PROTOCOL TO AMEND THE ASEAN SECTORAL MUTUAL RECOGNITION ARRANGEMENT FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION OF MANUFACTURERS OF MEDICINAL PRODUCTS

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 (hereinafter collectively referred to as "Member States" or singularly as "Member State");

RECALLING the ASEAN Trade in Goods Agreement signed on 26 February 2009 in Cha-am, Thailand which aims to achieve free flow of goods in ASEAN as one of the principal means to establish a single market and production base for the deeper economic integration of the region and the realisation of the ASEAN Economic Community;

RECALLING the ASEAN Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products (hereinafter referred to as the "Sectoral MRA") signed on 10 April 2009 in Pattaya, Thailand which aims to facilitate the movement of medicinal products in ASEAN;

RECOGNISING the need to expand the scope of medicinal products in the Sectoral MRA to include other categories to enhance the facilitation of movement of medicinal products in ASEAN; and

NOTING that Article 19 (Final Provisions) of the Sectoral MRA provides that the Sectoral MRA may only be reviewed or amended by mutual written agreement of all the Member States;

HAVE AGREED as follows:

Article 1
Amendment to Article 1 (Definitions)

The definition of "Medicinal Product" in Article 1 (Definitions) shall be amended to read as follows:

> "***"Medicinal Product"*** means products as prescribed in the Annex;"

Article 2
Amendment to Article 4 (Scope and Coverage)

Article 4 (Scope and Coverage) shall be amended to read as follows:

> "This Sectoral MRA applies to the GMP inspection and certification of manufacturers of medicinal products as defined in the Annex."

Article 3
Amendment to Subparagraph 2(d) of Article 6 (Joint Sectoral Committee)

Subparagraph 2(d) of Article 6 (Joint Sectoral Committee) shall be amended to read as follows:

> "(d) reviewing and proposing amendments to this Sectoral MRA, including any annexes, and proposing additional annexes; and"

Article 4
Amendment to the Paragraph 3 of Article 11 (Implementation)

Paragraph 3 of Article 11 (Implementation) shall be amended to read as follows:

> "Any Party may seek clarification or request further information on the GMP certificate and/or inspection report of a Listed Inspection Service if it has any queries relating to the GMP certificate and/or inspection report. If a Party decides not to accept the GMP certificate and/or inspection report of a Listed Inspection Service, it shall provide the necessary clarification of its reasons to the Party whose Inspection Service had furnished the GMP certificate and/or inspection report. Any dispute arising from the non-acceptance of a GMP certificate and/or inspection report by a Listed Inspection Service shall be brought by the aggrieved Party to the JSC for deliberation, whose decision shall bind the Parties to the dispute."

Article 5
Amendment to Article 19 (Final Provisions)

Article 19 (Final Provisions) shall be amended to read as follows:

1. The following new paragraph 2 shall be inserted after paragraph 1:

> "Notwithstanding paragraph 1 , amendments may be made to any annexes to this Sectoral MRA by the endorsement of Pharmaceutical Product Working Group. Such amendments shall be administratively annexed to this Sectoral MRA and shall form an integral part of this Sectoral MRA."

2. The existing paragraphs 2, 3, 4, and 5 shall be renumbered accordingly.

Article 6
Insertion of the Annex

The following shall be annexed to the Sectoral MRA:

"**Annex**
Definition of Medicinal Product

For the purpose of this Sectoral MRA, "***Medicinal Product***" refers to:

(a) pharmaceutical and biopharmaceutical products in finished dosage forms, and includes both prescription and non-prescription medicinal products for human use, but excludes blood-derived or plasma-derived products, radiopharmaceuticals, traditional medicines, investigational medicinal products and cell tissue and gene therapy products (CTGTPs); and

(b) active pharmaceutical ingredients used in the production of pharmaceuticals and bio pharmaceuticals in subparagraph (a)."

Article 7
Implementation

1. To the extent that Member States are obliged by this Protocol to expand the scope of medicinal products as provided in Articles 1 (Amendment to Article 1 (Definitions)), 2 (Amendment to Article 4 (Scope and Coverage)), and 6 (Insertion of the Annex), such Member States shall implement these provisions no later than five years after the entry into force of this Protocol.

2. Subject to review and agreement by the Member States, the period referred to in paragraph 1 may be extended for a period of up to two years.

Article 8
Final Provisions

1. This Protocol shall form an integral part of the Sectoral MRA and shall enter into force on the date of signature.

2. This Protocol shall be deposited with the Secretary-General of ASEAN, who shall promptly furnish a certified copy thereof to each Member State.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Governments, have signed this Protocol to Amend the ASEAN Sectoral Mutual Recognition Arrangement for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products.

DONE at Ha Noi , Viet Nam , this Third day of June in the Year Two Thousand and Twenty-Five , in a single original copy in the English Language.

For the Government of Brunei Darussalam:

DATO DR. AMIN LIEW ABDULLAH
Minister at the Prime Minister's Office and
Minister of Finance and Economy II

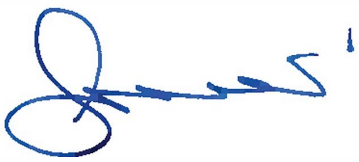
For the Government of the Kingdom of Cambodia:

CHAM NIMUL
Minister of Commerce

For the Government of the Republic of Indonesia:

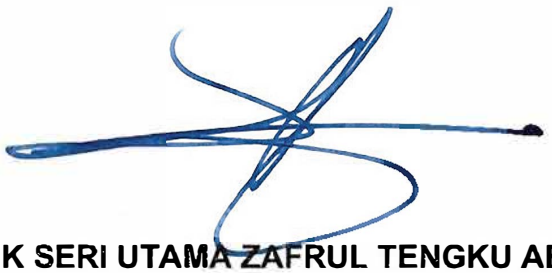
ZULKIFLI HASAN
Minister of Trade

For the Government of the Lao People's Democratic Republic:



MALAITHONG KOMMASITH
Minister of Industry and Commerce

For the Government of Malaysia:

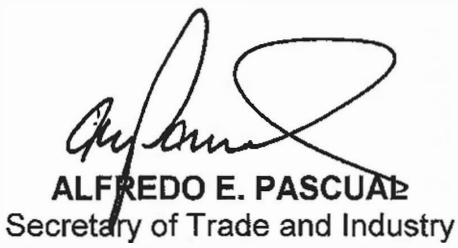


TENGKU DATUK SERI UTAMA ZAFRUL TENGKU ABDUL AZIZ
Minister of Investment, Trade and Industry

For the Government of the Republic of the Union of Myanmar:

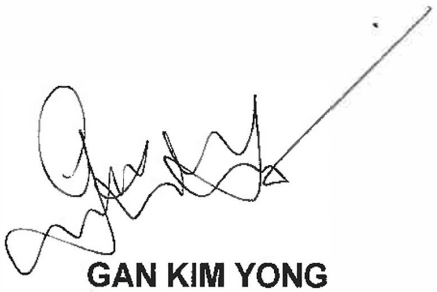
KAN ZAW
Union Minister for Investment and Foreign Economic Relations

For the Government of the Republic of the Philippines:



ALFREDO E. PASCUAL
Secretary of Trade and Industry

For the Government of the Republic of Singapore:



GAN KIM YONG
Minister for Trade and Industry

For the Government of the Kingdom of Thailand:

PHUMTHAM WECHAYACHAI
Deputy Prime Minister and Minister of Commerce

For the Government of the Socialist Republic of Viet Nam:

NGUYEN HONG DIEN
Minister of Industry and Trade