such notification to the AHSC 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, or its successor 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, the Annexes of this Agreement may be amended by the AHSC in accordance with subparagraph 3 (b) of Article 7. Such amendments shall be administratively annexed to this Agreement by the ASEAN Secretariat 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

DEPOSITARY

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

ARTICLE 13

ENTRY INTO FORCE

1. This Agreement shall be subject to notification or 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 December 2024], whichever is earlier.

3. In the event that a Member State notifies or deposits its instrument of ratification or acceptance with the Depositary after [31 December 2024], 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.

4. 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.

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

DONE at [City], [Country], this [Day] of [Month] in the Year [spelt out with Title case], in a single original copy in the English language.